

Financial results for the year  
ended March 31, 2022

< Supplement >

May 11, 2022

 **SHIONOGI & CO., LTD.**

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## 1. Financial results and forecast

(Billions of yen)

	FY2020 Actual	FY2021 Actual	FY2022 Forecast	Change		FY2022 1H Forecast
				FY2021	FY2022	
Revenue	297.2	335.1	400.0	38.0	64.9	180.0
<i>change %</i>	<i>(10.9)</i>	<i>12.8</i>	<i>19.4</i>			<i>24.1</i>
Operating profit	117.4	110.3	120.0	(7.1)	9.7	57.0
<i>change %</i>	<i>(10.1)</i>	<i>(6.1)</i>	<i>8.8</i>			<i>33.6</i>
Profit before tax	143.0	126.3	168.0	(16.8)	41.7	86.0
<i>change %</i>	<i>(9.8)</i>	<i>(11.7)</i>	<i>33.0</i>			<i>69.2</i>
Profit attributable to owners of parent	111.9	114.2	136.0	2.3	21.8	71.5
<i>change %</i>	<i>(8.5)</i>	<i>2.1</i>	<i>19.1</i>			<i>34.6</i>

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

## 2. Revenue by segment

(Billions of yen)

	FY2020 Actual	FY2021 Actual	FY2022 Forecast	Change		FY2022 1H Forecast
				FY2021	FY2022	
Prescription drugs	94.7	89.1	78.6	(5.6)	(10.5)	35.5
<i>change %</i>	(10.9)	(5.9)	(11.8)			(24.6)
CYMBALTA	26.5	15.9	6.1	(10.6)	(9.8)	3.1
INTUNIV	13.1	16.4	19.5	3.3	3.1	9.0
VYVANSE	0.3	0.8	1.1	0.5	0.3	0.5
Infectious Disease Drugs	9.8	11.8	13.4	2.0	1.6	4.3
OXYCONTIN Franchise	5.3	4.8	4.5	(0.5)	(0.3)	2.3
SYMPROIC	2.3	2.7	3.3	0.4	0.6	1.5
ACTAIR	0.3	0.5	0.6	0.2	0.1	0.3
MULPLETA	0.1	0.1	0.1	0.0	0.0	0.1
PIRESPA	5.1	3.8	2.4	(1.3)	(1.4)	1.2
Others	32.0	32.4	27.6	0.4	(4.7)	13.3
CRESTOR	6.7	5.9	3.3	(0.7)	(2.6)	1.7
IRBETAN Franchise	3.3	3.2	2.6	(0.2)	(0.6)	1.2
Overseas subsidiaries/Export	24.6	34.4	41.6	9.7	7.3	18.1
<i>change %</i>	(20.0)	39.5	21.2			3.7
Shionogi Inc.	7.5	13.8	13.0	6.3	(0.8)	6.0
Ping An-Shionogi / C&O	10.1	10.2	14.8	0.1	4.6	6.3
Shionogi B.V.	2.0	5.0	8.4	3.0	3.4	3.4
Contract manufacturing	19.7	17.4	14.8	(2.3)	(2.7)	6.3
<i>change %</i>	12.3	(11.7)	(15.3)			(25.0)
OTC and quasi-drugs	11.7	11.2	13.4	(0.6)	2.2	6.3
<i>change %</i>	20.7	(4.8)	20.0			4.5
Royalty income	144.6	181.3	140.4	36.6	(40.9)	68.2
<i>change %</i>	(13.3)	25.3	(22.5)			4.4
HIV Franchise	123.4	174.0	133.9	50.6	(40.1)	67.0
CRESTOR	16.6	1.2	-	(15.4)	(1.2)	-
Others	4.7	6.1	6.5	1.4	0.4	1.2
Others	1.8	1.8	1.2	0.0	(0.6)	0.6
<i>change %</i>	(18.5)	1.7	(32.7)			(21.0)
COVID-19-related	-	-	110.0	-	110.0	45.0
<i>change %</i>	-	-	-			-
<b>Total</b>	<b>297.2</b>	<b>335.1</b>	<b>400.0</b>	<b>38.0</b>	<b>64.9</b>	<b>180.0</b>
<i>change %</i>	(10.9)	12.8	19.4			24.1

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 below.

