

Financial results for the year
ended March 31, 2021

<Supplement>

May 10, 2021

 **SHIONOGI & CO., LTD.**

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1. Financial results and forecast

(Billions of yen)

	FY2019 Actual	FY2020 Actual	FY2021 Forecast	Change		FY2021 1H Forecast
				FY2020	FY2021	
Revenue	333.4	297.2	290.0	(36.2)	(7.2)	135.0
<i>change %</i>	-	(10.9)	(2.4)			(9.1)
Operating profit	130.6	117.4	90.0	(13.2)	(27.4)	38.5
<i>change %</i>	-	(10.1)	(23.4)			(33.9)
Profit before tax	158.5	143.0	115.0	(15.5)	(28.0)	48.5
<i>change %</i>	-	(9.8)	(19.6)			(30.9)
Profit attributable to owners of parent	122.2	111.9	100.0	(10.3)	(11.9)	49.5
<i>change %</i>	-	(8.5)	(10.6)			(5.4)

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

2. Revenue by segment

(Billions of yen)

	FY2019 Actual	FY2020 Actual	FY2021 Forecast	Change		FY2021 1H Forecast
				FY2020	FY2021	
Prescription drugs	106.3	94.7	94.4	(11.6)	(0.3)	46.1
<i>change %</i>	-	(10.9)	(0.3)			(2.2)
CYMBALTA	26.2	26.5	15.1	0.2	(11.3)	10.0
INTUNIV	10.6	13.1	18.2	2.4	5.2	8.5
VYVANSE	0.0	0.3	1.0	0.3	0.8	0.4
Infectious Disease Drugs	16.0	9.8	17.0	(6.3)	7.3	4.8
OXYCONTIN Franchise	5.8	5.3	5.0	(0.5)	(0.3)	2.6
SYMPROIC	2.1	2.3	3.1	0.1	0.8	1.3
ACTAIR	0.3	0.3	0.4	0.1	0.0	0.2
MULPLETA	0.1	0.1	0.1	(0.0)	0.0	0.1
PIRESPA	6.8	5.1	3.5	(1.6)	(1.6)	1.8
Others	38.3	32.0	30.9	(6.3)	(1.1)	16.4
CRESTOR	8.6	6.7	6.5	(1.9)	(0.2)	3.8
IRBETAN Franchise	4.2	3.3	3.1	(0.9)	(0.3)	1.7
Overseas subsidiaries/Export	30.8	24.6	31.1	(6.2)	6.5	12.2
<i>change %</i>	-	(20.0)	26.2			10.9
Shionogi Inc.	10.1	7.5	8.4	(2.7)	0.9	4.2
Ping An-Shionogi / C&O	13.1	10.1	14.3	(3.1)	4.2	3.9
Contract manufacturing	17.6	19.7	17.8	2.2	(1.9)	7.4
<i>change %</i>	-	12.3	(9.7)			11.0
OTC and quasi-drugs	9.7	11.7	15.4	2.0	3.7	6.9
<i>change %</i>	-	20.7	31.8			25.1
Royalty income	166.9	144.6	129.8	(22.2)	(14.8)	61.7
<i>change %</i>	-	(13.3)	(10.3)			(20.2)
HIV Franchise	128.1	123.4	125.2	(4.7)	1.9	60.8
CRESTOR	22.3	16.6	1.1	(5.7)	(15.5)	-
Others	16.5	4.7	3.5	(11.8)	(1.2)	0.9
Others	2.2	1.8	1.4	(0.4)	(0.3)	0.7
<i>change %</i>	-	(18.5)	(18.2)			(12.8)
Total	333.4	297.2	290.0	(36.2)	(7.2)	135.0
<i>change %</i>	-	(10.9)	(2.4)			(9.1)

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

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

Products included in infectious disease drugs are bellow.

