

Financial results for the second quarter
of fiscal year 2021

< Supplement >

November 1, 2021

 **SHIONOGI & CO., LTD.**

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1. Financial results and forecast

(Billions of yen)

	FY2021 1H actual	FY2021 2H forecast	FY2021 forecast	FY2020 1H actual	FY2020 2H actual	FY2020 actual	Y on Y change		
							1H	2H	full-year
Revenue	145.1	148.9	294.0	148.5	148.7	297.2	(3.4)	0.2	(3.2)
<i>change %</i>	<i>(2.3)</i>	<i>0.1</i>	<i>(1.1)</i>	<i>(9.3)</i>	<i>(12.4)</i>	<i>(10.9)</i>			
Operating profit	42.7	47.3	90.0	58.3	59.2	117.4	(15.6)	(11.8)	(27.4)
<i>change %</i>	<i>(26.8)</i>	<i>(20.0)</i>	<i>(23.4)</i>	<i>(7.8)</i>	<i>(12.3)</i>	<i>(10.1)</i>			
Profit before tax	50.8	64.2	115.0	70.1	72.9	143.0	(19.3)	(8.7)	(28.0)
<i>change %</i>	<i>(27.5)</i>	<i>(11.9)</i>	<i>(19.6)</i>	<i>(0.7)</i>	<i>(17.1)</i>	<i>(9.8)</i>			
Profit attributable to owners of parent	53.1	46.9	100.0	52.3	59.5	111.9	0.8	(12.7)	(11.9)
<i>change %</i>	<i>1.5</i>	<i>(21.3)</i>	<i>(10.6)</i>	<i>(3.8)</i>	<i>(12.2)</i>	<i>(8.5)</i>			

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

2. Revenue by segment

(Billions of yen)

	FY2021 1H	FY2021 2H	FY2021	FY2020 1H	FY2020 2H	FY2020	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Prescription drugs	47.1	47.3	94.4	47.2	47.5	94.7	(0.0)	(0.3)	(0.3)
<i>change %</i>	0.0	(0.6)	(0.3)	(8.3)	(13.3)	(10.9)			
CYMBALTA	11.5	5.6	17.1	13.5	13.0	26.5	(2.0)	(7.3)	(9.3)
INTUNIV	7.6	9.0	16.6	6.0	7.1	13.1	1.6	2.0	3.6
VYVANSE	0.3	0.7	1.0	0.1	0.2	0.3	0.2	0.5	0.8
Infectious Disease Drugs	5.8	10.9	16.6	4.9	4.9	9.8	0.9	6.0	6.9
OXYCONTIN Franchise	2.5	2.5	5.0	2.8	2.6	5.3	(0.3)	(0.0)	(0.3)
SYMPROIC	1.3	1.9	3.1	1.1	1.2	2.3	0.2	0.7	0.8
ACTAIR	0.2	0.1	0.4	0.1	0.2	0.3	0.1	(0.1)	0.0
MULPLETA	0.1	0.1	0.1	0.1	0.0	0.1	0.0	0.0	0.0
PIRESPA	2.0	1.5	3.5	2.8	2.3	5.1	(0.8)	(0.8)	(1.6)
Others	15.9	14.9	30.8	15.8	16.1	32.0	0.1	(1.2)	(1.1)
CRESTOR	3.1	2.6	5.7	3.7	3.0	6.7	(0.6)	(0.4)	(1.0)
IRBETAN Franchise	1.5	1.5	3.1	1.7	1.6	3.3	(0.2)	(0.1)	(0.3)
Overseas subsidiaries/Export	17.4	17.5	35.0	11.0	13.6	24.6	6.4	3.9	10.3
<i>change %</i>	58.2	28.6	41.8	(37.3)	2.9	(20.0)			
Shionogi Inc.	7.9	4.8	12.7	3.3	4.1	7.5	4.5	0.7	5.2
Ping An-Shionogi / C&O	4.7	7.6	12.3	4.2	5.8	10.1	0.5	1.8	2.2
Shionogi B.V.	2.3	2.7	5.0	0.7	1.2	2.0	1.5	1.5	3.0
Contract manufacturing	8.4	9.5	17.8	6.7	13.1	19.7	1.7	(3.6)	(1.9)
<i>change %</i>	25.1	(27.6)	(9.7)	(33.7)	73.7	12.3			
OTC and quasi-drugs	6.0	7.4	13.4	5.5	6.2	11.7	0.6	1.2	1.7
<i>change %</i>	10.3	18.7	14.8	24.5	17.6	20.7			
Royalty income	65.4	66.6	132.0	77.3	67.3	144.6	(11.9)	(0.7)	(12.7)
<i>change %</i>	(15.5)	(1.1)	(8.8)	(2.2)	(23.3)	(13.3)			
HIV Franchise	61.2	64.0	125.2	63.9	59.4	123.4	(2.7)	4.6	1.9
CRESTOR	-	-	-	11.1	5.4	16.6	(11.1)	(5.4)	(16.6)
Others	4.1	2.6	6.7	2.3	2.4	4.7	1.9	0.2	2.0
Others	0.8	0.7	1.4	0.8	0.9	1.8	(0.0)	(0.3)	(0.3)
<i>change %</i>	(5.4)	(29.6)	(18.2)	(27.1)	(9.0)	(18.5)			
Total	145.1	148.9	294.0	148.5	148.7	297.2	(3.4)	0.2	(3.2)
<i>change %</i>	(2.3)	0.1	(1.1)	(9.3)	(12.4)	(10.9)			

