

Financial results for the year
ended March 31, 2017

<Supplement>

May 10, 2017

 **SHIONOGI & CO., LTD.**

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1. Financial results and forecast

Billions of yen

	FY2015 Results	FY2016 Results	FY2017 Forecast	Change		FY2017 1H Forecast
				FY2016	FY2017	
Net Sales	310.0	338.9	340.0	28.9	1.1	162.5
<i>change %</i>	<i>13.1</i>	<i>9.3</i>	<i>0.3</i>			<i>4.8</i>
Operating Income	91.4	108.2	112.5	16.8	4.3	46.0
<i>change %</i>	<i>81.5</i>	<i>18.3</i>	<i>4.0</i>			<i>3.9</i>
Ordinary Income	100.9	123.0	123.5	22.2	0.5	51.5
<i>change %</i>	<i>29.5</i>	<i>22.0</i>	<i>0.4</i>			<i>22.2</i>
Profit attributable to owners of parent	66.7	83.9	92.0	17.2	8.1	38.5
<i>change %</i>	<i>51.4</i>	<i>25.8</i>	<i>9.7</i>			<i>23.4</i>

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

2. Sales of main merchandise and finished goods

Results

Billions of yen

	FY2015 Results	FY2016 Results	Change
Prescription drugs	162.1	158.0	(4.1)
<i>change %</i>	<i>0.4</i>	<i>(2.5)</i>	
CRESTOR	43.7	43.1	(0.6)
CYMBALTA	15.2	19.0	3.8
IRBETAN Franchise	15.7	15.3	(0.4)
Total of 3 key products	74.6	77.4	2.8
OXYCONTIN Franchise	10.0	9.7	(0.4)
FINIBAX	3.8	3.3	(0.5)
PIRESPA	6.0	5.8	(0.2)
RAPIACTA	2.0	2.9	0.8
Total of 7 strategic products	96.5	99.1	2.6
FLOMOX	11.3	8.4	(2.9)
RINDERON	8.0	7.2	(0.8)
CLARITIN	4.4	3.7	(0.6)
FLUMARIN	4.2	3.4	(0.8)
Export/Overseas subsidiaries	29.7	29.2	(0.5)
<i>change %</i>	<i>3.6</i>	<i>(1.7)</i>	
Shionogi Inc.	16.6	17.9	1.2
Osphena	4.8	4.7	(0.1)
C&O	6.7	5.8	(0.9)
Contract manufacturing	8.4	12.1	3.7
<i>change %</i>	<i>(45.9)</i>	<i>43.4</i>	
OTC and quasi-drugs	4.9	6.8	1.9
<i>change %</i>	<i>6.7</i>	<i>39.5</i>	
Royalty income	101.8	115.7	13.8
<i>change %</i>	<i>67.8</i>	<i>13.6</i>	
CRESTOR	47.6	33.0	(14.6)
HIV Franchise	40.5	73.3	32.8
Others	3.0	17.1	14.1
<i>change %</i>	<i>(2.2)</i>	<i>469.7</i>	
Total	310.0	338.9	28.9
<i>change %</i>	<i>13.1</i>	<i>9.3</i>	

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

Sales of each main 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.

Forecast

	FY2016 Results	FY2017 Forecast	Change	Billions of yen FY2017 1H Forecast
Prescription drugs	158.0	143.9	(14.1)	75.2
<i>change %</i>	(2.5)	(8.9)		(5.1)
CYMBALTA	19.0	25.3	6.3	11.1
INTUNIV	—	0.6	0.6	0.3
SYMPROIC	—	0.4	0.4	0.1
Total of key products	19.0	26.3	7.3	11.5
ACTAIR	0.1	0.1	0.1	0.0
MULPLETA	0.1	0.2	0.0	0.1
PIRESPA	5.8	6.0	0.1	3.1
OXYCONTIN Franchise	9.7	8.9	(0.8)	4.6
RAPIACTA	2.9	2.8	(0.1)	0.1
BRIGHTPOC Flu	1.0	0.9	(0.1)	0.1
GLASHVISTA	0.6	0.7	0.1	0.3
Total of new products	39.1	45.8	6.7	19.9
CRESTOR	43.1	36.4	(6.7)	24.7
IRBETAN Franchise	15.3	14.8	(0.5)	7.6
Other	60.5	46.9	(13.6)	23.0
Overseas subsidiaries/Export	29.2	25.4	(3.8)	12.3
<i>change %</i>	(1.7)	(13.1)		(19.4)
Shionogi Inc.	17.9	12.0	(5.9)	6.0
Osphena	4.7	4.6	(0.1)	2.2
C&O	5.8	6.9	1.1	3.1
Contract manufacturing	12.1	15.3	3.2	7.9
<i>change %</i>	43.4	26.1		45.9
OTC and quasi-drugs	6.8	7.5	0.7	3.4
<i>change %</i>	39.5	10.6		0.4
Royalty income	115.7	145.0	29.4	62.3
<i>change %</i>	13.6	25.4		23.0
CRESTOR	33.0	22.0	(11.0)	11.0
HIV Franchise	73.3	103.0	29.7	45.4
Others	17.1	2.9	(14.2)	1.4
<i>change %</i>	469.7	(83.1)		17.1
Total	338.9	340.0	1.1	162.5
<i>change %</i>	9.3	0.3		4.8

