



Financial Results for the First Quarter of Fiscal Year 2017(Consolidated)

July 31, 2017

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

Listed Exchanges: Section I of Tokyo

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

Representative: Isao Teshirogi, President and CEO

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Scheduled date of quarterly securities report submission: August 9, 2017

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, 2017 to June 30, 2017

(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, 2017	75,023	2.5	15,988	(11.4)	21,071	26.3	16,010	27.7
Three months ended June 30, 2016	73,158	14.6	18,036	43.9	16,685	14.3	12,536	29.8

Note: Comprehensive income Three months ended June 30, 2017: 21,354 million yen (—%)

Three months ended June 30, 2016: (6,375) million yen (—%)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Three months ended June 30, 2017	50.22	49.43
Three months ended June 30, 2016	38.50	37.91

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of June 30, 2017	656,742	535,448	80.9
As of March 31, 2017	670,271	526,211	77.9

Reference: Shareholders' equity As of June 30, 2017: 531,631 million yen As of March 31, 2017: 522,320 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, 2017	—	34.00	—	38.00	72.00
Year ending March 31, 2018	—				
Year ending March 31, 2018 (forecast)		38.00	—	38.00	76.00

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2018

(% 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, 2017	162,500	4.8	46,000	3.9	51,500	22.2	38,500	23.4	120.77
Year ending March 31, 2018	340,000	0.3	112,500	4.0	123,500	0.4	92,000	9.7	288.59

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, 2017:	329,136,165 shares
As of March 31, 2017:	329,136,165 shares
 - b) Number of treasury stock

As of June 30, 2017:	10,348,579 shares
As of March 31, 2017:	10,347,876 shares
 - c) Average number of shares issued during the period

Three months ended June 30, 2017:	318,787,772 shares
Three months ended June 30, 2016:	325,592,633 shares

※ *This report of financial results is unaudited.*

※ Notes to consolidated financial forecasts and other items

(Cautionary note concerning forward-looking statements)

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 2017 (Consolidated).

(Method of Obtaining Financial Results Supplementary Materials and Details of Results Briefing Meeting)

Financial results supplementary materials are posted via TDnet on the date of disclosure. The Company plans to hold a results briefing meeting for analysts on Monday, July 31, 2017. Plans are also in place to post audio explanatory details together with financial results explanatory materials distributed to analysts on July 31, 2017 on the Company's website in a timely manner after the results briefing.

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1. Qualitative Information on Quarterly Financial Results

(1) Description of Consolidated Operating Results

In the first quarter ended June 30, 2017 (April 1, 2017 to June 30, 2017), net sales were ¥75,023 million, operating income was ¥15,988 million, ordinary income was ¥21,071 million, and profit attributable to owners of parent was ¥16,010 million.

Overall domestic sales of prescription drugs decreased 6.6 percent compared with the same period of the previous fiscal year, due in part to a decline in sales of existing products in the domestic prescription drug market and a transfer of marketing rights to some products, although sales of strategic product Cymbalta expanded steadily, and sales of newly launched products Intuniv and Symproic were solid. Contract manufacturing sales increased 35.4 percent with the expansion of the dolutegravir active pharmaceutical ingredient (API). Royalty income increased 16.9 percent as global sales of anti-HIV drugs Tivicay and Triumeq expanded steadily, more than offsetting the decrease in royalty income from Crestor. As a result, overall net sales increased 2.5 percent compared with the same period of the previous fiscal year.

Gross profit increased 3.3 percent compared with the same period of the previous fiscal year due to the increase in royalty income. Research and development expenses increased 34.8 percent due to the steady progress of development of S-033188, an anti-influenza drug candidate on which Shionogi is placing priority, but the Company limited the increase in total selling, general and administrative expenses to 10.8 percent by rigorously controlling selling and administrative expenses. As a result, operating income decreased 11.4 percent. Ordinary income increased 26.3 percent due to the increase in dividends received from ViiV Healthcare and the effect of currency translation. Profit attributable to owners of parent increased 27.7 percent.

(2) Description of Consolidated Financial Position

As of June 30, 2017, total assets were ¥656,742 million, a decrease of ¥13,528 million from the end of the previous fiscal year. Current assets decreased ¥15,856 million to ¥327,527 million, mainly due to redemption of short-term investment securities for surplus fund management and collection of accounts receivable recorded in the previous fiscal year (mainly dividends received from ViiV Healthcare, included in "Other" in current assets). Non-current assets increased ¥2,328 million to ¥329,215 million, largely because of an increase in investment securities reflecting higher stock prices and the effect of currency translation, partially offset by a decrease in intangible assets due to amortization.

