Financial results for the second quarter of fiscal year 2017

< Supplement >

October 30, 2017

SHIONOGI & CO., LTD.

Contents

1 Financial results and forecast

2 Sales of main merchandise and finished goods

3 Management index

4 Capital investments and depreciation cost

5 R&D expenses

6 Employees

7 Consolidated statement of income

8 Consolidated balance sheets

9 Quarterly trend for FY2016 and FY2017

10 Group Companies

11 Pipeline (as of October 2017)

1. Financial results and forecast

(Billions of yen)

	FY2017 1H actual	FY2017 2H forecast	FY2017 forecast	FY2016 1H actual	FY2016 2H actual	FY2016 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Net Sales	172.2	172.8	345.0	155.1	183.8	338.9	17.1	(11.0)	6.1
change %	*11.0*	*(6.0)*	*1.8*	*12.2*	*7.0*	*9.3*			
Operating Income	55.8	57.7	113.5	44.3	63.9	108.2	11.5	(6.1)	5.3
change %	*25.9*	*(9.6)*	*4.9*	*30.5*	*11.2*	*18.3*			
Ordinary Income	65.6	66.4	132.0	42.1	80.9	123.0	23.4	(14.5)	9.0
change %	*55.6*	*(17.9)*	*7.3*	*21.1*	*22.4*	*22.0*			
Profit attributable to owners of parent	50.3	50.7	101.0	31.2	52.7	83.9	19.1	(2.0)	17.1
change %	*61.3*	*(3.8)*	*20.4*	*45.9*	*16.3*	*25.8*			

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

2. Sales of main merchandise and finished goods

(Billions of yen)

	FY2017 1H actual	FY2017 2H forecast	FY2017 forecast	FY2016 1H actual	FY2016 2H actual	FY2016 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Prescription drugs	73.2	70.9	144.1	79.2	78.8	158.0	(6.0)	(7.9)	(13.9)
change %	(7.6)	(10.1)	(8.8)	0.9	(5.8)	(2.5)			
CYMBALTA	11.7	14.2	26.0	8.9	10.1	19.0	2.8	4.1	6.9
INTUNIV	0.7	1.3	2.0	—	—	—	0.7	1.3	2.0
SYMPROIC	0.2	0.4	0.6	—	—	—	0.2	0.4	0.6
Total of strategic products	12.6	16.0	28.6	8.9	10.1	19.0	3.7	5.9	9.6
ACTAIR	0.1	0.1	0.1	0.0	0.0	0.1	0.0	0.0	0.1
MULPLETA	0.1	0.1	0.2	0.1	0.1	0.1	0.0	0.0	0.0
PIRESPA	3.1	2.9	6.0	3.0	2.8	5.8	0.1	0.0	0.1
OXYCONTIN Franchise	4.6	4.3	8.9	5.0	4.6	9.7	(0.5)	(0.3)	(0.8)
RAPIACTA	0.1	2.7	2.8	0.1	2.7	2.9	(0.0)	(0.0)	(0.1)
BRIGHTPOC Flu	0.1	0.8	0.9	0.1	0.9	1.0	0.0	(0.1)	(0.1)
GLASHVISTA	0.1	0.2	0.3	0.4	0.1	0.6	(0.3)	0.0	(0.2)
Total of new products	20.7	27.0	47.7	17.6	21.5	39.1	3.1	5.5	8.6
CRESTOR	22.0	12.4	34.4	21.9	21.2	43.1	0.0	(8.8)	(8.7)
IRBETAN Franchise	7.8	7.0	14.8	7.8	7.5	15.3	(0.0)	(0.4)	(0.5)
Other	22.7	24.5	47.2	31.8	28.7	60.5	(9.1)	(4.3)	(13.3)
Overseas subsidiaries/Export	12.2	13.3	25.5	15.3	13.9	29.2	(3.1)	(0.6)	(3.7)
change %	(20.2)	(4.4)	(12.7)	3.7	(7.0)	(1.7)			
Shionogi Inc.	6.0	5.2	11.2	9.1	8.8	17.9	(3.1)	(3.6)	(6.7)
Osphena	2.0	1.9	3.9	2.0	2.7	4.7	(0.0)	(0.8)	(0.8)
C&O	3.4	4.4	7.8	3.1	2.7	5.8	0.3	1.7	2.0
Contract manufacturing	8.4	7.0	15.4	5.4	6.7	12.1	3.0	0.3	3.3
change %	56.1	3.8	27.0	46.4	41.1	43.4			
OTC and quasi-drugs	3.4	3.6	7.0	3.4	3.4	6.8	(0.1)	0.3	0.2
change %	(1.5)	7.7	3.1	33.3	46.5	39.5			
Royalty income	73.8	76.5	150.3	50.6	65.0	115.7	23.2	11.5	34.7
change %	45.7	17.7	30.0	35.2	1.0	13.6			
HIV Franchise	46.2	57.1	103.3	28.6	44.6	73.3	17.6	12.4	30.0
CRESTOR	11.4	11.1	22.5	17.3	15.7	33.0	(6.0)	(4.6)	(10.5)
Others	1.2	1.5	2.7	1.2	15.9	17.1	0.0	(14.4)	(14.4)
change %	1.2	(90.8)	(84.4)	(14.4)	898.2	469.7			
Total	172.2	172.8	345.0	155.1	183.8	338.9	17.1	(11.0)	6.1
change %	11.0	(6.0)	1.8	12.2	7.0	9.3			

