Financial results for the second quarter of fiscal year 2018

< Supplement >

October 29, 2018

SHIONOGI & CO., LTD.

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1. Financial results and forecast

(Billions of yen)

	FY2018 1H actual	FY2018 2H forecast	FY2018 forecast	FY2017 1H actual	FY2017 2H actual	FY2017 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Net Sales	168.2	185.8	354.0	172.2	172.5	344.7	(4.0)	13.3	9.3
change %	*(2.3)*	*7.7*	*2.7*	*11.0*	*(6.1)*	*1.7*			
Operating Income	57.3	67.2	124.5	55.8	59.5	115.2	1.5	7.7	9.3
change %	*2.8*	*13.0*	*8.1*	*25.9*	*(6.9)*	*6.5*			
Ordinary Income	70.1	78.4	148.5	65.6	73.1	138.7	4.5	5.3	9.8
change %	*6.8*	*7.3*	*7.1*	*55.6*	*(9.6)*	*12.7*			
Profit attributable to owners of parent	57.9	60.6	118.5	50.3	58.5	108.9	7.6	2.1	9.6
change %	*15.0*	*3.5*	*8.8*	*61.3*	*11.1*	*29.8*			

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

2. Sales of segments

(Billions of yen)

	FY2018 1H actual	FY2018 2H forecast	FY2018 forecast	FY2017 1H actual	FY2017 2H actual	FY2017 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Prescription drugs	50.0	69.3	119.3	73.2	66.0	139.2	(23.2)	3.3	(19.9)
change %	*(31.7)*	*4.9*	*(14.3)*	*(7.6)*	*(16.2)*	*(11.9)*			
CYMBALTA	11.9	14.0	26.0	11.7	11.8	23.5	0.2	2.3	2.5
INTUNIV	2.4	3.8	6.1	0.7	1.2	1.9	1.7	2.5	4.2
XOFLUZA	0.5	12.5	13.0	—	2.4	2.4	0.5	10.1	10.6
RAPIACTA	0.0	1.1	1.1	0.1	3.3	3.3	(0.1)	(2.2)	(2.2)
BRIGHTPOC Flu	0.2	1.0	1.3	0.1	1.0	1.1	0.1	0.0	0.1
OXYCONTIN Franchise	3.8	4.8	8.7	4.6	4.1	8.7	(0.7)	0.7	0.0
SYMPROIC	0.7	0.8	1.6	0.2	0.4	0.6	0.6	0.4	1.0
Total of strategic products	19.6	38.2	57.7	17.3	24.2	41.6	2.2	13.9	16.2
ACTAIR	0.1	0.1	0.2	0.1	0.1	0.1	0.0	0.0	0.1
MULPLETA	0.1	0.1	0.2	0.1	0.1	0.2	0.0	0.0	0.0
PIRESPA	2.9	3.0	5.9	3.1	3.3	6.5	(0.2)	(0.3)	(0.6)
Total of new products	22.6	41.4	64.0	20.6	27.7	48.3	2.0	13.7	15.7
CRESTOR	5.2	4.5	9.7	22.0	7.3	29.3	(16.8)	(2.8)	(19.6)
IRBETAN Franchise	3.1	2.9	6.0	7.8	6.8	14.6	(4.7)	(3.9)	(8.6)
Other	19.1	20.5	39.6	22.9	24.2	47.0	(3.7)	(3.7)	(7.4)
Overseas subsidiaries/Export	15.4	15.9	31.3	12.2	11.4	23.6	3.2	4.5	7.7
change %	*26.2*	*39.3*	*32.5*	*(20.2)*	*(18.0)*	*(19.1)*			
Shionogi Inc.	7.4	5.0	12.4	6.0	4.6	10.6	1.3	0.5	1.8
Osphena	1.4	2.7	4.1	2.0	1.7	3.7	(0.6)	1.0	0.4
C&O	5.0	7.3	12.4	3.4	3.5	6.9	1.6	3.8	5.5
Contract manufacturing	5.7	7.2	12.9	8.4	8.5	16.9	(2.7)	(1.3)	(4.0)
change %	*(31.9)*	*(15.8)*	*(23.8)*	*56.1*	*26.8*	*39.8*			
OTC and quasi-drugs	3.8	3.6	7.4	3.4	3.9	7.2	0.4	(0.3)	0.1
change %	*12.3*	*(7.5)*	*1.7*	*(1.5)*	*15.0*	*6.7*			
Royalty income	92.2	88.4	180.6	73.8	81.2	155.0	18.4	7.2	25.6
change %	*24.9*	*8.9*	*16.5*	*45.7*	*24.9*	*34.0*			
HIV Franchise	57.1	67.8	124.9	46.2	57.2	103.5	10.9	10.6	21.4
CRESTOR	10.9	10.2	21.1	11.4	11.2	22.6	(0.5)	(1.0)	(1.5)
Others	24.2	10.4	34.6	16.2	12.7	29.0	8.0	(2.3)	5.7
Others	1.1	1.4	2.5	1.2	1.4	2.6	(0.1)	(0.0)	(0.1)
change %	*(7.0)*	*(2.4)*	*(4.5)*	*1.2*	*(91.3)*	*(84.8)*			
Total	168.2	185.8	354.0	172.2	172.5	344.7	(4.0)	13.3	9.3
change %	*(2.3)*	*7.7*	*2.7*	*11.0*	*(6.1)*	*1.7*			