Total liabilities decreased ¥22,764 million from the end of the previous fiscal year to ¥121,294 million. Current liabilities decreased ¥23,634 million to ¥66,960 million, mainly because of payment of income taxes and a decrease due to payment of accounts payable related to intangible assets (included in "Other" in current liabilities). Non-current liabilities increased ¥870 million to ¥54,334 million.

Net assets increased ¥9,236 million from the end of the previous fiscal year to ¥535,448 million. Shareholders' equity increased ¥3,892 million to ¥526,338 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 increased ¥5,418 million to ¥5,293 million, mainly due to an increase in foreign currency translation adjustment due to the effect of currency translation. Non-controlling interests decreased ¥74 million to ¥3,400 million.

(3) Description of Consolidated Financial Forecast

There are no revisions to the consolidated financial forecast announced on May 10, 2017.

2. Consolidated Financial Statements and Notes

(1) Consolidated balance sheets

	<i>Millions of yen</i>	
	As of March 31, 2017	As of June 30, 2017
Assets		
Current assets		
Cash and deposits	107,847	109,260
Notes and accounts receivable-trade	59,336	56,564
Short-term investment securities	98,800	89,500
Merchandise and finished goods	19,152	20,726
Work in process	8,294	5,604
Raw materials and supplies	13,940	15,333
Other	36,047	30,573
Allowance for doubtful accounts	(34)	(34)
Total current assets	343,384	327,527
Non-current assets		
Property, plant and equipment	78,788	78,223
Intangible assets		
Goodwill	37,630	36,430
Other	53,494	51,710
Total intangible assets	91,125	88,141
Investments and other assets		
Investment securities	135,970	141,556
Other	21,045	21,336
Allowance for doubtful accounts	(42)	(42)
Total investments and other assets	156,972	162,850
Total non-current assets	326,886	329,215
Total assets	670,271	656,742
Liabilities		
Current liabilities		
Notes and accounts payable-trade	11,943	12,497
Income taxes payable	28,746	12,794
Provision for bonuses	9,182	11,306
Provision for sales returns	1,565	1,604
Other provision	110	-
Other	39,046	28,757
Total current liabilities	90,595	66,960
Non-current liabilities		
Bonds payable	20,054	20,049
Long-term loans payable	10,000	10,000
Net defined benefit liability	9,581	9,720
Other	13,828	14,564
Total non-current liabilities	53,464	54,334
Total liabilities	144,059	121,294

Millions of yen

	As of March 31, 2017	As of June 30, 2017
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,227	20,227
Retained earnings	508,049	511,946
Treasury stock	(27,110)	(27,114)
Total shareholders' equity	522,445	526,338
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	25,041	27,575
Deferred gains or losses on hedges	122	(1,021)
Foreign currency translation adjustment	(20,026)	(16,757)
Remeasurements of defined benefit plans	(5,262)	(4,503)
Total accumulated other comprehensive income	(125)	5,293
Subscription rights to shares	416	416
Non-controlling interests	3,474	3,400
Total net assets	526,211	535,448
Total liabilities and net assets	670,271	656,742

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

Consolidated statements of income

	<i>Millions of yen</i>	
	Three months ended June 30, 2016	Three months ended June 30, 2017
Net sales	73,158	75,023
Cost of sales	19,813	19,918
Gross profit	53,345	55,105
Selling, general and administrative expenses	35,308	39,116
Operating income	18,036	15,988
Non-operating income		
Interest income	172	234
Dividends income	595	5,716
Other	155	190
Total non-operating income	923	6,141
Non-operating expenses		
Interest expenses	48	160
Contribution	225	253
Foreign exchange losses	1,682	257
Other	317	387
Total non-operating expenses	2,274	1,059
Ordinary income	16,685	21,071
Extraordinary loss		
Loss on valuation of investment securities	—	523
Total extraordinary losses	—	523
Income before income taxes	16,685	20,547
Income taxes-current	4,767	6,920
Income taxes-deferred	(573)	(2,400)
Total income taxes	4,193	4,519
Profit	12,491	16,027
Profit (loss) attributable to non-controlling interests	(44)	17
Profit attributable to owners of parent	12,536	16,010

Consolidated statements of comprehensive income

	<i>Millions of yen</i>	
	Three months ended June 30, 2016	Three months ended June 30, 2017
Profit	12,491	16,027
Other comprehensive income		
Valuation difference on available-for-sale securities	(5,868)	2,534
Deferred gains or losses on hedges	2,710	(1,143)
Foreign currency translation adjustment	(16,375)	3,177
Remeasurements of defined benefit plans	665	759
Total other comprehensive income	(18,867)	5,326
Comprehensive income	(6,375)	21,354
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	(6,089)	21,429
Comprehensive income attributable to non-controlling interests	(286)	(74)

(3) Notes

Going concern assumption

None

Significant changes in shareholders' equity

None

Supplemental material for financial results for the 1st quarter of fiscal year 2017

July 31, 2017
Shionogi & Co., Ltd.

