Financial results for the year ended March 31, 2016

＜ Supplement ＞

May 11, 2016

SHIONOGI & CO., LTD.

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1. Financial results and forecast

（billions of yen）

	FY2014 Results	FY2015 Results	FY2016 Forecast	Change FY2015	Change FY2016	FY2016 1H Forecast
Net Sales	274.0	310.0	318.0	36.0	8.0	145.0
change %	*(5.4)*	*13.1*	*2.6*			*4.9*
Operating Income	50.4	91.4	91.5	41.0	0.1	33.0
change %	*(18.6)*	*81.5*	*0.1*			*(2.8)*
Ordinary Income	77.9	100.9	101.5	23.0	0.6	33.0
change %	*25.2*	*29.5*	*0.6*			*(5.1)*
Profit attributable to owners of parent *	44.1	66.7	71.0	22.6	4.3	21.0
change %	*8.5*	*51.4*	*6.5*			*(1.8)*

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

** The company changed "Profit attributable to owners of parent " from " Net income"*

2. Sales of main merchandise and finished goods

(billions of yen)

	FY2014 Results	FY2015 Results	FY2016 Forecast	Change FY2015	Change FY2016	FY2016 1H Forecast
Prescription drugs	161.4	162.1	158.2	0.7	(3.9)	76.3
change %	*(4.1)*	*0.4*	*(2.4)*			*(2.7)*
CRESTOR	43.6	43.7	41.5	0.1	(2.2)	20.9
IRBETAN Franchise	15.1	15.7	15.1	0.6	(0.6)	7.4
CYMBALTA	10.9	15.2	19.3	4.3	4.1	8.9
Total of 3 key products	69.7	74.6	75.9	4.9	1.3	37.2
OXYCONTIN Franchise	10.3	10.0	10.5	(0.3)	0.5	5.5
FINIBAX	4.0	3.8	3.9	(0.2)	0.1	2.0
DIFFERIN	3.9	3.0	0.3	(0.9)	(2.7)	0.3
PIRESPA	5.4	6.0	6.3	0.6	0.3	3.3
RAPIACTA	2.6	2.0	2.3	(0.6)	0.3	0.1
Total of 8 strategic products	95.8	99.4	99.2	3.6	(0.2)	48.4
FLOMOX	12.6	11.3	9.0	(1.3)	(2.3)	4.5
RINDERON	8.0	8.0	7.4	0.0	(0.6)	3.7
CLARITIN	4.3	4.4	3.5	0.1	(0.9)	1.5
FLUMARIN	4.6	4.2	3.7	(0.4)	(0.5)	2.1
Export/Overseas subsidiaries	28.7	29.7	24.7	1.0	(5.0)	12.4
change %	*(15.8)*	*3.6*	*(16.8)*			*(16.0)*
Shionogi Inc.	15.9	16.6	12.4	0.7	(4.2)	6.0
Osphena	4.6	4.8	5.3	0.2	0.5	2.6
C&O	6.9	6.7	6.4	(0.2)	(0.3)	3.1
Contract manufacturing	15.6	8.4	10.9	(7.2)	2.5	5.3
change %	*86.4*	*(45.9)*	*28.8*			*44.2*
OTC and quasi-drugs	4.6	4.9	7.0	0.3	2.1	3.5
change %	*1.1*	*6.7*	*42.9*			*36.6*
Royalty income	60.7	101.8	114.9	41.1	13.1	46.3
change %	*(14.2)*	*67.8*	*12.8*			*23.7*
CRESTOR	47.4	47.6	33.0	0.2	(14.6)	16.5
HIV Franchise	5.8	40.5	62.0	34.7	21.5	26.0
Others	3.1	3.0	2.4	(0.1)	(0.6)	1.2
change %	*(19.6)*	*(2.2)*	*(20.8)*			*(17.1)*
Total	274.0	310.0	318.0	36.0	8.0	145.0
change %	*(5.4)*	*13.1*	*2.6*			*4.9*

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

3. Management index

(Management index trend)