• Xofluz • Rapiacta • Brightpoc Flu Neo • Finibax • Flumarin • Flomox

• Shiomarin • Vancomycin • Baktar • Flagyl • Isodine

COVID-19-related : Revenue from S-217622, S-268019

### 3. Management index

( Management index trend )

		FY2019	FY2020	FY2021
Return on equity attributable to owners of parent (ROE)	%	15.5	13.9	12.5
Ratio of profit before tax to total assets (ROA)	%	17.5	15.3	11.7
Ratio of operating profit to revenue	%	39.2	39.5	32.9
Ratio of profit before tax to revenue	%	47.5	48.1	37.7
Total assets turnover		0.37	0.32	0.31
Ratio of equity attributable to owners of parent to total assets	%	87.6	84.7	84.8
Dividend payout ratio	%	26.0	29.6	30.4
Ratio of dividends to equity attributable to owners of parent (DOE)	%	4.0	4.1	3.8
Basic earnings per share	yen	395.71	365.03	378.75
Diluted earnings per share	yen	395.28	364.89	378.63

#### 4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2020 Actual	FY2021 Actual	FY2022 Forecast	Change		FY2022 1H Forecast
				FY2021	FY2022	
Investments in equipments	27.4	27.3	20.5	(0.1)	(6.7)	7.8
Depreciation and Amortization	14.8	16.4	17.3	1.6	1.0	8.5

#### 5. R&D expenses

(Billions of yen)

	FY2020 Actual	FY2021 Actual	FY2022 Forecast	Change		FY2022 1H Forecast
				FY2021	FY2022	
R&D expenses	54.2	73.0	70.0	18.7	(3.0)	32.0
<i>change %</i>	<i>13.1</i>	<i>34.6</i>	<i>(4.1)</i>			<i>13.6</i>
% to net revenue	18.3	21.8	17.5			17.8

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

#### 6. Employees

	FY2020 Actual	FY2021 Actual	FY2022 Forecast	Change		FY2022 1H Forecast
				FY2021	FY2022	
Employees	5,485	5,693	5,749	208	56	5,785

## 7. Consolidated statement of profit or loss

*(Millions of yen)*

	FY2020 Actual	FY2021 Actual	Y on Y Change	
Revenue	297,177	335,138	37,960	Increasing/(decreasing) in Prescription drugs: (5.6) billion yen Overseas subsidiaries/Export: 9.7 billion yen Contract manufacturing: (2.3) billion yen OTC and quasi-drugs: (0.6) billion yen Royalty income: 36.6 billion yen
Cost of sales	(52,523)	(55,415)	2,891	
Gross profit	244,654	279,722	35,068	
Selling, general and administrative expenses	(91,902)	(91,771)	(131)	
Research and development expenses	(54,249)	(72,996)	18,746	Increasing in research and development investments for treatments and vaccines for COVID-19
Amortization of intangible assets associated with products	(3,209)	(3,476)	267	
Other income	26,403	3,384	(23,018)	(FY2020) Gain on exchange from redevelopment of Shionogi Shibuya Building 22.9 billion yen
Other expenses	(4,257)	(4,551)	293	
Operating profit	117,438	110,312	(7,126)	
Finance income	26,522	16,797	(9,724)	Shionogi B.V. Decrease in dividends due to the effect of the postponement of dividend income from ViiV
Finance costs	(941)	(841)	(100)	
Profit before tax	143,018	126,268	(16,750)	
Income tax expense	(30,956)	(12,829)	(18,127)	Refund received in relation to a favorable judgment of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau
Profit	112,061	113,439	1,377	
Profit attributable to				
Owners of parent	111,858	114,185	2,326	
Non-controlling interests	203	(746)	(949)	
Profit	112,061	113,439	1,377	