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

Sales of prescription drugs are shown on non-consolidated basis.

3. Management index

(Management index trend)

		FY2016	FY2017	FY2017 1H	FY2018 1H
Return on equity (ROE)	%	16.3	19.4	9.2	9.3
Return on asset (ROA)	%	19.0	20.2	9.7	9.6
Ratio of operating income to net sales	%	31.9	33.4	32.4	34.1
Ratio of ordinary income to net sales	%	36.3	40.2	38.1	41.7
Ratio of net income to net sales	%	24.8	31.6	29.2	34.4
Total asset turnover		0.52	0.50	0.26	0.23
Equity ratio	%	79.0	84.5	83.2	86.6
Dividend payout ratio	%	27.7	23.9	-	-
Dividend on Equity (DOE)	%	4.5	4.6	-	-
Earnings per share	yen	259.88	342.71	157.90	184.28
Earnings per share (diluted)	yen	255.87	337.43	155.42	181.64

Shionogi has adopted the "Partial Amendments to Accounting Standard for Tax-Effect Accounting" etc. April 1, 2018.
Figures for FY2016, FY2017 and FY2017 1H have been restated to reflect this adoption.

4. Capital investments and depreciation cost

(Billions of yen)

	FY2018 1H actual	FY2018 2H forecast	FY2018 forecast	FY2017 1H actual	FY2017 2H actual	FY2017 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Investment in equipments	2.7	6.3	9.0	3.1	2.6	5.7	(0.4)	3.7	3.3
Depreciation cost	8.3	9.0	17.3	7.8	8.1	16.0	0.5	0.8	1.3
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)

	FY2018 1H actual	FY2018 2H forecast	FY2018 forecast	FY2017 1H actual	FY2017 2H actual	FY2017 actual	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
R&D expenses	38.6	29.9	68.5	30.1	29.8	59.9	8.5	0.0	8.6
change %	*28.4*	*0.0*	*14.3*	*12.9*	*(10.2)*	*0.1*			
% to net sales	23.0	16.1	19.4	17.5	17.3	17.4			

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

6. Employees

	End of FY2016 actual	End of 2017 1H actual	End of FY2017 actual	End of 2018 1H actual	End of FY2018 forecast	Y on Y change 1H	Y on Y change 2H	Y on Y change full-year
Employees	5,511	5,226	5,120	5,242	5,225	122	(17)	105

7. Consolidated statement of income

(Millions of yen)