3. Management index

(Management index trend)

		FY2014	FY2015	FY2016
Return on equity (ROE)	%	9.4	13.6	16.3
Return on asset (ROA)	%	13.2	16.2	18.8
Ratio of operating income to net sales	%	18.4	29.5	31.9
Ratio of ordinary income to net sales	%	28.4	32.5	36.3
Ratio of net income to net sales	%	16.1	21.5	24.8
Total asset turnover		0.46	0.50	0.52
Equity ratio	%	78.7	79.6	77.9
Dividend payout ratio	%	39.2	30.3	27.7
Dividend on Equity (DOE)	%	3.7	4.1	4.5
Earnings per share	yen	132.67	204.83	259.88
Earnings per share (diluted)	yen	132.04	201.70	255.87

4. Capital investments and depreciation cost

Billions of yen

	FY2015 Results	FY2016 Results	FY2017 Forecast	Change		FY2017 1H Forecast
				FY2016	FY2017	
Investment in equipments	9.9	9.7	10.0	(0.2)	0.3	5.5
Depreciation cost	12.6	13.4	16.8	0.8	3.4	8.0
Amortization of goodwill	3.3	3.0	3.1	(0.3)	0.1	1.6

5. R&D expenses

Billions of yen

	FY2015 Results	FY2016 Results	FY2017 Forecast	Change		FY2017 1H Forecast
				FY2016	FY2017	
R&D expenses	49.8	59.9	52.0	10.1	(7.9)	27.5
<i>change %</i>	<i>1.9</i>	<i>20.3</i>	<i>(13.2)</i>			<i>3.1</i>
% to net sales	16.1	17.7	15.3			16.9

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

6. Employees

	FY2015 Results	FY2016 Results	FY2017 Forecast	Change		FY2017 1H Forecast
				FY2016	FY2017	
Employees	5,896	5,511	5,761	(385)	250	5,669

7. Consolidated statement of income

	<i>Million of yen</i>		
	FY2015 Results	FY2016 Results	Change
Net sales	309,973	338,890	28,917
Cost of sales	74,758	77,777	3,018
Gross profit	235,214	261,113	25,898
Selling, general and administrative expenses	143,808	152,934	9,126
Operating income	91,406	108,178	16,772
Non-operating income	12,663	19,312	6,649
Interest income	774	808	33
Dividends income	11,136	18,031	6,895
Other	752	472	(280)
Non-operating expenses	3,200	4,459	1,259
Interest expenses	207	220	12
Contribution	1,069	1,031	(37)
Foreign exchange losses	828	1,305	477
Litigation expenses	339	758	418
Other	755	1,144	388
Ordinary income	100,869	123,031	22,161
Extraordinary income	3,066	2,182	(884)
Gain on sales of investment securities	3,066	2,182	(884)
Extraordinary losses	6,483	2,517	(3,965)
Business structure improvement expenses	—	2,158	2,158
Impairment loss	2,583	359	(2,223)
Settlement package	1,900	—	(1,900)
Special retirement expenses	1,295	—	(1,295)
Loss on valuation of investment securities	704	—	(704)
Income before income taxes	97,452	122,695	25,242
Income taxes-current	28,724	35,745	7,021
Income taxes-deferred	2,100	3,339	1,238
Profit	66,628	83,610	16,982
Loss attributable to non-controlling interests	(58)	(268)	(209)
Profit attributable to owners of parent	66,687	83,879	17,192

Increase/(Decrease) in
Prescription drugs: (4.1) billion yen
Royalty income.: 13.8 billion yen
Contract manufacturing: 3.7 billion yen