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

*(Millions of yen)*

	As of Mar. 31 2021	As of Mar. 31 2022	Y on Y change	
<b>Assets</b>				
<b>Non-Current assets</b>				
Property, plant and equipment	90,883	108,893	18,009	Increase due to construction of vaccine manufacturing facilities
Goodwill	9,357	9,638	281	
Intangible assets	76,558	81,223	4,665	
Right-of-use assets	4,827	3,524	(1,303)	
Investment property	26,759	26,672	(86)	
Other financial assets	217,437	242,479	25,042	Increase in fair value of ViiV stock
Deferred tax assets	11,729	12,907	1,177	
Other non-current assets	5,200	6,055	854	
<b>Total non-current assets</b>	<b>442,754</b>	<b>491,396</b>	<b>48,641</b>	
<b>Current assets</b>				
Inventories	38,003	45,892	7,889	
Trade receivables	78,047	122,965	44,917	Increase in trade receivables to ViiV
Other financial assets	142,151	210,757	68,605	Increase in time deposits over 3 months and bonds
Income taxes receivable	164	51	(112)	
Other current assets	21,697	25,117	3,420	
Cash and cash equivalents	276,173	254,420	(21,752)	
<b>Total current assets</b>	<b>556,238</b>	<b>659,205</b>	<b>102,967</b>	
<b>Total assets</b>	<b>998,992</b>	<b>1,150,601</b>	<b>151,608</b>	



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

(Millions of yen)

	As of Mar. 31 2021	As of Mar. 31 2022	Y on Y change
Equity and liabilities			
Equity			
Share capital	21,279	21,279	—
Capital surplus	13,733	14,455	722
Treasury shares	(57,989)	(57,857)	132
Retained earnings	752,248	832,958	80,709
Other components of equity	116,836	164,824	47,987
Equity attributable to owners of parent	846,108	975,661	129,552
Non-controlling interests	18,442	17,624	(818)
Total equity	864,550	993,285	128,734
Liabilities			
Non-current liabilities			
Lease liabilities	4,608	3,729	(879)
Other financial liabilities	5,242	5,616	373
Retirement benefit liability	16,318	15,412	(906)
Deferred tax liabilities	7,749	7,807	58
Other non-current liabilities	341	354	12
Total non-current liabilities	34,261	32,920	(1,341)
Current liabilities			
Lease liabilities	3,379	2,945	(433)
Trade payables	9,902	16,372	6,469
Other financial liabilities	21,383	22,027	643
Income taxes payable	28,033	17,973	(10,059)
Other current liabilities	37,481	65,078	27,596
Total current liabilities	100,180	124,396	24,215
Total liabilities	134,442	157,316	22,874
Total equity and liabilities	998,992	1,150,601	151,608

Exchange rate fluctuations

## 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
<b>Total</b>	<b>71.4</b>	<b>(11.6)</b>	<b>77.1</b>	<b>(7.0)</b>	<b>76.0</b>	<b>(16.6)</b>	<b>72.8</b>	<b>(7.5)</b>

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

Fiscal year ended March 31, 2022

FY2021	FY2021 1Q Actual	Y on Y Change %	FY2021 2Q Actual	Y on Y Change %	FY2021 3Q Actual	Y on Y Change %	FY2021 4Q Actual	Y on Y Change %
Prescription drugs	23.5	5.1	23.7	(4.6)	22.4	(9.2)	19.6	(14.3)
CYMBALTA	6.8	(1.5)	4.7	(29.0)	2.7	(62.0)	1.8	(70.7)
INTUNIV	3.6	37.3	4.0	18.2	4.5	27.4	4.2	21.6
VYVANSE	0.1	436.2	0.2	223.0	0.2	170.0	0.2	124.6
Infectious Disease Drugs	2.1	(1.6)	3.7	34.4	3.0	9.3	3.0	40.3
OXYCONTIN Franchise	1.3	(8.9)	1.2	(12.0)	1.3	(1.1)	1.0	(18.4)
SYMPROIC	0.6	24.8	0.7	11.8	0.7	26.5	0.7	9.9
ACTAIR	0.1	79.1	0.1	56.2	0.1	36.2	0.1	25.4
MULPLETA	0.0	18.0	0.0	(4.3)	0.0	21.0	0.0	(0.5)
PIRESPA	1.0	(32.2)	1.0	(27.6)	1.1	(8.5)	0.8	(31.4)
Others	7.9	8.1	8.1	(5.6)	8.7	7.4	7.8	(3.8)
CRESTOR	1.4	(7.7)	1.6	(22.4)	1.6	12.9	1.3	(20.1)
IRBETAN Franchise	0.8	(7.3)	0.8	(10.7)	0.9	0.4	0.8	(2.1)
Overseas subsidiaries/Export	9.3	70.0	8.1	46.7	8.7	35.1	8.2	14.6
Shionogi Inc.	4.7	182.7	3.2	89.2	3.3	58.6	2.6	27.8
Ping An-Shionogi / C&O	2.4	0.2	2.4	24.1	2.5	(7.4)	3.0	(5.0)
Shionogi B.V.	0.9	144.1	1.4	267.6	1.6	180.6	1.2	72.3
Contract manufacturing	3.7	30.2	4.6	21.3	3.5	(3.1)	5.6	(40.7)
OTC and quasi-drugs	2.5	9.0	3.6	11.1	2.4	(28.8)	2.8	(5.6)
Royalty income	29.6	(22.1)	35.8	(9.1)	37.0	(1.4)	78.9	164.7
HIV Franchise	28.8	(6.8)	32.4	(1.7)	35.0	12.3	77.8	174.8
CRESTOR	-	-	-	-	1.2	(78.9)	-	-
Others	0.8	(47.4)	3.3	328.6	0.9	(3.4)	1.1	(25.6)
Others	0.4	(17.3)	0.4	8.6	0.6	37.3	0.4	(14.6)
<b>Total</b>	<b>69.0</b>	<b>(3.4)</b>	<b>76.1</b>	<b>(1.2)</b>	<b>74.5</b>	<b>(1.9)</b>	<b>115.5</b>	<b>58.8</b>