•Xofluza •Rapiacta •Brightpoc Flu Neo •Finibax •Flumarin •Flomox
•Seftem •Shiomarin •Vancomycin •Baktar •Flagyl •Fluconazole •Isodine

3. Management index

(Management index trend)

		FY2018	FY2019	FY2020
Return on equity attributable to owners of parent (ROE)	%	17.8	15.5	13.9
Ratio of profit before tax to total assets (ROA)	%	19.4	17.5	15.3
Ratio of operating profit to revenue	%	39.4	39.2	39.5
Ratio of profit before tax to revenue	%	47.3	47.5	48.1
Total assets turnover		0.41	0.37	0.32
Ratio of equity attributable to owners of parent to total assets	%	86.2	87.6	84.7
Dividend payout ratio	%	21.4	26.0	29.6
Ratio of dividends to equity attributable to owners of parent (DOE)	%	3.8	4.0	4.1
Basic earnings per share	yen	438.47	395.71	365.03
Diluted earnings per share	yen	434.71	395.28	364.89

4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2019 Actual	FY2020 Actual	FY2021 Forecast	Change		FY2021 1H Forecast
				FY2020	FY2021	
Investments in equipments	10.0	27.4	29.6	17.4	2.2	9.4
Depreciation and Amortization	14.1	14.8	16.3	0.7	1.5	8.0

5. R&D expenses

(Billions of yen)

	FY2019 Actual	FY2020 Actual	FY2021 Forecast	Change		FY2021 1H Forecast
				FY2020	FY2021	
R&D expenses	47.9	54.2	52.0	6.3	(2.2)	25.0
<i>change %</i>	-	13.1	(4.1)			0.6
% to net revenue	14.4	18.3	17.9			18.5

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

6. Employees

	FY2019 Actual	FY2020 Actual	FY2021 Forecast	Change		FY2021 1H Forecast
				FY2020	FY2021	
Employees	5,222	5,485	5,523	263	38	5,536

7. Consolidated statement of profit or loss

(Millions of yen)

	FY2019 Actual	FY2020 Actual	Y on Y Change		
Revenue	333,371	297,177	(36,193)	Increasing/(decreasing) in Prescription drugs: (11.6) billion yen Overseas subsidiaries/Export(6.2) billion yen Contract manufacturing: 2.2 billion yen OTC and quasi-drugs: 2.0 billion yen Royalty income: (22.2) billion yen	
Cost of sales	(56,782)	(52,523)	(4,258)		
Gross profit	276,589	244,654	(31,935)		
Selling, general and administrative expenses	(95,094)	(91,902)	(3,192)		Refrained voluntarily from sales activities to prevent the spread of COVID-19
Research and development expenses	(47,949)	(54,249)	6,300		
Amortization of intangible assets associated with products	(3,255)	(3,209)	(46)	Gain on exchange from redevelopment of Shionogi Shibuya Building 22.9 billion yen	
Other income	4,291	26,403	22,112	Gain on step acquisition of Tetra 3.0 billion yen	
Other expenses	(3,951)	(4,257)	306		
Operating profit	130,628	117,438	(13,190)		
Finance income	30,504	26,522	(3,982)	Shionogi B.V. Decreasing in dividend income from ViiV	
Finance costs	(2,616)	(941)	(1,674)		
Profit before tax	158,516	143,018	(15,498)		
Income tax expense	(36,322)	(30,956)	(5,365)		
Profit	122,194	112,061	(10,132)		
Profit attributable to					
Owners of parent	122,193	111,858	(10,334)		
Non-controlling interests	1	203	202		
Profit	122,194	112,061	(10,132)		

8-1. Consolidated statement of financial position (Assets)

(Millions of yen)