Shionogi Limited
Dividends income from ViiV

Shionogi Inc.
FY2016:Shionogi
Buildings etc. in Settsu Plant
FY2015:Shionogi Ltd & Shionogi Inc.
Sales rights

8-1. Consolidated balance sheets (Assets)

	<i>Million of yen</i>		
	As of Mar. 31 2016	As of Mar. 31 2017	Change
(Assets)			
Current assets			
Cash and deposits	80,230	107,847	27,616
Notes and accounts receivable-trade	65,207	59,336	(5,871)
Short-term investment securities	97,200	98,800	1,600
Merchandise and finished goods	21,263	19,152	(2,110)
Work in process	8,839	8,294	(544)
Raw materials and supplies	12,080	13,940	1,859
Deferred tax assets	13,301	11,347	(1,954)
Other	17,532	24,700	7,167
Allowance for doubtful accounts	(45)	(34)	10
Total current assets	315,611	343,384	27,773
Non-current assets			
Property, plant and equipment	78,673	78,788	114
Intangible assets			
Goodwill	41,208	37,630	(3,577)
Sales rights	26,282	49,969	23,686
Other	4,135	3,525	(609)
Total intangible assets	71,626	91,125	19,499
Investments and other assets			
Investment securities	146,451	135,970	(10,481)
Net defined benefit asset	19,663	18,407	(1,256)
Other	7,655	2,637	(5,017)
Allowance for doubtful accounts	(44)	(42)	1
Total investments and other assets	173,727	156,972	(16,754)
Total non-current assets	324,027	326,886	2,858
Total assets	639,638	670,271	30,632

Increased / (decreased) by:
Amortization: (3.0) billion yen
Exchange rate fluctuations:
(0.6) billion yen

Increased / (decreased) by:
Purchase: 28.3 billion yen
Amortization: (4.3) billion yen

Increased / (decreased) by:
Falling in stock prices: (0.4) billion yen
Exchange rate fluctuations:
(8.3) billion yen
Selling: (1.8) billion yen

8-2. Consolidated balance sheets (Liabilities/Net Assets)

	<i>Million of yen</i>		
	As of Mar. 31 2016	As of Mar. 31 2017	Change
(Liabilities)			
Current liabilities			
Notes and accounts payable-trade	11,050	11,943	892
Income taxes payable	20,294	28,746	8,451
Provision for bonuses	10,118	9,182	(936)
Provision for sales returns	2,414	1,565	(848)
Other provision	88	110	22
Other	28,016	39,046	11,029
Total current liabilities	71,982	90,595	18,612
Non-current liabilities			
Bonds payable	20,074	20,054	(20)
Long-term loans payable	10,000	10,000	—
Deferred tax liabilities	12,856	9,372	(3,484)
Net defined benefit liability	9,447	9,581	133
Other	1,400	4,456	3,056
Total non-current liabilities	53,778	53,464	(314)
Total liabilities	125,761	144,059	18,297
(Net Assets)			
Shareholders' equity			
Capital stock	21,279	21,279	—
Capital surplus	20,227	20,227	—
Retained earnings	503,946	508,049	4,102
Treasury stock	(49,759)	(27,110)	22,649
Total shareholders' equity	495,693	522,445	26,751
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	26,748	25,041	(1,706)
Deferred gains or losses on hedges	—	122	122
Foreign currency translation adjustment	(7,333)	(20,026)	(12,693)
Remeasurements of defined benefit plans	(5,669)	(5,262)	407
Total accumulated other comprehensive income	13,745	(125)	(13,870)
Subscription rights to shares	352	416	64
Non-controlling interests	4,085	3,474	(611)
Total net assets	513,877	526,211	12,334
Total liabilities and net assets	639,638	670,271	30,632

Increased by accounts payable of the purchase of intangible assets

Retirement of treasury stock

Due to the strong yen

9-1. 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)
Total of 3 key products	18.2	6.3	17.7	4.7	21.2	18.1	17.5	(0.9)
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
Total of 8 strategic products	24.2	5.7	23.3	2.1	28.0	9.7	23.9	(2.6)
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
Total	63.9	1.8	74.4	10.9	87.6	24.4	84.0	14.0

Fiscal year ended March 31, 2017

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)

Note: 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.