		FY2013	FY2014	FY2015
Ratio of operating income to net sales	%	21.4	18.4	29.5
Ratio of ordinary income to net sales	%	21.5	28.4	32.5
Ratio of net income to net sales	%	14.0	16.1	21.5
Total asset turnover		0.50	0.46	0.50
Equity ratio	%	79.9	78.7	79.6
Return on asset（ROA)	%	10.8	13.2	16.2
Return on equity（ROE)	%	9.2	9.4	13.6
Dividend payout ratio	%	37.9	39.2	30.3
Dividends on Equity（DOE)	%	3.5	3.7	4.1
Earnings per share	yen	121.29	132.67	204.83
Earnings per share (diluted)	yen	121.23	132.04	201.70

The Company changed its accounting policy for R&D expenses effective April 1, 2014.
Figures for FY2013 has been restated to reflect this change.

4. Capital investments and depreciation cost

（billions of yen）

	FY2014 Results	FY2015 Results	FY2016 Forecast	Change FY2015	Change FY2016	FY2016 1H Forecast
Investment in equipments	8.2	9.9	10.5	1.7	0.6	5.0
Depreciation cost	12.7	12.6	13.8	(0.1)	1.2	6.4
Amortization of goodwill	3.0	3.3	3.2	0.3	(0.1)	1.6

5. R&D expenses

（billions of yen）

	FY2014 Results	FY2015 Results	FY2016 Forecast	Change FY2015	Change FY2016	FY2016 1H Forecast
R&D expenses	48.9	49.8	50.0	0.9	0.2	24.5
change %	*(8.8)*	*1.9*	*0.4*			*12.2*
% to net sales	17.8	16.1	15.7			16.9

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

6. Employees

	FY2014 Results	FY2015 Results	FY2016 Forecast	Change FY2015	Change FY2016	FY2016 1H Forecast
Employees	6,059	5,896	5,840	(163)	(56)	5,860

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7. Consolidated statement of income

(Unites: Million yen)

	FY2014 Results	FY2015 Results	Change
Net sales	273,991	309,973	35,982
Cost of sales	82,189	74,758	(7,431)
Gross profit	191,801	235,214	43,413
Selling, general and administrative expenses	141,436	143,808	2,372
Operating income	50,365	91,406	41,041
Non-operating income	31,495	12,663	(18,832)
Interest income	500	774	274
Dividends income	22,022	11,136	(10,886)
Foreign exchange gains	8,094	-	(8,094)
Other	878	752	(126)
Non-operating expenses	3,979	3,200	(779)
Interest expenses	274	207	(67)
Contribution	1,160	1,069	(91)
Foreign exchange losses	-	828	828
Litigation expenses	625	339	(286)
Other	1,919	755	(1,164)
Ordinary income	77,880	100,869	22,989
Extraordinary income	5,860	3,066	(2,794)
Gain on sales of investment securities	86	3,066	2,980
Gain on sales of non-current assets	5,584	-	(5,584)
Gain on transfer of business	189	-	(189)
Extraordinary loss	1,689	6,483	4,794
Impairment loss	-	2,583	2,583
Settlement package	1,306	1,900	594
Special retirement expenses	383	1,295	912
Loss on valuation of investment securities	-	704	704
Income before income taxes	82,051	97,452	15,401
Income taxes-current	20,820	28,724	7,904
Income taxes for prior periods	13,543	-	(13,543)
Income taxes-deferred	3,468	2,100	(1,368)
Profit	44,218	66,628	22,410
Profit (loss) attributable to non-controlling interests	158	(58)	(216)
Profit attributable to owners of parent	44,060	66,687	22,627

Increase / (Decrease) in
Prescription drugs: 0.7 billion yen
Royalty income.: 41.1 billion yen
Contract manufacturing: (7.2)billion yen

Shionogi Limited
Two years of devidends income from ViiV were recorded in FY2014

Shionogi Limited and Shionogi Inc.
Sales rights

FY2015:Shionogi
FY2014:Shionogi Inc.