	As of Mar. 31 2020	As of Mar. 31 2021	Y on Y change	
Assets				
Non-Current assets				
Property, plant and equipment	71,350	90,883	19,532	Increase due to construction of vaccine manufacturing facilities
Goodwill	7,854	9,357	1,502	
Intangible assets	51,705	76,558	24,852	Increase due to acquisition of Tetra
Right-of-use assets	4,657	4,827	169	
Investment property	2,496	26,759	24,262	Increase due to redevelopment of Shionogi Shibuya Building
Other financial assets	202,161	217,437	15,276	
Deferred tax assets	3,048	11,729	8,681	
Other non-current assets	14,394	5,200	(9,193)	
Total non-current assets	357,669	442,754	85,085	
Current assets				
Inventories	33,818	38,003	4,184	
Trade receivables	79,804	78,047	(1,757)	
Other financial assets	171,157	142,151	(29,006)	Decreased in time deposits over 3 months
Income taxes receivable	192	164	(28)	
Other current assets	22,191	21,697	(493)	
Cash and cash equivalents	208,861	276,173	67,312	
Total current assets	516,026	556,238	40,211	
Total assets	873,695	998,992	125,297	

8-2. Consolidated statement of financial position (Equity/Liabilities)

	<i>(Millions of yen)</i>		
	As of Mar. 31 2020	As of Mar. 31 2021	Y on Y change
Equity and liabilities			
Equity			
Share capital	21,279	21,279	—
Capital surplus	21,025	13,733	(7,291)
Treasury shares	(77,292)	(57,989)	19,302
Retained earnings	708,291	752,248	43,956
Other components of equity	91,848	116,836	24,988
Equity attributable to owners of parent	765,152	846,108	80,956
Non-controlling interests	51	18,442	18,391
Total equity	765,203	864,550	99,347
Liabilities			
Non-current liabilities			
Lease liabilities	4,791	4,608	(182)
Other financial liabilities	4,179	5,242	1,063
Retirement benefit liability	16,089	16,318	229
Deferred tax liabilities	1,949	7,749	5,799
Other non-current liabilities	362	341	(20)
Total non-current liabilities	27,372	34,261	6,889
Current liabilities			
Lease liabilities	3,361	3,379	17
Trade payables	10,763	9,902	(860)
Other financial liabilities	17,557	21,383	3,826
Income taxes payable	21,886	28,033	6,146
Other current liabilities	27,551	37,481	9,930
Total current liabilities	81,119	100,180	19,060
Total liabilities	108,492	134,442	25,949
Total equity and liabilities	873,695	998,992	125,297

Due to Cancellation	30.9 billion yen
Disposal through third-party allotment	37.8 billion yen
Purchase	(50.0) billion yen

Exchange rate fluctuations

Increase due to establishment of subsidiary with Ping An Group
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9-1. Quarterly trend for FY2019 and FY2020 (Revenue by segment)

Fiscal year ended March 31, 2020

(Billions of yen)

FY2019	FY2019 1Q Actual	Y on Y Change %	FY2019 2Q Actual	Y on Y Change %	FY2019 3Q Actual	Y on Y Change %	FY2019 4Q Actual	Y on Y Change %
Prescription drugs	26.3	-	25.1	-	28.8	-	26.0	-
CYMBALTA	6.7	-	6.1	-	7.3	-	6.0	-
INTUNIV	1.8	-	2.6	-	2.6	-	3.6	-
VYVANSE	-	-	-	-	0.0	-	0.0	-
Infectious Disease Drugs	3.6	-	3.7	-	5.5	-	3.2	-
OXYCONTIN Franchise	1.7	-	1.4	-	1.6	-	1.1	-
SYMPROIC	0.5	-	0.5	-	0.5	-	0.6	-
ACTAIR	0.1	-	0.1	-	0.1	-	0.1	-
MULPLETA	0.0	-	0.0	-	0.0	-	0.0	-
PIRESPA	1.7	-	1.7	-	1.5	-	1.8	-
Others	10.2	-	8.9	-	9.7	-	9.6	-
CRESTOR	2.4	-	2.0	-	2.1	-	2.0	-
IRBETAN Franchise	1.2	-	1.0	-	1.1	-	1.0	-
Overseas subsidiaries/Export	10.7	-	6.8	-	6.5	-	6.8	-
Shionogi Inc.	5.3	-	1.5	-	1.7	-	1.6	-
C&O	3.8	-	3.4	-	3.0	-	2.9	-
Contract manufacturing	2.4	-	7.6	-	1.9	-	5.6	-
OTC and quasi-drugs	1.8	-	2.6	-	2.6	-	2.7	-
Royalty income	38.9	-	40.1	-	50.7	-	37.1	-
HIV Franchise	31.7	-	33.2	-	32.8	-	30.3	-
CRESTOR	5.7	-	5.6	-	5.5	-	5.6	-
Others	1.5	-	1.3	-	12.4	-	1.2	-
Others	0.5	-	0.6	-	0.6	-	0.4	-
Total	80.8	-	82.9	-	91.1	-	78.6	-