9-2. 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 %
Net sales	63.9	1.8	74.4	10.9	87.6	24.4	84.0	14.0
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 & Administrative 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
Operating income	19.6 12.5	55.7	28.8 21.4	45.9	36.0 31.5	136.2	30.9 25.9	81.5
Non-operating income & expenses	2.1		(1.2)		0.2		8.4	
Ordinary income	22.9 14.6	7.1	27.1 20.2	13.5	36.2 31.8	56.4	40.8 34.3	31.2
Extraordinary income & losses	-		(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	
Profit attributable to owners of parent	15.1 9.7	(6.4)	15.8 11.7	-	23.1 20.3	22.5	29.8 25.0	40.6

Fiscal year ended March 31, 2017

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 profit attributable to non-controlling interests	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)

10. Group companies

<Consolidated affiliated companies >

No	Company name	Location	Common stock	Business status	Establish	Closing date	Ownership (%)
1	Shionogi Pharma Chemicals Co., Ltd.	Tokushima, Japan	JPY 200 million	Mfg. of pharmaceutical raw materials	August 24, 1976	March 31	100
2	Shionogi Analysis Center Co., Ltd.	Osaka, Japan	JPY 200 million	Contract testing and analysis on medicine	December 21, 2007	March 31	100
3	Shionogi General Service Co., Ltd. **	Osaka, Japan	JPY 10 million	Real estate rental, Insurance agency and contract general services	November 2, 1992	March 31	100
4	Shionogi Healthcare Co., Ltd.	Osaka, Japan	JPY 10 million	Mfg., and sale of OTC and quasi-drugs	January 15, 2016	March 31	100
5	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	September 8, 2010	March 31	100
6	Aburahi AgroResearch Co., Ltd.	Shiga, Japan	JPY 10 million	Contract Laboratories for agro chemicals	February 26, 2004	March 31	* 100
7	Saishin Igaku Co., Ltd.	Osaka, Japan	JPY 90 million	Publication of medical information	December 21, 1998	March 31	100
8	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg.,sale and development of pharmaceuticals	August 25, 2008	March 31	100
9	SG Holding, Inc.	New Jersey, U.S.A.	USD 140	Holding company	September 10, 2001	March 31	* 100
10	Shionogi Ltd.	London, U.K.	GBP 700 thousand	Mfg.,sale and development of pharmaceuticals	February 10, 2012	March 31	100
11	C&O Pharmaceutical Technology (Holdings) Limited	Shenzhen, China	HKD 165,840 thousand	Mfg.,sale and development of pharmaceuticals	July 28, 2003	December 31	71
12	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg. and sale of pharmaceuticals	December 26, 1963	March 31	100
13	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	March 29, 2013	December 31	100
14	Shionogi Singapore Pte. Ltd.	Singapore	SGD 9 million	Development of pharmaceuticals	December 30, 2013	March 31	100

* Incl. Indirect ownership

**On December 21, 2016, the Board of Directors decided to split Shionogi General Service Co., Ltd. into five subsidiaries. The split was implemented on April 3, 2017.

Note: Twenty-four consolidated affiliated companies are not shown on this table as the scale of their business is very small.

11. Pipeline (as of May 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	Global: Phase III	In-house	Shionogi/Roche (Switzerland)
	S-033188	Anti-influenza virus infection (oral)	Influenza virus infection (pediatric)	Japan: Phase III	In-house	Shionogi/Roche (Switzerland)
Pain/CNS	S-877503 (guanfacine hydrochloride) [Intuniv®]	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (pediatric)	Japan: Approval (Mar. 2017)	Shire (Ireland)	Shionogi/Shire
	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®]	Thrombopoetin (TPO) receptor agonist (oral)	Thrombocytopenia associated with chronic liver disease	Japan: Approval (Sep. 2015) Global: Phase III	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	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/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 February 2017

Change of phase	S-877503 (ADHD (pediatric)):Japan: NDA submission(Jan. 2016)→Japan: Approval (Mar. 2017)
	S-297995: USA, Japan: NDA submission (Mar. 2016)→ USA, Japan: Approval (Mar. 2017), Europe:NDA submission (Mar. 2017)
	S-877489 (ADHD):Japan: NDA submission (in preparation) →Japan: NDA submission(Apr. 2017)
	S-120083: Japan: Phase I , USA: Phase I → Japan: Phase I , USA: Phase II
	S-524101(Pediatric patients with perennial allergic rhinitis caused by HDM):Japan: NDA submission (in preparation) →Japan: NDA submission(Mar. 2017)
Ospemifene(Vaginal dryness associated with postmenopausal VVA): move to <Out-Licensing Activity>	
Compound erased from the list	LY248686(Pain associated with osteoarthritis):Approval (Dec. 2016)