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

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

3. Management index

(Management index trend)

		FY2015	FY2016	FY2016 1H	FY2017 1H
Return on equity (ROE)	%	13.6	16.3	6.1	9.2
Return on asset (ROA)	%	16.2	18.8	6.7	9.6
Ratio of operating income to net sales	%	29.5	31.9	28.6	32.4
Ratio of ordinary income to net sales	%	32.5	36.3	27.2	38.1
Ratio of net income to net sales	%	21.5	24.8	20.1	29.2
Total asset turnover		0.50	0.52	0.25	0.25
Equity ratio	%	79.6	77.9	81.4	82.0
Dividend payout ratio	%	30.3	27.7	-	-
Dividend on Equity (DOE)	%	4.1	4.5	-	-
Earnings per share	yen	204.83	259.88	95.82	157.90
Earnings per share (diluted)	yen	201.70	255.87	94.35	155.42

4. Capital investments and depreciation cost

(Billions of yen)

	FY2017 1H actual	FY2017 2H forecast	FY2017 forecast	FY2016 1H actual	FY2016 2H actual	FY2016 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Investment in equipments	3.1	5.4	8.5	5.0	4.7	9.7	(1.9)	0.7	(1.2)
Depreciation cost	7.8	9.0	16.8	6.4	7.0	13.4	1.4	2.0	3.4
Amortization of goodwill	1.5	1.6	3.1	1.5	1.5	3.0	0.0	0.1	0.1

5. R&D expenses

(Billions of yen)

	FY2017 1H actual	FY2017 2H forecast	FY2017 forecast	FY2016 1H actual	FY2016 2H actual	FY2016 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
R&D expenses	30.1	24.9	55.0	26.7	33.2	59.9	3.4	(8.3)	(4.9)
change %	*12.9*	*(25.1)*	*(8.2)*	*22.1*	*19.0*	*20.3*			
% to net sales	17.5	14.4	15.9	17.2	18.1	17.7			

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

6. Employees

	End of FY2015 actual	End of 2016 1H actual	End of FY2016 actual	End of 2017 1H actual	End of FY2017 forecast	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Employees	5,896	5,806	5,511	5,226	5,365	(285)	139	(146)

7. Consolidated statement of income

(Millions of yen)

	FY2016 1H actual	FY2017 1H actual	Y on Y change
Net sales	155,101	172,172	17,070
Cost of sales	38,707	39,671	964
Gross profit	116,394	132,500	16,105
Selling, general and administrative expenses	72,106	76,744	4,637
Operating income	44,288	55,756	11,467
Non-operating income	1,326	11,703	10,376
Interest income	377	499	122
Dividends income	729	10,867	10,138
Other	219	335	116
Non-operating expenses	3,467	1,867	(1,600)
Interest expenses	105	204	99
Contribution	418	425	6
Other	2,942	1,236	(1,706)
Ordinary income	42,147	65,592	23,444
Extraordinary loss	—	685	685
Loss on valuation of investment securities	—	685	685
Income before income taxes	42,147	64,907	22,759
Income taxes-current	11,194	15,930	4,735
Income taxes-deferred	(152)	(1,313)	(1,160)
Profit	31,105	50,289	19,184
Loss attributable to non-controlling interests	(93)	(46)	46
Profit attributable to owners of parent	31,198	50,336	19,137

Increasing/(decreasing) in
Prescription drugs: (6.0) billion yen
Royalty income.: 23.2 billion yen

Shionogi Limited
Dividends income from ViiV

8-1. Consolidated balance sheets (Assets)

(Millions of yen)