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

Fiscal year ended March 31, 2021

FY2020	FY2020 1Q Actual	Y on Y Change %	FY2020 2Q Actual	Y on Y Change %	FY2020 3Q Actual	Y on Y Change %	FY2020 4Q Actual	Y on Y Change%
Prescription drugs	22.4	(15.1)	24.8	(1.2)	24.7	(14.4)	22.9	(12.1)
CYMBALTA	6.9	2.9	6.6	6.8	7.0	(4.2)	6.0	(1.0)
INTUNIV	2.6	42.2	3.4	30.1	3.6	36.3	3.5	(2.3)
VYVANSE	0.0	-	0.1	-	0.1	1,586.9	0.1	1,827.2
Infectious Disease Drugs	2.1	(40.7)	2.7	(26.5)	2.7	(50.4)	2.2	(32.4)
OXYCONTIN Franchise	1.4	(17.3)	1.4	(1.5)	1.3	(19.9)	1.2	11.2
SYMPROIC	0.5	(7.9)	0.6	9.2	0.6	22.3	0.6	4.7
ACTAIR	0.1	3.4	0.1	40.1	0.1	44.3	0.1	14.6
MULPLETA	0.0	(26.3)	0.0	(19.8)	0.0	(28.6)	0.0	(16.1)
PIRESPA	1.4	(17.1)	1.4	(18.2)	1.2	(22.1)	1.1	(38.8)
Others	7.3	(28.4)	8.5	(3.5)	8.1	(16.2)	8.1	(15.9)
CRESTOR	1.5	(35.3)	2.1	4.7	1.4	(34.2)	1.6	(22.0)
IRBETAN Franchise	0.8	(30.5)	0.9	(11.4)	0.9	(17.8)	0.8	(23.1)
Overseas subsidiaries/Export	5.5	(49.1)	5.5	(18.5)	6.5	0.1	7.2	5.5
Shionogi Inc.	1.7	(68.6)	1.7	11.1	2.1	20.9	2.1	26.6
C&O	2.4	(37.5)	1.9	(44.1)	2.7	(11.5)	3.1	6.6
Contract manufacturing	2.9	17.6	3.8	(50.1)	3.6	88.0	9.5	68.9
OTC and quasi-drugs	2.3	26.1	3.2	23.4	3.3	27.3	2.9	8.3
Royalty income	38.0	(2.4)	39.3	(2.1)	37.5	(26.0)	29.8	(19.7)
HIV Franchise	31.0	(2.4)	33.0	(0.7)	31.1	(5.2)	28.3	(6.7)
CRESTOR	5.6	(1.6)	5.6	(0.8)	5.4	(0.4)	(0.0)	(100.0)
Others	1.5	(3.6)	0.8	(40.7)	0.9	(92.5)	1.5	24.1
Others	0.4	(17.2)	0.4	(36.0)	0.4	(33.0)	0.5	26.2
Total	71.4	(11.6)	77.1	(7.0)	76.0	(16.6)	72.8	(7.5)

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

9-2. Quarterly trend for FY2019 and FY2020 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2020

(Billions of yen)