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

Sales 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
- Shiomarin • Vancomycin • Baktar • Flagyl • Fluconazole • Isodine

3. Management index

(Management index trend)

		FY2019	FY2020	FY2020 1H	FY2021 1H
Return on equity attributable to owners of parent (ROE)	%	15.5	13.9	6.5	6.2
Ratio of profit before tax to total assets (ROA)	%	17.5	15.3	7.7	5.0
Ratio of operating profit to revenue	%	39.2	39.5	39.2	29.4
Ratio of profit before tax to revenue	%	47.5	48.1	47.3	35.0
Total assets turnover		0.37	0.32	0.16	0.14
Ratio of equity attributable to owners of parent to total assets	%	87.6	84.7	89.1	86.3
Dividend payout ratio	%	26.0	29.6	-	-
Ratio of dividends to equity attributable to owners of parent (DOE)	%	4.0	4.1	-	-
Basic earnings per share	yen	395.71	365.03	170.47	176.24
Diluted earnings per share	yen	395.28	364.89	170.40	176.18

4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2021 1H	FY2021 2H	FY2021	FY2020 1H	FY2020 2H	FY2020	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Investments in equipments	8.6	21.0	29.6	2.8	24.6	27.4	5.7	(3.5)	2.2
Depreciation and Amortization	7.8	8.0	15.9	7.3	7.5	14.8	0.6	0.5	1.1

5. R&D expenses

(Billions of yen)

	FY2021 1H	FY2021 2H	FY2021	FY2020 1H	FY2020 2H	FY2020	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
R&D expenses	28.2	27.3	55.5	24.9	29.4	54.2	3.3	(2.1)	1.3
<i>change %</i>	<i>13.4</i>	<i>(7.0)</i>	<i>2.3</i>	<i>6.5</i>	<i>19.4</i>	<i>13.1</i>			
% to revenue	19.4	18.3	18.9	16.7	19.8	18.3			

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

6. Employees

	End of FY2019	End of 2020 1H	End of FY2020	End of 2021 1H	End of FY2021	Y on Y change		
	actual	actual	actual	actual	forecast	1H	2H	full-year
Employees	5,222	5,313	5,485	5,561	5,484	76	(77)	(1)