1. Sales of main merchandise and finished goods

(Billions of yen)

	FY2017 1H forecast	FY2017 forecast	FY2017 1Q actual	FY2016 1Q actual	change	Progress% vs. 2017 1H forecast
Prescription drugs	75.2	143.9	37.3	39.9	(2.6)	49.6
<i>change %</i>	<i>(5.1)</i>	<i>(8.9)</i>	<i>(6.6)</i>	<i>0.5</i>		
CYMBALTA	11.1	25.3	5.8	4.4	1.3	51.7
INTUNIV	0.3	0.6	0.4	-	0.4	123.8
SYMPROIC	0.1	0.4	0.0	-	0.0	61.6
Total of strategic products	11.5	26.3	6.2	4.4	1.8	53.6
ACTAIR	0.0	0.1	0.0	0.0	0.0	55.5
MULPLETA	0.1	0.2	0.0	0.0	0.0	58.1
PIRESPA	3.1	6.0	1.4	1.6	(0.2)	47.0
OXYCONTIN Franchise	4.6	8.9	2.4	2.6	(0.2)	51.0
RAPIACTA	0.1	2.8	0.1	0.1	(0.1)	38.5
BRIGHTPOC Flu	0.1	0.9	0.0	0.0	0.0	53.5
GLASHVISTA	0.3	0.7	0.1	0.1	(0.1)	25.6
Total of new products	19.9	45.8	10.2	9.0	1.3	51.4
CRESTOR	24.7	36.4	12.1	11.4	0.6	48.9
IRBETAN Franchise	7.6	14.8	3.7	4.2	(0.5)	49.0
Other	23.0	46.9	11.3	15.3	(4.0)	49.1
Overseas subsidiaries/Export	12.3	25.4	6.6	6.5	0.1	53.7
<i>change %</i>	<i>(19.4)</i>	<i>(13.1)</i>	<i>1.2</i>	<i>(8.1)</i>		
Shionogi Inc.	6.0	12.0	3.5	3.6	(0.1)	58.1
Osphena	2.2	4.6	1.1	1.2	(0.1)	50.7
C&O	3.1	6.9	1.8	1.5	0.3	57.2
Contract manufacturing	7.9	15.3	3.5	2.6	0.9	44.5
<i>change %</i>	<i>45.9</i>	<i>26.1</i>	<i>35.4</i>	<i>71.9</i>		
OTC and quasi-drugs	3.4	7.5	1.6	1.7	(0.1)	45.8
<i>change %</i>	<i>0.4</i>	<i>10.6</i>	<i>(7.8)</i>	<i>37.0</i>		
Royalty income	62.3	145.0	25.5	21.8	3.7	40.9
<i>change %</i>	<i>23.0</i>	<i>25.4</i>	<i>16.9</i>	<i>60.8</i>		
HIV Franchise	45.4	103.0	18.6	10.2	8.4	41.0
CRESTOR	11.0	22.0	5.7	10.5	(4.8)	52.2
Others	1.4	2.9	0.6	0.6	(0.1)	40.0
<i>change %</i>	<i>17.1</i>	<i>(83.1)</i>	<i>(8.4)</i>	<i>(15.7)</i>		
Total	162.5	340.0	75.0	73.2	1.9	46.2
<i>change %</i>	<i>4.8</i>	<i>0.3</i>	<i>2.5</i>	<i>14.6</i>		

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

2 - 1. Quarterly trend for FY2016 and FY2017 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2017

(Billions of yen)