	FY2017 1H actual	FY2018 1H actual	Y on Y change	
Net sales	172,172	168,203	(3,968)	Increasing/(decreasing) in Prescription drugs: (23.2) billion yen Royalty income.: 18.4 billion yen
Cost of sales	39,671	24,724	(14,947)	
Gross profit	132,500	143,478	10,978	
Selling, general and administrative expenses	76,744	86,173	9,429	Increasing in R&D expenses by strategic business investments
Operating income	55,756	57,304	1,548	
Non-operating income	11,703	14,563	2,859	
Interest income	499	1,009	509	
Dividends income	10,867	12,150	1,282	Shionogi Limited Dividends income from ViiV
Other	335	1,403	1,067	
Non-operating expenses	1,867	1,790	(76)	
Interest expenses	204	173	(31)	
Contribution	425	370	(54)	
Loss on retirement of non-current assets	235	565	330	
Other	1,001	679	(322)	
Ordinary income	65,592	70,077	4,485	
Extraordinary income	—	2,920	2,920	C&O Nanjing factory in China Shionogi Company dormitory in Omori, Tokyo
Gain on sales of non-current assets	—	2,920	2,920	
Extraordinary losses	685	826	141	
Loss on disaster	—	826	826	North Osaka earthquake
Loss on valuation of investment securities	685	—	(685)	
Income before income taxes	64,907	72,172	7,264	
Income taxes-current	15,930	12,801	(3,128)	
Income taxes-deferred	(1,313)	987	2,300	
Profit	50,289	58,382	8,092	
Profit (Loss) attributable to non-controlling interests	(46)	486	532	
Profit attributable to owners of parent	50,336	57,896	7,560	

8-1. Consolidated balance sheets (Assets)

(Millions of yen)

	As of Mar. 31 2018	As of Sep. 30 2018	Y on Y change	
(Assets)				
Current assets				
Cash and deposits	140,106	194,400	54,294	Receipt of the dividend from ViiV Fund for share buyback
Notes and accounts receivable-trade	53,240	48,855	(4,384)	
Short-term investment securities	124,300	103,712	(20,588)	Decreasing in NCD
Merchandise and finished goods	14,716	16,671	1,954	
Work in process	6,993	7,525	532	
Raw materials and supplies	12,926	14,672	1,745	
Other	27,257	20,571	(6,686)	
Allowance for doubtful accounts	(36)	(35)	0	
Total current assets	379,504	406,373	26,869	
Non-current assets				
Property, plant and equipment	75,956	73,578	(2,377)	
Intangible assets				Increased / (decreased) by: Amortization: (1.5) billion yen Exchange rate fluctuations: 1.4 billion yen
Goodwill	32,852	32,742	(109)	
Other	42,207	39,772	(2,434)	
Total intangible assets	75,060	72,515	(2,544)	
Investments and other assets				Increased by: Rising in stock prices: 8.6 billion yen Purchase 2.0 billion yen
Investment securities	155,675	166,117	10,441	
Other	25,309	26,535	1,226	
Allowance for doubtful accounts	(42)	(42)	－	
Total investments and other assets	180,942	192,610	11,668	
Total non-current assets	331,959	338,705	6,746	
Total assets	711,463	745,079	33,615	

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

(Millions of yen)

	As of Mar. 31 2018	As of Sep. 30 2018	Y on Y change	
(Liabilities)				
Current liabilities				
Notes and accounts payable-trade	8,016	9,167	1,151	
Current portion of long-term loans payable	10,000	10,000	–	
Income taxes payable	19,513	20,848	1,335	
Provision for bonuses	8,741	7,564	(1,176)	
Provision for sales returns	1,360	1,474	114	
Other provision	105	–	(105)	
Other	24,829	23,535	(1,294)	
Total current liabilities	72,565	72,590	24	
Non-current liabilities				
Bonds payable	18,491	3,173	(15,317)	Due to the conversion of convertible bonds
Net defined benefit liability	8,096	7,953	(143)	
Other	7,468	11,372	3,904	
Total non-current liabilities	34,056	22,500	(11,556)	
Total liabilities	106,622	95,090	(11,532)	
(Net Assets)				
Shareholders' equity				
Capital stock	21,279	21,279	–	
Capital surplus	20,227	20,512	285	
Retained earnings	574,392	617,597	43,204	
Treasury stock	(36,641)	(42,892)	(6,250)	
Total shareholders' equity	579,257	616,497	37,239	
Accumulated other comprehensive income				
Valuation difference on available-for-sale securities	35,856	42,012	6,155	Due to rising in stock prices
Deferred gains or losses on hedges	1,174	461	(713)	
Foreign currency translation adjustment	(15,330)	(14,620)	710	
Remeasurements of defined benefit plans	(111)	699	810	
Total accumulated other comprehensive income	21,589	28,553	6,963	
Subscription rights to shares	527	527	–	
Non-controlling interests	3,466	4,410	943	
Total net assets	604,840	649,988	45,147	
Total liabilities and net assets	711,463	745,079	33,615	