FY2019	FY2019 1Q Actual	Y on Y Change %	FY2019 2Q Actual	Y on Y Change %	FY2019 3Q Actual	Y on Y Change %	FY2019 4Q Actual	Y on Y Change %
Revenue	80.8	-	82.9	-	91.1	-	78.6	-
Cost of sales	15.7 (12.7)	-	18.2 (15.0)	-	14.3 (13.0)	-	20.4 (16.1)	-
Gross profit	68.1	-	67.8	-	78.1	-	62.5	-
SG & A expenses	28.6 (23.1)	-	28.5 (23.6)	-	26.4 (24.0)	-	31.1 (24.4)	-
R & D expenses	14.5 (11.7)	-	14.1 (11.6)	-	12.6 (11.5)	-	16.7 (13.1)	-
Amortization of intangible assets associated with products	1.0 (0.8)	-	1.0 (0.8)	-	0.9 (0.8)	-	1.0 (0.8)	-
Other income & expenses	(0.9)		(0.3)		1.7		(0.3)	
Operating profit	39.2 31.7	-	38.0 31.5	-	47.7 43.5	-	30.4 23.9	-
Finance income & costs	3.7	-	3.8	-	9.5	-	10.9	-
Profit before tax	43.8 35.3	-	42.6 35.3	-	58.2 53.0	-	44.4 34.9	-
Income tax expense etc.	(8.2)	-	(8.1)	-	(13.1)	-	(6.9)	-
Profit attributable to owners of parent	33.6 27.1	-	32.9 27.3	-	43.8 39.9	-	35.5 27.9	-

Fiscal year ended March 31, 2021

FY2020	FY2020 1Q Actual	Y on Y Change %	FY2020 2Q Actual	Y on Y Change %	FY2020 3Q Actual	Y on Y Change %	FY2020 4Q Actual	Y on Y Change %
Revenue	71.4	(11.6)	77.1	(7.0)	76.0	(16.6)	72.8	(7.5)
Cost of sales	16.1 (11.5)	(9.3)	14.8 (11.4)	(24.4)	17.2 (13.1)	0.6	22.8 (16.6)	3.1
Gross profit	59.9	(12.0)	65.7	(3.1)	62.9	(19.5)	56.2	(10.2)
SG & A expenses	29.2 (20.9)	(9.5)	28.9 (22.3)	(5.5)	30.4 (23.1)	(3.9)	35.3 (25.7)	5.1
R & D expenses	17.0 (12.2)	4.2	16.5 (12.7)	8.9	18.9 (14.4)	24.8	20.6 (15.0)	14.7
Amortization of intangible assets associated with products	1.1 (0.8)	(0.1)	1.0 (0.8)	(0.8)	1.0 (0.8)	(2.9)	1.1 (0.8)	(1.9)
Other income & expenses	2.5		(0.2)		22.3		(2.4)	
Operating profit	40.0 28.6	(9.8)	38.5 29.7	(5.8)	61.7 46.9	7.8	16.9 12.3	(48.7)
Finance income & costs	4.4	21.1	7.4	96.3	2.7	(71.0)	11.0	0.1
Profit before tax	46.2 33.0	(6.6)	48.2 37.1	5.1	65.3 49.6	(6.3)	31.9 23.2	(33.4)
Income tax expense etc.	(8.5)	3.8	(9.3)	15.2	(12.9)	(1.2)	(0.4)	(94.2)
Profit attributable to owners of parent	34.3 24.5	(9.7)	36.1 27.8	2.2	48.3 36.7	(8.0)	31.4 22.8	(18.3)

Note : The provisional accounting for the business combination of Tetra was finalized, and the consolidated financial statements have been retrospectively adjusted from the time of acquisition.