FY2016	FY2016 1Q actual	Y on Y change%	FY2016 2Q actual	Y on Y change%	FY2016 3Q actual	Y on Y change%	FY2016 4Q actual	Y on Y change%
Prescription drugs	39.9	0.5	39.2	1.4	42.1	(6.5)	36.8	(4.9)
CRESTOR	11.4	7.5	10.5	7.6	11.2	(15.3)	10.0	(1.2)
CYMBALTA	4.4	27.0	4.5	20.7	5.3	22.0	4.9	30.9
IRBETAN Franchise	4.2	3.1	3.6	(15.4)	4.0	7.5	3.5	(4.5)
Total of 3 key products	20.0	10.2	18.6	4.9	20.4	(3.7)	18.4	4.9
OXYCONTIN Franchise	2.6	(0.1)	2.4	(5.0)	2.7	(5.7)	2.0	(3.7)
FINIBAX	0.9	(5.6)	0.8	(26.4)	0.9	(1.4)	0.7	(15.4)
PIRESPA	1.6	3.9	1.4	15.7	1.5	(18.7)	1.3	(3.9)
RAPIACTA	0.1	-	(0.0)	-	1.1	150.0	1.6	2.6
Total of 7 strategic products	25.3	8.5	23.2	2.7	26.6	(2.4)	23.9	2.8
FLOMOX	2.2	(22.9)	1.8	(37.2)	2.6	(17.0)	1.8	(27.3)
RINDERON	2.0	(8.3)	1.9	(12.2)	1.9	(11.1)	1.6	(7.1)
CLARITIN	0.8	5.9	0.6	(25.8)	0.8	(20.9)	1.5	(14.8)
FLUMARIN	0.9	(16.3)	0.9	(30.4)	0.9	(11.4)	0.7	(18.4)
Export/Overseas subsidiaries	6.5	(8.1)	8.7	14.7	7.6	(4.9)	6.3	(9.3)
Shionogi Inc.	3.6	(17.4)	5.5	35.5	4.8	(1.4)	4.0	18.4
Osphena	1.2	(5.4)	0.8	(38.6)	1.3	7.8	1.4	36.5
C&O	1.5	(4.8)	1.6	(9.8)	1.2	(5.9)	1.5	(27.8)
Contract manufacturing	2.6	71.9	2.8	28.7	3.4	107.2	3.3	6.4
OTC and quasi-drugs	1.7	37.0	1.7	29.7	2.1	68.1	1.3	21.0
Royalty income	21.8	60.8	28.9	20.7	31.0	0.4	34.0	1.5
CRESTOR	10.5	(6.2)	6.8	(45.4)	7.8	(35.2)	7.9	(33.6)
HIV Franchise	10.2	637.5	18.4	84.6	20.6	50.9	24.0	55.6
Others	0.6	(15.7)	0.6	(13.0)	15.2	-	0.7	(9.2)
Total	73.2	14.6	81.9	10.1	101.4	15.7	82.4	(2.0)

Fiscal year ending March 31, 2018

FY2017	FY2017 1Q actual	Y on Y change%
Prescription drugs	37.3	(6.6)
CYMBALTA	5.8	30.6
INTUNIV	0.4	-
SYMPROIC	0.0	-
Total of strategic products	6.2	39.9
ACTAIR	0.0	131.4
MULPLETA	0.0	41.4
PIRESPA	1.4	(11.6)
OXYCONTIN Franchise	2.4	(8.2)
RAPIACTA	0.1	(57.5)
BRIGHTPOC Flu	0.0	3.9
GLASHVISTA	0.1	(40.3)
Total of new products	10.2	14.0
CRESTOR	12.1	5.6
IRBETAN Franchise	3.7	(11.8)
Other	11.3	(26.3)
Overseas subsidiaries/Export	6.6	1.2
Shionogi Inc.	3.5	(3.9)
Osphena	1.1	(5.6)
C&O	1.8	20.3
Contract manufacturing	3.5	35.4
OTC and quasi-drugs	1.6	(7.8)
Royalty income	25.5	16.9
HIV Franchise	18.6	82.3
CRESTOR	5.7	(45.6)
Others	0.6	(8.4)
Total	75.0	2.5

Note: Sales of each merchandise and finished goods are shown on non-consolidated basis

2 - 2. Quarterly trend for FY2016 and FY2017 (Consolidated statements of income)

Fiscal year ended March 31, 2017

(Billions of yen)