Note: Revenue 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 ended March 31, 2022

FY2021	FY2021 1Q Actual	Y on Y Change %	FY2021 2Q Actual	Y on Y Change %	FY2021 3Q Actual	Y on Y Change %	FY2021 4Q Actual	Y on Y Change %
Revenue	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)	115.5	58.8
Cost of sales	17.9 (12.3)	7.3	19.2 (14.7)	28.9	17.3 (12.9)	(1.7)	13.5 (15.6)	(6.1)
Gross profit	56.6	(5.5)	61.5	(6.4)	61.7	(1.9)	99.9	77.9
SG & A expenses	31.5 (21.8)	4.2	29.6 (22.5)	0.9	29.9 (22.3)	(3.4)	21.8 (25.2)	(1.7)
R & D expenses	21.4 (14.7)	21.1	17.7 (13.4)	6.0	26.9 (20.0)	39.4	21.4 (24.8)	65.0
Amortization of intangible assets associated with products	1.2 (0.8)	1.2	1.1 (0.8)	2.6	1.1 (0.8)	5.4	0.9 (1.0)	24.1
Other income & expenses	(0.5)		(0.8)		(0.7)		0.9	
Operating profit	27.3 18.8	(34.2)	31.4 23.9	(19.6)	23.8 17.8	(62.1)	43.2 49.9	306.3
Finance income & costs	4.1	(6.7)	4.0	(45.9)	6.2	125.4	1.6	(85.4)
Profit before tax	33.3 22.9	(30.5)	36.6 27.9	(24.9)	32.1 24.0	(51.7)	44.6 51.5	121.6
Income tax expense etc.	9.3	(209.0)	(0.7)	(24.6)	(6.1)	(53.0)	(8.3)	-
Profit attributable to owners of parent	46.7 32.2	(31.6)	27.4 20.9	(25.0)	24.0 17.9	(51.3)	37.4 43.2	89.2