	As of Mar. 31 2017	As of Sep. 30 2017	Y on Y change	
(Assets)				
Current assets				
Cash and deposits	107,847	122,408	14,560	Receipt of the dividend from ViiV
Notes and accounts receivable-trade	59,336	69,257	9,920	Royalty income from Roche
Short-term investment securities	98,800	105,800	7,000	
Merchandise and finished goods	19,152	19,474	322	
Work in process	8,294	6,532	(1,762)	
Raw materials and supplies	13,940	14,314	374	
Other	36,047	28,376	(7,671)	
Allowance for doubtful accounts	(34)	(34)	0	
Total current assets	343,384	366,128	22,744	
Non-current assets				
Property, plant and equipment	78,788	77,941	(847)	
Intangible assets				Increased / (decreased) by: Amortization: (1.5) billion yen Exchange rate fluctuations: (0.3) billion yen
Goodwill	37,630	35,793	(1,837)	
Other	53,494	50,147	(3,347)	
Total intangible assets	91,125	85,941	(5,184)	
Investments and other assets				
Investment securities	135,970	145,787	9,817	Increased / (decreased) by: Rise of the current prices: 5.0 billion yen Exchange rate fluctuations: 4.3 billion yen Buying: 0.6 billion yen
Other	21,045	21,556	511	
Allowance for doubtful accounts	(42)	(42)	0	
Total investments and other assets	156,972	167,302	10,329	
Total non-current assets	326,886	331,184	4,298	
Total assets	670,271	697,313	27,042	

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

(Millions of yen)

	As of Mar. 31 2017	As of Sep. 30 2017	Y on Y change	
(Liabilities)				
Current liabilities				
Notes and accounts payable-trade	11,943	9,814	(2,128)	
Income taxes payable	28,746	22,662	(6,083)	
Provision for bonuses	9,182	7,856	(1,325)	
Provision for sales returns	1,565	1,546	(19)	
Other provision	110	－	(110)	
Other	39,046	25,573	(13,473)	Decreased by payment of the accounts payable
Total current liabilities	90,595	67,453	(23,141)	
Non-current liabilities				
Bonds payable	20,054	19,933	(120)	
Long-term loans payable	10,000	10,000	－	
Net defined benefit liability	9,581	9,198	(382)	
Other	13,828	15,168	1,340	
Total non-current liabilities	53,464	54,301	837	
Total liabilities	144,059	121,754	(22,304)	
(Net Assets)				
Shareholders' equity				
Capital stock	21,279	21,279	－	
Capital surplus	20,227	20,268	40	
Retained earnings	508,049	546,271	38,222	
Treasury stock	(27,110)	(27,050)	60	
Total shareholders' equity	522,445	560,768	38,323	
Accumulated other comprehensive income				
Valuation difference on available-for-sale securities	25,041	29,400	4,358	Due to rise of the current prices
Deferred gains or losses on hedges	122	(2,204)	(2,327)	
Foreign currency translation adjustment	(20,026)	(12,547)	7,479	Due to the weak yen
Remeasurements of defined benefit plans	(5,262)	(3,744)	1,518	
Total accumulated other comprehensive income	(125)	10,903	11,028	
Subscription rights to shares	416	527	110	
Non-controlling interests	3,474	3,358	(116)	
Total net assets	526,211	575,558	49,346	
Total liabilities and net assets	670,271	697,313	27,042	

9-1. 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%	FY2017 2Q actual	Y on Y change %
Prescription drugs	37.3	(6.6)	35.9	(8.6)
CYMBALTA	5.8	30.6	6.0	32.9
INTUNIV	0.4	-	0.3	-
SYMPROIC	0.0	-	0.1	-
Total of strategic products	6.2	39.9	6.4	42.8
ACTAIR	0.0	131.4	0.0	50.9
MULPLETA	0.0	41.4	0.0	33.8
PIRESPA	1.4	(11.6)	1.7	20.8
OXYCONTIN Franchise	2.4	(8.2)	2.2	(10.5)
RAPIACTA	0.1	(57.5)	0.0	(417.7)
BRIGHTPOC Flu	0.0	3.9	0.1	86.5
GLASHVISTA	0.1	(40.3)	0.1	(78.3)
Total of new products	10.2	14.0	10.5	21.1
CRESTOR	12.1	5.6	9.9	(5.7)
IRBETAN Franchise	3.7	(11.8)	4.0	12.6
Other	11.3	(26.3)	11.4	(30.7)
Overseas subsidiaries/Export	6.6	1.2	5.6	(36.1)
Shionogi Inc.	3.5	(3.9)	2.6	(53.1)
Osphena	1.1	(5.6)	0.9	6.4
C&O	1.8	20.3	1.6	(1.7)
Contract manufacturing	3.5	35.4	4.9	75.2
OTC and quasi-drugs	1.6	(7.8)	1.8	4.8
Royalty income	25.5	16.9	48.3	67.5
HIV Franchise	18.6	82.3	27.6	49.7
CRESTOR	5.7	(45.6)	5.6	(17.1)
Others	0.6	(8.4)	0.7	11.3
Total	75.0	2.5	97.1	18.6