FY2016	FY2016 1Q actual	Y on Y change %	FY2016 2Q actual	Y on Y change %	FY2016 3Q actual	Y on Y change %	FY2016 4Q actual	Y on Y change %
Net sales	73.2	14.6	81.9	10.1	101.4	15.7	82.4	(2.0)
Cost of sales	27.1 19.8	9.8	23.1 18.9	2.7	20.7 20.9	11.9	22.0 18.1	(7.5)
Gross profit	53.3	16.4	63.0	12.6	80.5	16.8	64.2	(0.4)
SG & A expenses	48.3 35.3	6.1	44.9 36.8	6.3	36.5 37.1	(0.9)	53.2 43.8	13.6
Selling & administrative expenses	22.7	0.2	22.8	(2.8)	23.4	(2.3)	24.2	0.7
R & D expenses	12.6	18.7	14.0	25.3	13.7	1.5	19.6	35.2
Operating income	24.7 18.0	43.9	32.0 26.3	22.7	42.8 43.4	37.8	24.8 20.5	(21.2)
Non-operating income & expenses	(1.4)		(0.8)		5.4		11.6	
Ordinary income	22.8 16.7	14.3	31.1 25.5	26.1	48.1 48.8	53.8	38.9 32.1	(6.6)
Extraordinary income & losses	-		-		-		(0.3)	
Income before income taxes	16.7		25.5		48.8		31.7	
Income taxes and etc.	4.1		6.8		12.5		15.4	
Profit attributable to owners of parent	17.1 12.5	29.8	22.8 18.7	59.1	35.8 36.3	79.2	19.8 16.3	(34.7)

Fiscal year ending March 31, 2018

FY2017	FY2017 1Q actual	Y on Y change %
Net sales	75.0	2.5
Cost of sales	26.5 19.9	0.5
Gross profit	55.1	3.3
SG & A expenses	52.1 39.1	10.8
Selling & administrative expenses	22.1	(2.6)
R & D expenses	17.0	34.8
Operating income	21.3 16.0	(11.4)
Non-operating income & expenses	5.1	
Ordinary income	28.1 21.1	26.3
Extraordinary income & losses	(0.5)	
Income before income taxes	20.5	
Income taxes and etc.	4.5	
Profit attributable to owners of parent	21.3 16.0	27.7

3. Pipeline (as of July 2017)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (cefiderocol)	Cephem antibiotic (injection)	Multidrug-resistant Gram -negative bacterial infections	Global: Phase III USA: NDA submission (in preparation)	In-house	In-house
	S-033188	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: NDA in preparation Global: Phase III	In-house	Shionogi/Roche (Switzerland)
	S-033188	Anti-influenza virus infection (oral)	Influenza virus infection (pediatric)	Japan: NDA in preparation	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-297995 (naldemedine tosilate) [Symproic®]	Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	USA, Japan: Approval (Mar. 2017) Europe: NDA submission (Mar. 2017)	In-house	In-house
	S-877489 (lisdexamfetamine mesilate)	DA and NE reuptake inhibitor/releaser of DA, NE (oral)	ADHD (pediatric)	Japan: NDA submission (Apr. 2017)	Shire (Ireland)	Shionogi/Shire
	S-877503 (guanfacine hydrochloride) [Intuniv®]	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 USA: Phase II	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: Mupleta®]	Thrombopoietin (TPO) receptor agonist (oral)	Thrombocytopenia associated with chronic liver disease	Japan: Approval (Sep. 2015) Global: NDA/MAA submission (in preparation)	In-house	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: NDA submission (Mar. 2017)	Stallergenes (France)	In-house
	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: Phase III	OncoTherapy Science, Inc. (Japan)	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 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (dolutegravir)	Integrase inhibitor (oral)	For the treatment of HIV infection	Global: NDA/MAA submission (DTG/rilpivirine 2-drug fixed dose combination tablet) Global: Phase III (DTG/3TC)	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
S/GSK1265744 LAP* (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	Global: Phase III (treatment) Global: Phase III (prevention)	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV, HPTN, NIAID and Gilead Sciences, Inc. (USA) for prevention
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)
Ospemifene [USA: Osphena®]	Selective estrogen receptor modulator (oral)	Vaginal dryness associated with postmenopausal VVA	USA: Phase III	QuatRx (USA)	Duchesnay(Canada)

*: 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: NDA submission (Nov. 2016)	Napp Pharmaceuticals Limited (UK)	In-house

Since May 2017

Change of phase	S-033188: Global: Phase III, →Japan:NDA in preparation,Global: Phase III
	S-033188(pediatric): Japan: Phase III→Japan: NDA in preparation
	S-888711: Global: Phase III → Global: NDA/MAA submission (in preparation)
Compound added to the list	S/GSK1349572 : DTG/rilpivirine 2-drug fixed dose combination tablet : Global:NDA/MAA submission (Jun.2017) : DTG/3TC:Global: Phase III
Compound erased from the list	S-877503 (ADHD (pediatric)):Approval (Mar. 2017)