FY2015:Shionogi 1.0 billion yen
Shionogi Inc. 0.3 billion yen
FY2014:Shionogi Inc.

8-1. Consolidated balance sheets (Assets)

(Unites: Million yen)

	As of Mar. 31 2015	As of Mar. 31 2016	Change
(Assets)			
Current assets			
Cash and deposits	50,784	80,230	29,446
Notes and accounts receivable-trade	70,584	65,207	(5,377)
Short-term investment securities	58,700	97,200	38,500
Merchandise and finished goods	18,943	21,263	2,320
Work in process	11,786	8,839	(2,947)
Raw materials and supplies	13,751	12,080	(1,671)
Other	35,425	30,834	(4,591)
Allowance for doubtful accounts	(28)	(45)	(17)
Total current assets	259,948	315,611	55,663
Non-current assets			
Property, plant and equipment	77,022	78,673	1,651
Intangible assets			
Goodwill	46,534	41,208	(5,326)
Sales rights	29,055	26,282	(2,773)
Other	4,738	4,135	(603)
Total intangible assets	80,328	71,626	(8,702)
Investments and other assets			
Investment securities	158,339	146,451	(11,888)
Other	27,323	27,319	(4)
Allowance for doubtful accounts	(62)	(44)	18
Total investments and other assets	185,600	173,727	(11,873)
Total non-current assets	342,951	324,027	(18,924)
Total assets	602,900	639,638	36,738

Increase in Marketable securities
41.0 billion yen

Increased / (decreased) by:
Amortization: (3.3) billion yen
Exchange rate fluctuations:
(2.0) billion yen

Increased / (decreased) by:
Purchase: 4.3 billion yen
Amortization: (3.4) billion yen
Impairment loss: (2.6) billion yen
Exchange rate fluctuations:
(0.9) billion yen

Increased / (decreased) by:
Falling in stock prices: (1.4) billion yen
Exchange rate fluctuatuin: (6.2) billion yen
Selling: (3.7)billion yen

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

(Unites: Million yen)

	As of Mar. 31 2015	As of Mar. 31 2016	Change
(Liabilities)			
Current liabilities			
Notes and accounts payable-trade	11,572	11,050	(522)
Current portion of long-term loans payable	38	-	(38)
Income taxes payable	16,447	20,294	3,847
Provision for bonuses	8,315	10,118	1,803
Provision for sales returns	2,873	2,414	(459)
Other provision	45	88	43
Other	28,501	28,016	(485)
Total current liabilities	67,794	71,982	4,188
Non-current liabilities			
Bonds payable	20,094	20,074	(20)
Long-term loans payable	10,000	10,000	-
Net defined benefit liability	9,901	9,447	(454)
Other	16,226	14,256	(1,970)
Total non-current liabilities	56,222	53,778	(2,444)
Total liabilities	124,016	125,761	1,745
(Net Assets)			
Shareholders' equity			
Capital stock	21,279	21,279	-
Capital surplus	20,227	20,227	(0)
Retained earnings	455,497	503,946	48,449
Treasury stock	(49,754)	(49,759)	(5)
Total shareholders' equity	447,249	495,693	48,444
Accumulated other comprehensive income			
Valuation difference on available-for-sale securities	28,675	26,748	(1,927)
Foreign currency translation adjustment	3,843	(7,333)	(11,176)
Remeasurements of defined benefit plans	(5,508)	(5,669)	(161)
Total accumulated other comprehensive income	27,010	13,745	(13,265)
Subscription rights to shares	270	352	82
Non-controlling interests	4,353	4,085	(268)
Total net assets	478,883	513,877	34,994
Total liabilities and net assets	602,900	639,638	36,738

Decrease in Deferred tax liabilities due to falling in stock prices

Due to the strong yen

9-1. Quarterly trend for FY2014 and FY2015 (Sales of main merchandise and finished goods)

Fiscal year ended March 31, 2015

(Billions of yen)