9-1. Quarterly trend for FY2017 and FY2018 (Sales of segments)

Fiscal year ended March 31, 2018 *(Billions of yen)*

FY2017	FY2017 1Q actual	Y on Y change %	FY2017 2Q actual	Y on Y change %	FY2017 3Q actual	Y on Y change %	FY2017 4Q actual	Y on Y change %
Prescription drugs	37.3	(6.6)	35.9	(8.6)	35.2	(16.3)	30.8	(16.2)
CYMBALTA	5.8	30.6	6.0	32.9	6.5	23.8	5.3	8.7
INTUNIV	0.4	-	0.3	-	0.5	-	0.7	-
SYMPROIC	0.0	-	0.1	-	0.2	-	0.2	-
XOFLUZA	-	-	-	-	-	-	2.4	-
Total of strategic products	6.2	39.9	6.4	42.8	7.3	37.9	8.6	77.1
ACTAIR	0.0	131.4	0.0	50.9	0.0	48.7	0.0	45.0
MULPLETA	0.0	41.4	0.0	33.8	0.0	38.8	0.0	(3.2)
PIRESPA	1.4	(11.6)	1.7	20.8	1.8	18.6	1.5	17.3
OXYCONTIN Franchise	2.4	(8.2)	2.2	(10.5)	2.4	(8.9)	1.7	(14.5)
RAPIACTA	0.1	(57.5)	0.0	(417.7)	1.2	2.3	2.1	30.8
BRIGHTPOC Flu	0.0	3.9	0.1	86.5	0.4	(14.8)	0.6	38.4
GLASHVISTA	0.1	(40.3)	0.1	(78.3)	0.0	(53.8)	0.1	198.5
Total of new products	10.2	14.0	10.5	21.1	13.2	17.5	14.7	43.2
CRESTOR	12.1	5.6	9.9	(5.7)	4.3	(61.3)	3.0	(70.1)
IRBETAN Franchise	3.7	(11.8)	4.0	12.6	4.1	3.2	2.7	(22.2)
Other	11.3	(26.3)	11.4	(30.7)	13.6	(13.4)	10.5	(19.7)
Overseas subsidiaries/Export	6.6	1.2	5.6	(36.1)	5.3	(30.9)	6.2	(2.3)
Shionogi Inc.	3.5	(3.9)	2.6	(53.1)	2.3	(51.0)	2.2	(44.6)
Osphena	1.1	(5.6)	0.9	6.4	1.0	(24.9)	0.7	(49.9)
C&O	1.8	20.3	1.6	(1.7)	1.4	12.4	2.1	42.9
Contract manufacturing	3.5	35.4	4.9	75.2	3.4	(1.4)	5.2	55.7
OTC and quasi-drugs	1.6	(7.8)	1.8	4.8	2.3	12.1	1.5	19.6
Royalty income	25.5	16.9	48.3	67.5	44.3	42.6	37.0	8.7
HIV Franchise	18.6	82.3	27.6	49.7	27.8	34.9	29.4	22.5
CRESTOR	5.7	(45.6)	5.6	(17.1)	5.6	(27.8)	5.6	(29.0)
Others	0.6	(8.4)	0.7	11.3	0.8	(95.0)	0.6	(5.8)
Total	75.0	2.5	97.1	18.6	91.2	(10.1)	81.3	(1.3)