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

9-2. 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 %	FY2017 2Q actual	Y on Y change %
Net sales	**75.0**	**2.5**	**97.1**	**18.6**
Cost of sales	26.5 19.9	0.5	20.3 19.8	4.6
Gross profit	55.1	3.3	77.4	22.8
SG & A expenses	52.1 39.1	10.8	38.7 37.6	2.3
Selling & administrative expenses	22.1	(2.6)	24.5	7.8
R & D expenses	17.0	34.8	13.1	(6.8)
Operating income	**21.3** **16.0**	**(11.4)**	**40.9** **39.8**	**51.5**
Non-operating income & expenses	5.1		4.8	
Ordinary income	**28.1** **21.1**	**26.3**	**45.8** **44.5**	**74.9**
Extraordinary income & losses	(0.5)		(0.2)	
Income before income taxes	20.5		44.4	
Income taxes and etc.	4.5		10.0	
Profit attributable to owners of parent	**21.3** **16.0**	**27.7**	**35.3** **34.3**	**83.9**

10. Group companies

＜Consolidated affiliated companies (as of September 2017)＞

№	Company name	Location	Common stock	Business status	Establish	Closing date	Ownership (%)
1	Shionogi Healthcare Co., Ltd.	Osaka, Japan	JPY 10 million	Mfg., and sale of OTC and quasi-drugs	January 15, 2016	March 31	100
2	Shionogi Pharma Chemicals Co., Ltd.	Tokushima, Japan	JPY 200 million	Mfg. of pharmaceutical raw materials	August 24, 1976	March 31	100
3	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	September 8, 2010	March 31	100
4	Shionogi Analysis Center Co., Ltd.	Osaka, Japan	JPY 200 million	Contract testing and analysis on medicine	December 21, 2007	March 31	100
5	Shionogi Administration Service Co., Ltd. *	Osaka, Japan	JPY 10 million	Real estate rental and shared services	November 2, 1992	March 31	100
6	Shionogi Career Development Center Co., Ltd.	Osaka, Japan	JPY 10 million	Career development support to the group companies	April 3, 2017	March 31	100
7	Shionogi Digital Science Co., Ltd.	Osaka, Japan	JPY 10 million	ICT solution service to the group companies	April 3, 2017	March 31	100
8	Shionogi Business Partner Co., Ltd.	Osaka, Japan	JPY 2,260 million	Insurance agency and shared services	April 3, 2017	March 31	100
9	Shionogi Pharmacovigilance Center Co., Ltd.	Osaka, Japan	JPY 10 million	Pharmacovigilance activity for the group companies	April 3, 2017	March 31	100
10	Shionogi Marketing Solutions Co., Ltd.	Osaka, Japan	JPY 10 million	Market research,Making of the sales promotion materials, Support of the Sales department	April 3, 2017	March 31	100
11	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg.,sale and development of pharmaceuticals	August 25, 2008	March 31	100
12	Shionogi Ltd.	London, U.K.	GBP 700 thousand	Mfg.,sale and development of pharmaceuticals	February 10, 2012	March 31	100
13	C&O Pharmaceutical Technology (Holdings) Limited	Shenzhen, China	HKD 165,840 thousand	Mfg.,sale and development of pharmaceuticals	July 28, 2003	December 31	71
14	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg. and sale of pharmaceuticals	December 26, 1963	March 31	100
15	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	March 29, 2013	December 31	100
16	Shionogi Singapore Pte. Ltd.	Singapore	SGD 9 million	Development of pharmaceuticals	December 30, 2013	March 31	100

** Shionogi General Service Co., Ltd. split into five subsidiaries on April 3, 2017, and the name of this company was changed to Shionogi Administration Service Co.,Ltd.*

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

11. Pipeline (as of October 2017)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate)	Cephem antibiotic (injection)	Multidrug-resistant Gram -negative bacterial infections	Global: Phase III USA: NDA submission (in preparation)	In-house	In-house
	S-033188 (baloxavir marboxil)	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: NDA submission (Oct. 2017) Global: Phase III	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil)	Anti-influenza virus infection (oral)	Influenza virus infection (pediatric)	Japan: NDA submission (Oct. 2017)	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
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
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®]	Thrombopoetin (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 July 2017

Change of phase	S-033188:Japan:NDA in preparation,Global: Phase III →Japan: NDA submission(Oct. 2017),Global: Phase III
	S-033188(pediatric):Japan: NDA in preparation→Japan: NDA submission(Oct. 2017)
Compound added to the list	LY248686 (Depression (pediatric)): Japan:Phase III