FY2014	FY2014 1Q actual	Y on Y change %	FY2014 2Q actual	Y on Y change %	FY2014 3Q actual	Y on Y change %	FY2014 4Q actual	Y on Y change %
Prescription drugs	38.7	(4.3)	38.3	(5.5)	43.8	(5.8)	40.6	(0.7)
CRESTOR	10.8	8.2	10.3	(3.2)	11.1	4.4	11.4	15.7
IRBETAN Franchise	3.7	30.4	3.8	(0.1)	3.9	(0.8)	3.7	12.7
CYMBALTA	2.5	(2.5)	3.0	10.9	3.0	(4.2)	2.4	(18.0)
Total of 3 key products	17.1	10.5	16.9	(0.4)	17.9	1.7	17.8	8.9
OXYCONTIN Franchise	2.7	(1.7)	2.6	(1.7)	2.9	(6.6)	2.1	(3.5)
FINIBAX	0.9	(22.0)	1.0	(7.8)	1.1	(18.4)	1.0	(11.9)
DIFFERIN	0.9	(5.8)	0.9	(5.1)	1.1	(13.9)	1.0	(19.7)
PIRESPA	1.3	2.9	1.3	19.4	1.4	3.3	1.4	23.7
RAPIACTA	0.1	(30.7)	(0.0)	-	1.1	172.9	1.4	(2.6)
Total of 8 strategic products	22.9	6.0	22.8	(0.1)	25.5	1.6	24.6	5.2
FLOMOX	3.1	(19.6)	2.7	(25.3)	3.7	(19.2)	3.1	(19.3)
RINDERON	2.1	(13.2)	2.1	(8.8)	2.1	(8.2)	1.7	(8.8)
CLARITIN	0.9	(7.8)	0.7	(16.7)	0.9	(21.0)	1.8	(6.4)
FLUMARIN	1.1	(21.0)	1.3	(6.3)	1.2	(21.8)	1.0	(10.9)
Export/Overseas subsidiaries	6.0	(28.7)	7.8	11.9	7.5	(37.0)	7.4	9.3
Shionogi Inc.	2.8	(47.0)	4.6	9.9	4.6	(44.9)	3.9	11.6
Osphena	0.8	-	0.9	833.0	1.4	227.2	1.5	158.1
C&O	1.8	37.6	1.5	(6.8)	1.7	31.4	1.9	15.8
Contract manufacturing	3.5	49.0	3.4	24.6	3.0	288.7	5.7	123.0
OTC and quasi-drugs	1.1	11.3	1.4	1.4	1.2	7.5	0.9	(15.0)
Royalty income	12.7	(9.8)	15.6	(19.3)	14.0	(22.4)	18.4	(4.4)
CRESTOR	11.8	(10.1)	12.6	(30.2)	10.7	(35.7)	12.3	(30.9)
HIV Franchise	-	-	-	-	1.3	-	4.5	-
Others	0.7	(29.9)	0.8	14.2	0.8	(11.1)	0.8	(36.8)
Total	62.7	(6.7)	67.1	(6.1)	70.4	(11.3)	73.8	2.9

Fiscal year ended March 31, 2016

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)
IRBETAN Franchise	4.1	9.4	4.2	11.6	3.7	(4.0)	3.6	(2.2)
CYMBALTA	3.5	36.2	3.7	27.5	4.3	44.0	3.7	49.6
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

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

9-2. Quarterly trend for FY2014 and FY2015 (Consolidated statements of income)

Fiscal year ended March 31, 2015

(Billions of yen)