7. Consolidated statement of profit or loss

			<i>(Millions of yen)</i>	
	FY2020 1H actual	FY2021 1H actual	Y on Y change	
Revenue	148,452	145,085	(3,367)	Increasing/(decreasing) in Prescription drugs: (0.0) billion yen Overseas subsidiaries/Export: 6.4 billion yen Contract manufacturing: 1.7 billion yen OTC and quasi-drugs: 0.6 billion yen Royalty income: (11.9) billion yen
Cost of sales	(22,857)	(26,984)	4,126	
Gross profit	125,594	118,101	(7,493)	
Selling, general and administrative expenses	(43,157)	(44,248)	1,091	Increasing in selling expenses for Cefiderocol
Research and development expenses	(24,854)	(28,175)	3,321	Increasing in research and development investments for treatments and vaccines for COVID-19
Amortization of intangible assets associated with products	(1,611)	(1,641)	30	
Other income	3,204	1,606	(1,598)	
Other expenses	(909)	(2,977)	2,068	Loss on disposal of property, plant and equipment Costs to address dichloromethane leakage
Operating profit	58,266	42,664	(15,602)	Shionogi B.V. Decreasing in dividend income from ViiV.
Finance income	12,805	8,338	(4,467)	
Finance costs	(925)	(170)	(754)	
Profit before tax	70,147	50,832	(19,315)	Refund received in relation to a favorable judgment of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau
Income tax expense	(17,806)	2,191	(19,997)	
Profit	52,340	53,023	682	
Profit attributable to				
Owners of parent	52,339	53,131	791	
Non-controlling interests	1	(107)	(109)	
Profit	52,340	53,023	682	

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

	<i>(Millions of yen)</i>		
	As of Mar. 31 2021	As of Sep. 30 2021	Y on Y change
Assets			
Non-Current assets			
Property, plant and equipment	90,883	95,024	4,140
Goodwill	9,357	9,460	102
Intangible assets	76,558	78,231	1,673
Right-of-use assets	4,827	4,142	(685)
Investment property	26,759	26,528	(230)
Other financial assets	217,437	208,559	(8,878)
Deferred tax assets	11,729	10,795	(934)
Other non-current assets	5,200	5,786	586
Total non-current assets	442,754	438,528	(4,226)
Current assets			
Inventories	38,003	40,316	2,312
Trade receivables	78,047	79,347	1,300
Other financial assets	142,151	206,788	64,636
Income taxes receivable	164	94	(70)
Other current assets	21,697	19,316	(2,380)
Cash and cash equivalents	276,173	236,059	(40,114)
Total current assets	556,238	581,922	25,684
Total assets	998,992	1,020,450	21,458

Increase due to construction of vaccine manufacturing facilities

Increased in time deposits over 3 months

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

(Millions of yen)

	As of Mar. 31 2021	As of Sep. 30 2021	Y on Y change
Equity and liabilities			
Equity			
Share capital	21,279	21,279	-
Capital surplus	13,733	14,588	855
Treasury shares	(57,989)	(57,851)	138
Retained earnings	752,248	789,134	36,885
Other components of equity	116,836	113,973	(2,862)
Equity attributable to owners of parent	846,108	881,125	35,016
Non-controlling interests	18,442	17,770	(671)
Total equity	864,550	898,896	34,345
Liabilities			
Non-current liabilities			
Lease liabilities	4,608	4,169	(439)
Other financial liabilities	5,242	4,480	(761)
Retirement benefit liability	16,318	15,560	(757)
Deferred tax liabilities	7,749	7,149	(599)
Other non-current liabilities	341	332	(9)
Total non-current liabilities	34,261	31,693	(2,568)
Current liabilities			
Lease liabilities	3,379	3,264	(114)
Trade payables	9,902	10,264	361
Other financial liabilities	21,383	18,735	(2,647)
Income taxes payable	28,033	18,153	(9,879)
Other current liabilities	37,481	39,443	1,961
Total current liabilities	100,180	89,861	(10,318)
Total liabilities	134,442	121,554	(12,887)
Total equity and liabilities	998,992	1,020,450	21,458

9-1. Quarterly trend for FY2020 and FY2021 (Revenue by segment)

Fiscal year ended March 31, 2021

(Billions of yen)