## 10. Group companies

< Consolidated affiliated companies (as of March 31, 2022) >

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 Business Partner Co., Ltd.	Osaka, Japan	JPY 10 million	Insurance agency and shared services	Apr.3, 2017	Mar.31	100
7	Shionogi Pharmacovigilance Center Co.,Ltd.	Osaka, Japan	JPY 10 million	Pharmacovigilance activity for the group companies	Apr.3, 2017	Mar.31	100
8	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
9	UMN Pharma Inc.	Akita, Japan	JPY 90 million	Research, development, mfg., and marketing of biopharmaceuticals	Apr.20, 2004	Mar.31	100
10	Nagase Medicals Co., Ltd	Hyogo, Japan	JPY 498 million	Mfg., of pharmaceuticals and contract manufacturing	July.1, 1972	Mar.31	* 100
11	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg., sale and development of pharmaceuticals	Aug.25, 2008	Mar.31	100
12	Tetra Therapeutics Inc. (Official name : Tetra Discovery Partners Inc.)	Michigan, U.S.A.	USD 37 thousand	Research and development of pharmaceuticals	Jul.21, 2016	Mar.31	100
13	Shionogi B.V.	Amsterdam, Netherlands	GBP 630 thousand	Mfg., sale and development of pharmaceuticals	Nov.29, 2018	Mar.31	100
14	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg., and sale of pharmaceuticals	Dec.26, 1963	Mar.31	100
15	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	Mar.29, 2013	Dec.31	100
16	Ping An-Shionogi (Hong Kong) Ltd.	Hong Kong, China	HKD 361,794 thousand	Sale of pharmaceuticals	Aug.24, 2020	Mar.31	* 51
17	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 one consolidated affiliated companies are not shown on this table as the scale of their business is very small.

## 11. Pipeline (as of May 11, 2022)

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 Europe: Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options Japan: Various infectious diseases caused by Gram-negative bacteria that are resistant to carbapenem antibiotics	Global: Phase III (pediatric) Japan: NDA submission (Mar. 2022)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan: Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: NDA submission (body weight <20kg) (Aug. 2018)	In-house	Shionogi/Roche (Switzerland)
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Phase III Global: Phase III	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Japan: Phase II/III	In-house	In-house
	S-217622 (Emsitrelvir Fumaric Acid)	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: NDA submission (Feb. 2022), Phase II/III Global: Phase 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: Phase I/II	In-house	In-house
	S-120083	Not disclosed (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Not disclosed (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-117957	Not disclosed (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918 (sivopixant)	P2X <sub>3</sub> receptor antagonist (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-600918 (sivopixant)	P2X <sub>3</sub> receptor antagonist (oral)	Refractory/unexplained chronic cough	Global: Phase II	In-house	In-house
	S-812217 (zuranolone)	GABA <sub>A</sub> receptor positive allosteric modulator (oral)	Depression	Japan: Phase III	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan: Phase III	Akili (USA)	Shionogi/Akili
	BPN14770 (zatolmilast)	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: Phase II/III	Tetra (USA)	Shionogi/Tetra
	BPN14770 (zatolmilast)	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA: Phase II Japan: Phase II	Tetra (USA)	Shionogi/Tetra
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto (Japan)	Shionogi/Rohto
	S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	In-house
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: Phase I	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: 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-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK: Phase I	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	Antifibrotic (inhalation)	Idiopathic pulmonary fibrosis	Japan: Phase I	In-house	In-house
	SR-0379	Promote granulation formation (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase III	FunPep (Japan)	Shionogi/FunPep
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Japan: Phase II	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan: Phase II	StemRIM (Japan)	In-house
	S-531011	CCR8-specific monoclonal antibody (injection)	Solid tumor	Japan,USA: Phase Ib/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* <sup>1</sup> (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB* <sup>2</sup> LAP for prevention) Global: Phase III	Shionogi-ViiV Healthcare LLC	Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc.(USA)for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan: NDA submission(Dec. 2021)	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA:Xofluz <sup>TM</sup> ]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA: NDA submission (pediatric, >1 year old) (Mar. 2020) Global: Phase III (pediatric, < 1 year old) Global: Phase III (transmission)	In-house	Shionogi/Roche (Switzerland)
S-555739 (asapiprant)	Prostaglandin D2 DP1 receptor antagonist (oral)	Control of the aggravation of COVID-19	USA: Phase II	In-house	BioAge Labs, Inc. (USA)

\*1 Long acting parenteral formulation, \*2 Cabotegravir,

Since Jan. 31, 2022

Change of phase	S-649266 : Japan: NDA submission (Mar. 2022)
	S-217622 : Japan : NDA submission (Feb. 2022) Phase II/III Global: Phase II/III→ Phase III
	SDT-001 : Japan: Phase II → Phase III
	BPN14770 (Fragile X syndrome) : USA: Phase II→Phase II/III
Phase added to the list	S-268019 (Prevention of COVID-19 (Adolescent)) : Japan: Phase II/III
Compound erased from the list	S-637880 (Neuropathic Low Back pain) : Closed