FY2014	FY2014 1Q actual	Y on Y change %	FY2014 2Q actual	Y on Y change %	FY2014 3Q actual	Y on Y change %	FY2014 4Q actual	Y on Y change %
Net sales	**62.7**	**(6.7)**	**67.1**	**(6.1)**	**70.4**	**(11.3)**	**73.7**	**2.9**
Cost of sales	31.6 19.8	8.1	27.3 18.3	(3.1)	29.3 20.6	2.2	31.8 23.4	13.9
Gross profit	42.9	(12.3)	48.8	(7.2)	49.8	(15.9)	50.3	(1.5)
SG & A expenses	55.6 34.9	(5.3)	50.9 34.1	(7.1)	51.8 36.5	(5.0)	48.8 36.0	(5.2)
Selling & general expenses	23.1	(2.2)	22.7	(4.7)	24.1	(2.9)	22.7	(5.5)
R & D expenses	11.7	(10.7)	11.4	(11.5)	12.4	(8.7)	13.3	(4.7)
Operating income	**12.8** **8.0**	**(33.6)**	**21.9** **14.7**	**(7.3)**	**19.0** **13.3**	**(36.0)**	**19.4** **14.3**	**9.3**
Non-operating income & expenses	5.6		3.1		7.0		11.9	
Ordinary income	**21.7** **13.6**	**8.4**	**26.5** **17.8**	**20.7**	**28.8** **20.3**	**(10.4)**	**35.5** **26.2**	**113.6**
Extraordinary income & loss	-		0.2		4.3		(0.3)	
Income before income taxes	13.6		18.0		24.6		25.8	
Income taxes and profit attributable to non-controlling interests	3.3		18.6		8.0		8.0	
* **Profit attributable to owners of parent**	**16.5** **10.3**	**(4.6)**	**(0.9)** **(0.6)**	**(4.6)**	**23.5** **16.6**	**9.8**	**24.1** **17.8**	**299.3**

Fiscal year ended March 31, 2016

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 & 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
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 & 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	
* **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**

** The Company changed "Profit attributable to owners of parent" from "Net income".*

10. Group companies

＜Consolidated affiliated companies＞

№	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	Saishin Igaku Co., Ltd.	Osaka, Japan	JPY 90 million	Publication of medical information	December 21, 1998	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 Analysis Center Co., Ltd.	Osaka, Japan	JPY 200 million	Contract testing and analysis on medicine	December 21, 2007	March 31	100
5	Aburahi AgroResearch Co., Ltd.	Shiga, Japan	JPY 10 million	Contract Laboratories for agro chemicals	February 26, 2004	March 31	＊ 100
6	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	September 8, 2010	March 31	100
7	Shionogi Healthcare Co., Ltd.	Osaka, Japan	JPY 10 million	Mfg., and sale of OTC and quasi-drugs	January 15, 2016	March 31	100
8	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg. and sale of pharmaceuticals	December 26, 1963	March 31	100
9	Shionogi Inc.	Delaware, U.S.A.	USD 12	Mfg.,sale and development of pharmaceuticals	August 25, 2008	March 31	100
10	SG Holding, Inc.	Delaware, U.S.A.	USD 140	Holding company	September 10, 2001	March 31	＊ 100
11	C&O Pharmaceutical Technology (Holdings) Limited	Bermuda Islands	HKD 165,840 thousand	Mfg.,sale and development of pharmaceuticals	July 28, 2003	December 31	71
12	Shionogi Ltd.	London, U.K.	GBP 700 thousand	Mfg.,sale and development of pharmaceuticals	February 10, 2012	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 4 million	Development of pharmaceuticals	December 30, 2013	March 31	100

＊Incl. Indirect ownership

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

11. Pipeline (as of May 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	LY248686 (duloxetine hydrochloride) 【Cymbalta®】	SNRI (serotonin & noradrenaline reuptake inhibitor) (oral)	Pain associated with chronic low back pain	Japan: Approval (Mar. 2016)	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	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.
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II	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: 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 February 2016

Change of phase	S-033188: Japan: Phase II → Japan: Phase II, US: Phase I
	LY248686 (pain associated with chronic low back pain): Japan: NDA submission (Dec. 2014) → Japan: Approval (Mar. 2016)
	LY248686 (pain associated with osteoarthritis): Japan: NDA submission (in preparation) → Japan: NDA submission (Feb. 2016)
	S-297995: Global: NDA submission (in preparation) → US, Japan: NDA submission (Mar. 2016)
	S-120083: Japan: Phase I → Japan: Phase I, US: Phase I