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

Fiscal year ending March 31, 2022

FY2021	FY2021 1Q actual	Y on Y change %	FY2021 2Q actual	Y on Y change %
Prescription drugs	23.5	5.1	23.7	(4.6)
CYMBALTA	6.8	(1.5)	4.7	(29.0)
INTUNIV	3.6	37.3	4.0	18.2
VYVANSE	0.1	436.2	0.2	223.0
Infectious Disease Drugs	2.1	(1.6)	3.7	34.4
OXYCONTIN Franchise	1.3	(8.9)	1.2	(12.0)
SYMPROIC	0.6	24.8	0.7	11.8
ACTAIR	0.1	79.1	0.1	56.2
MULPLETA	0.0	18.0	0.0	(4.3)
PIRESPA	1.0	(32.2)	1.0	(27.6)
Others	7.9	8.1	8.1	(5.6)
CRESTOR	1.4	(7.7)	1.6	(22.4)
IRBETAN Franchise	0.8	(7.3)	0.8	(10.7)
Overseas subsidiaries/Export	9.3	70.0	8.1	46.7
Shionogi Inc.	4.7	182.7	3.2	89.2
Ping An-Shionogi / C&O	2.4	0.2	2.4	24.1
Shionogi B.V.	0.9	144.1	1.4	267.6
Contract manufacturing	3.7	30.2	4.6	21.3
OTC and quasi-drugs	2.5	9.0	3.6	11.1
Royalty income	29.6	(22.1)	35.8	(9.1)
HIV Franchise	28.8	(6.8)	32.4	(1.7)
CRESTOR	-	-	-	-
Others	0.8	(47.4)	3.3	328.6
Others	0.4	(17.3)	0.4	8.6
Total	69.0	(3.4)	76.1	(1.2)

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

9-2. Quarterly trend for FY2020 and FY2021 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2021

(Billions of yen)

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)

Fiscal year ending March 31, 2022

FY2021	FY2021 1Q actual	Y on Y change %	FY2021 2Q actual	Y on Y change %
Revenue	69.0	(3.4)	76.1	(1.2)
Cost of sales	17.9 (12.3)	7.3	19.2 (14.7)	28.9
Gross profit	56.6	(5.5)	61.5	(6.4)
SG & A expenses	31.5 (21.8)	4.2	29.6 (22.5)	0.9
R & D expenses	21.4 (14.7)	21.1	17.7 (13.4)	6.0
Amortization of intangible assets associated with products	1.2 (0.8)	1.2	1.1 (0.8)	2.6
Other income & expenses	(0.5)		(0.8)	
Operating profit	27.3 18.8	(34.2)	31.4 23.9	(19.6)
Finance income & costs	4.1	(6.7)	4.0	(45.9)
Profit before tax	33.3 22.9	(30.5)	36.6 27.9	(24.9)
Income tax expense etc.	9.3	(209.0)	(7.0)	(24.6)
Profit attributable to owners of parent	46.7 32.2	31.6	27.4 20.9	(25.0)

10. Group companies

< Consolidated affiliated companies (as of September 30, 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	Jul. 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 November 1, 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-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Phase II/III	In-house	In-house
	S-217622	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Phase II/III	In-house	In-house
Pain/CNS	S-297995 (naldemedine 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)	GABA _A 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 (zatolmilast)	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: PhaseII	Tetra (USA)	Shionogi/Tetra
	BPN14770 (zatolmilast)	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
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: 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: PhaseIII	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 an additional clinical trial)	StemRIM (Japan)	In-house
	S-531011	CCR8-specific monoclonal antibody (injection)	Solid tumor	Japan,USA: PhaseIb/II	In-house	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: Xofluza™]	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 Aug. 2, 2021

Change of phase	S-268019 : Japan : PhaseI/II→PhaseII/III
	S-217622 : Japan : PhaseI→PhaseII/III
	S-005151(Epidermolysis bullosa) : Japan: PhaseII (preparing NDA submission)→PhaseII (preparing an additional clinical trial)
Compound added to the list	S-309309 : USA : PhaseI
	S-531011 : Japan · USA : PhaseIb/II
Compound erased from the list	S-648414 : Closed (Sep. 2021)