Fiscal year ending March 31, 2019

FY2018	FY2018 1Q actual	Y on Y change %	FY2018 2Q actual	Y on Y change %
Prescription drugs	25.4	(31.9)	24.6	(31.5)
CYMBALTA	6.1	6.1	5.8	(2.2)
INTUNIV	1.1	209.9	1.3	284.8
XOFLUZA	0.0	—	0.4	—
RAPIACTA	0.0	(76.4)	(0.0)	(131.8)
BRIGHTPOC Flu	0.0	(90.5)	0.2	168.5
OXYCONTIN Franchise	2.0	(15.2)	1.8	(16.8)
SYMPROIC	0.3	526.3	0.4	257.6
Total of strategic products	9.6	11.0	10.0	14.8
ACTAIR	0.0	47.4	0.0	63.3
MULPLETA	0.0	0.6	0.0	3.0
PIRESPA	1.4	(5.1)	1.5	(10.5)
Total of new products	11.0	8.8	11.6	10.8
CRESTOR	2.6	(78.1)	2.5	(74.6)
IRBETAN Franchise	1.9	(48.5)	1.1	(71.5)
Other	9.8	(13.8)	9.3	(18.6)
Overseas subsidiaries/Export	9.9	49.3	5.5	(1.1)
Shionogi Inc.	6.1	75.7	1.3	(49.7)
Osphena	0.8	(32.7)	0.7	(21.4)
C&O	2.3	31.0	2.7	69.2
Contract manufacturing	2.8	(20.5)	2.9	(40.1)
OTC and quasi-drugs	1.6	1.3	2.2	21.9
Royalty income	48.3	89.7	43.9	(9.2)
HIV Franchise	24.5	31.4	32.6	18.2
CRESTOR	5.5	(4.3)	5.4	(3.9)
Others	18.3	—	5.9	(61.1)
Others	0.6	1.8	0.6	(14.5)
Total	88.5	18.0	79.7	(18.0)

Note: Sales of prescription drugs are shown on non-consolidated basis.

9-2. Quarterly trend for FY2017 and FY2018 (Consolidated statements of income)

Fiscal year ended March 31, 2018 *(Billions of yen)*

FY2017	FY2017 1Q actual	Y on Y change %	FY2017 2Q actual	Y on Y change %	FY2017 3Q actual	Y on Y change %	FY2017 4Q actual	Y on Y change %
Net sales	**75.0**	**2.5**	**97.1**	**18.6**	**91.2**	**(10.1)**	**81.3**	**(1.3)**
Cost of sales	26.5 19.9	0.5	20.3 19.8	4.6	18.7 17.1	(18.6)	21.1 17.2	(5.1)
Gross profit	55.1	3.3	77.4	22.8	74.1	(7.9)	64.1	(0.2)
SG & A expenses	52.1 39.1	10.8	38.7 37.6	2.3	43.6 39.8	7.3	48.0 39.0	(10.9)
Selling & administrative expenses	22.1	(2.6)	24.5	7.8	24.3	3.8	24.7	2.0
R & D expenses	17.0	34.8	13.1	(6.8)	15.5	13.4	14.4	(26.7)
Operating income	**21.3** **16.0**	**(11.4)**	**40.9** **39.8**	**51.5**	**37.7** **34.4**	**(20.9)**	**30.9** **25.1**	**22.7**
Non-operating income & expenses	5.1		4.8		5.5		8.1	
Ordinary income	**28.1** **21.1**	**26.3**	**45.8** **44.5**	**74.9**	**43.7** **39.9**	**(18.3)**	**40.9** **33.2**	**3.6**
Extraordinary income & losses	(0.5)		(0.2)		(0.4)		(0.2)	
Income before income taxes	20.5		44.4		39.5		33.0	
Income taxes and etc.	4.5		10.0		10.1		3.8	
Profit attributable to owners of parent	**21.3** **16.0**	**27.7**	**35.3** **34.3**	**83.9**	**32.2** **29.4**	**(19.1)**	**35.8** **29.1**	**78.4**