10. Group companies

<Consolidated affiliated companies (as of March 31, 2021)>

No	Company name	Location	Common stock	Business status	Establish	Closing date	Ownership (%)
1	Shionogi Pharma Co., Ltd.	Osaka, Japan	JPY 90 million	Mfg., of pharmaceuticals and contract manufacturing, Contract testing and analysis on medicine	Oct.1, 2018	Mar.31	100
2	Shionogi Healthcare Co., Ltd.	Osaka, Japan	JPY 10 million	Mfg., and sales of OTC and quasi-drugs	Jan.15, 2016	Mar.31	* 51
3	Shionogi Techno Advance Research Co., Ltd.	Osaka, Japan	JPY 9 million	Contract support services for experimental research	Sep.8, 2010	Mar.31	100
4	Shionogi Administration Service Co., Ltd.	Osaka, Japan	JPY 10 million	Real estate rental and shared services	Nov.2, 1992	Mar.31	100
5	Shionogi Career Development Center Co., Ltd.	Hyogo, Japan	JPY 10 million	Career development support to the group companies	Apr.3, 2017	Mar.31	100
6	Shionogi Digital Science Co., Ltd.	Osaka, Japan	JPY 10 million	ICT solution service to the group companies	Apr.3, 2017	Mar.31	100
7	Shionogi Business Partner Co., Ltd.	Osaka, Japan	JPY 10 million	Insurance agency and shared services	Apr.3, 2017	Mar.31	100
8	Shionogi Pharmacovigilance Center Co.,Ltd.	Osaka, Japan	JPY 10 million	Pharmacovigilance activity for the group companies	Apr.3, 2017	Mar.31	100
9	Shionogi Marketing Solutions Co., Ltd.	Osaka, Japan	JPY 10 million	Market research, Making of the sales promotion materials, Support of the sales department	Apr.3, 2017	Mar.31	100
10	UMN Pharma Inc.	Akita, Japan	JPY 90 million	Research, development, mfg., and marketing of biopharmaceuticals	Apr.20, 2004	Mar.31	100
11	Nagase Medicals Co., Ltd	Hyogo, Japan	JPY 498 million	Mfg., of pharmaceuticals and contract manufacturing	July.1, 1972	Mar.31	* 100
12	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg., sale and development of pharmaceuticals	Aug.25, 2008	Mar.31	100
13	Tetra Therapeutics Inc.	Michigan, U.S.A.	USD 37 thousand	Research and development of pharmaceuticals	Jul.21, 2016	Dec.31	100
14	Shionogi B.V.	Amsterdam, Netherlands	GBP 630 thousand	Mfg., sale and development of pharmaceuticals	Nov.29, 2018	Mar.31	100
15	C&O Pharmaceutical Technology (Holdings) Limited	Shenzhen, China	HKD 165,840 thousand	Mfg., sale and development of pharmaceuticals	Jul.28, 2003	Dec.31	100
16	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg., and sale of pharmaceuticals	Dec.26, 1963	Mar.31	100
17	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	Mar.29, 2013	Dec.31	100
18	Ping An-Shionogi (Hong Kong) Ltd.	Hong Kong, China	HKD 361,794 thousand	Sale of pharmaceuticals	Aug.24, 2020	Mar.31	* 51
19	Ping An-Shionogi Co., Ltd.	Shanghai, China	RMB 1,061,224 thousand	Mfg., sale and development of pharmaceuticals	Nov.18, 2020	Dec.31	* 51

*Incl. Indirect ownership

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

11. Pipeline (as of May 10, 2021)

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja®] [EU:Fetroja®]	Cell-wall synthesis inhibition (injection)	USA:Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia with no or limited treatment options Europe:Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options	Global:PhaseIII (pediatric) USA:Approval (cUTI) (Nov.2019) Approval (Nosocomial pneumonia) (Sep.2020) Europe: Approval (Apr.2020)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan:Approval (body weight ≥20kg) (Sep.2018) Japan:NDA submission (body weight <20kg) (Aug.2018)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Not disclosed (oral)	HIV infection	USA,Japan:PhaseI	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan:PhaseI/II	In-house	In-house
Pain/CNS	S-297995 (nalmededine tosilate) [US/Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation(pediatric)	Europe:PhaseI/II	In-house	In-house
	S-120083	Not disclosed (oral)	Inflammatory pain	Japan:PhaseI USA:PhaseII	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Not disclosed (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-117957	Not disclosed (oral)	Insomnia	USA:PhaseI	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918 (sivopixant)	P2X ₃ receptor antagonist (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-600918 (sivopixant)	P2X ₃ receptor antagonist (oral)	Refractory/unexplained chronic cough	Global:PhaseII	In-house	In-house
	S-600918 (sivopixant)	P2X ₃ receptor antagonist (oral)	Sleep Apnea Syndrome	Japan:PhaseII	In-house	In-house
	S-637880	Not disclosed (oral)	Neuropathic Low Back pain	Japan:PhaseII	In-house	In-house
	S-812217 (zuranolone)	GABAA receptor positive allosteric modulator (oral)	Depression	Japan:PhaseII	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan:PhaseII	Akili (USA)	Shionogi/Akili
	BPN14770	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA:PhaseII	Tetra (USA)	Shionogi/Tetra
	BPN14770	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA:PhaseII Japan:PhaseII	Tetra (USA)	Shionogi/Tetra
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan:PhaseII	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan:PhaseI/II	Rohto	Shionogi/Rohto
	S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan:PhaseI	In-house	In-house

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Frontier	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan:PhaseIII	OncoTherapy Science, Inc. (Japan)	In-house
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan,Europe:PhaseII	OncoTherapy Science, Inc. (Japan)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe:PhaseI/II	OncoTherapy Science, Inc.(Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK:PhaseI	OncoTherapy Science, Inc.(Japan)	In-house
	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe:PhaseI/II	In-house	In-house
	S-770108	Antifibrotic (inhalation)	Idiopathic pulmonary fibrosis	Japan:PhaseI	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan:PhaseII	FunPep (Japan)	Shionogi/FunPep
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Japan:PhaseII	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan:PhaseII (preparing NDA submission)	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
S/GSK1265744 LAP*1 (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB*2 LAP+RPV*3 LAP 2-drug regimen for treatment) Canada:Approval(Mar.2020) USA:Approval (Jan. 2021) Europe:Approval (Dec. 2020) (CAB LAP for prevention) Global:PhaseIII	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:PhaseIII (preparing NDA submission)	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA:Xofluzax™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA:Approval(Oct.2018) USA:Approval(high risk patients) (Oct.2019) USA:NDA submission(pediatric, ≥ 1 year old)(Mar.2020) USA:Approval(granule, ≥12 years old) (Nov.2020) USA:Approval(prophylaxis, ≥12 years old) (Nov.2020) Europe:Approval(treatment, ≥12 years old) (prophylaxis, ≥12 years old)(Jan.2021) Global:PhaseIII(pediatric, < 1 year old) Global:PhaseIII(transmission)	In-house	Shionogi/Roche (Switzerland)
S-555739 (asapirant)	Prostaglandin D2 DP1 receptor antagonist (oral)	Control of the aggravation of COVID-19	USA: PhaseII	In-house	BioAge Labs, Inc. (USA)

*1 Long acting parenteral formulation, *2 Cabotegravir, *3 Rilpivirine

Since Feb. 1, 2021

Change of phase	BPN14770 (Alzheimer's disease) : Japan : PhaseI→PhaseII
	S-0373 (Spinocerebellar ataxia) : Japan : PhaseIII→preparing NDA submission
Compound added to the list	S-555739 (Control of the aggravation of COVID-19) : USA : PhaseII
Compound erased from the list	S-033188(high dosage for children) : Japan : Closed
	S-033188 (Prophylaxis)(body weight >20kg) : Japan : Approval
	S-297995 (Postoperative ileus) : USA : Closed
	LY248686 (Depression)(pediatric) : Japan : Closed
	S-237648 (Obesity) : USA : Closed
	S-707106 (Type 2 diabetes) : USA : Closed
S-033188(severe influenza virus infection) : Global : Closed	