Fiscal year ending March 31, 2019

FY2018	FY2018 1Q actual	Y on Y change %	FY2018 2Q actual	Y on Y change %
Net sales	**88.5**	**18.0**	**79.7**	**(18.0)**
Cost of sales	13.5 11.9	(40.2)	16.1 12.8	(35.1)
Gross profit	76.6	39.0	66.9	(13.6)
SG & A expenses	55.3 49.0	25.2	46.7 37.2	(1.1)
Selling & administrative expenses	24.3	9.7	23.3	(5.2)
R & D expenses	24.7	45.3	13.9	6.5
Operating income	**31.2** **27.6**	**72.9**	**37.2** **29.7**	**(25.4)**
Non-operating income & expenses	10.3		2.5	
Ordinary income	**42.9** **37.9**	**80.1**	**40.3** **32.1**	**(27.8)**
Extraordinary income & losses	2.1		(0.0)	
Income before income taxes	40.1		32.1	
Income taxes and etc.	8.2		6.1	
Profit attributable to owners of parent	**36.0** **31.9**	**99.2**	**32.6** **26.0**	**(24.2)**

10. Group companies

＜Consolidated affiliated companies (as of September 30, 2018)＞

№	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	85
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 10 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 10 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

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

11. Pipeline (as of October 29, 2018)

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) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Approval (Feb.2018) Taiwan: NDA submission (Jun.2018) Global: Phase III	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Approval (Sep.2018)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: Phase III	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:MAA 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: NDA submission (Aug.2018)	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
	S-600918	Antitussive agent (oral)	Refractory/unexplained chronic cough	Japan: Phase II	In-house	In-house
	S-637880	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) [Mulpleta®]	Thrombopoetin (TPO) receptor agonist (oral)	Thrombocytopenia associated with chronic liver disease	Japan: Approval (Sep.2015) USA: Approval (Jul.2018) Europe:MAA submission (Jan.2018)	In-house	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

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
Frontier	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
	S-770108	Anti-fibrosis (inhalation)	Idiopathic pulmonary fibrosis	Japan: Phase I	In-house	In-house
	SR-0379	Cutaneous ulcer (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase II	FunPep (Japan)	In-house
	S-005151	Stroke (injection)	Stroke	Japan: Phase I	StemRIM (Japan)	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	(DTG/3TC 2-drug fixed dose combination tablet for naïve patients) Europe: MAA submission (Sep.2018) USA: NDA submission (Oct.2018) (DTG+3TC 2-drug fixed dose combination tablet for maintenance therapy) Global: Phase III	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)
Ospemifene [USA: Osphena®]	Selective estrogen receptor modulator (oral)	Vaginal dryness associated with postmenopausal VVA	USA: NDA submission (Mar.2018)	QuatRx (USA)	Duchesnay(Canada)
S-033188 (baloxavir marboxil) [USA: Xofluza™]	Anti-influenza virus infection (oral)	Influenza virus infection	USA: Approval (Oct.2018) Global: Phase III	In-house	Shionogi/Roche (Switzerland)
S-033188 (baloxavir marboxil) [USA: Xofluza™]	Anti-influenza virus infection (oral)	Severe influenza virus infection	Global: Phase III	In-house	Shionogi/Roche (Switzerland)

*: 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) Japan: Phase III	Napp Pharmaceuticals Limited (UK)	In-house

Since July 2018

Change of phase	S-033188: USA: NDA submission (Apr.2018) → USA: Approval (Oct.2018)
	S-033188 (granule): Japan: NDA submission (Apr.2018) → Japan:Approval (Sep.2018)
	S-877503 (adult): Japan: Phase III → Japan: NDA submission (Aug.2018)
	S-888711: USA: NDA submission (Dec.2017) → USA: Approval (Jul.2018)
	S/GSK1349572 (DTG/3TC 2-drug fixed dose combination tablet for naïve patients): Global: PhaseIII → Europe: MAA submission (Sep.2018), USA: NDA submission (Oct.2018)
Compound added to the list	S-033188 (prophylaxis): Japan: Phase III
	S-033188 (severe): Global: Phase III
Compound erased from the list	S/GSK1349572 (DTG/rilpivirine 2-drug fixed dose combination tablet): Approval (May.2018)