

Financial results for the second quarter
of fiscal year 2022

< Supplement >

October 31, 2022



Contents

- 1 Financial results and forecast
- 2 Revenue by segment
- 3 Management index
- 4 Capital investments and Depreciation and Amortization
- 5 R&D expenses
- 6 Employees
- 7 Consolidated statement of profit or loss
- 8 Consolidated statement of financial position
- 9 Quarterly trend for FY2021 and FY2022
- 10 Group Companies
- 11 Pipeline (as of October 31, 2022)

1. Financial results and forecast

(Billions of yen)

	FY2022 1H actual	FY2022 2H forecast	FY2022 forecast	FY2021 1H actual	FY2021 2H actual	FY2021 actual	Y on Y change		
							1H	2H	full-year
Revenue	150.8	259.2	410.0	145.1	190.1	335.1	5.7	69.2	74.9
<i>change %</i>	3.9	36.4	22.3	(2.3)	27.8	12.8			
Operating profit	28.2	91.8	120.0	42.7	67.6	110.3	(14.4)	24.1	9.7
<i>change %</i>	(33.8)	35.7	8.8	(26.8)	14.3	(6.1)			
Profit before tax	68.0	106.0	174.0	50.8	75.4	126.3	17.1	30.6	47.7
<i>change %</i>	33.7	40.5	37.8	(27.5)	3.5	(11.7)			
Profit attributable to owners of parent	57.3	84.7	142.0	53.1	61.1	114.2	4.1	23.7	27.8
<i>change %</i>	7.8	38.8	24.4	1.5	2.6	2.1			

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

2. Revenue by segment

(Billions of yen)

	FY2022 1H	FY2022 2H	FY2022	FY2021 1H	FY2021 2H	FY2021	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Prescription drugs	33.4	43.1	76.4	47.1	42.0	89.1	(13.8)	1.1	(12.7)
change %	(29.2)	2.6	(14.3)	0.0	(11.7)	(5.9)			
INTUNIV	9.5	10.5	20.0	7.6	8.8	16.4	1.8	1.7	3.6
VYVANSE	0.6	0.6	1.3	0.3	0.5	0.8	0.3	0.2	0.5
Infectious Disease Drugs	(0.6)	9.3	8.8	5.8	6.0	11.8	(6.4)	3.3	(3.0)
CYMBALTA	3.0	3.0	6.1	11.5	4.4	15.9	(8.4)	(1.4)	(9.8)
OXYCONTIN Franchise	2.3	2.2	4.5	2.5	2.3	4.8	(0.2)	(0.1)	(0.3)
SYMPROIC	1.6	1.8	3.4	1.3	1.4	2.7	0.4	0.4	0.7
ACTAIR	0.3	0.3	0.6	0.2	0.3	0.5	0.0	0.1	0.1
MULPLETA	0.1	0.1	0.1	0.1	0.1	0.1	(0.0)	0.0	0.0
PIRESPA	1.4	1.0	2.4	2.0	1.8	3.8	(0.6)	(0.8)	(1.4)
Others	15.2	14.2	29.4	15.9	16.4	32.4	(0.7)	(2.2)	(3.0)
CRESTOR	2.1	1.8	3.9	3.1	2.8	5.9	(0.9)	(1.0)	(2.0)
Overseas subsidiaries/Export	19.9	19.4	39.3	17.4	17.0	34.4	2.5	2.4	5.0
change %	14.5	14.3	14.4	58.2	24.3	39.5			
Shionogi Inc.	7.4	7.1	14.4	7.9	5.9	13.8	(0.5)	1.2	0.7
Ping An-Shionogi / C&O	5.6	4.8	10.4	4.7	5.5	10.2	0.9	(0.7)	0.2
Shionogi B.V.	4.3	4.3	8.6	2.3	2.7	5.0	2.0	1.6	3.6
Contract manufacturing	7.4	7.4	14.8	8.4	9.1	17.4	(1.0)	(1.7)	(2.7)
change %	(12.0)	(18.3)	(15.3)	25.1	(30.5)	(11.7)			
OTC and quasi-drugs	6.3	7.0	13.2	6.0	5.1	11.2	0.2	1.9	2.1
change %	3.7	36.3	18.7	10.3	(17.9)	(4.8)			
Royalty income	83.3	71.8	155.0	65.4	115.9	181.3	17.9	(44.1)	(26.2)
change %	27.4	(38.1)	(14.5)	(15.5)	72.2	25.3			
HIV Franchise	80.4	69.9	150.2	61.2	112.7	174.0	19.1	(42.8)	(23.7)
Others	2.9	1.9	4.8	4.1	3.2	7.3	(1.2)	(1.3)	(2.5)
COVID-19 related products	—	110.0	110.0	—	—	—	—	110.0	110.0
change %	—	—	—	—	—	—			
Others	0.6	0.6	1.2	0.8	1.0	1.8	(0.2)	(0.4)	(0.6)
change %	(21.9)	(40.9)	(32.6)	(5.4)	8.1	1.7			
Total	150.8	259.2	410.0	145.1	190.1	335.1	5.7	69.2	74.9
change %	3.9	36.4	22.3	(2.3)	27.8	12.8			

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 • Isodine

COVID-19 related products : Revenue from Ensitrelvir and S-268019

3. Management index

(Management index trend)

		FY2020	FY2021	FY2021 1H	FY2022 1H
Return on equity attributable to owners of parent (ROE)	%	13.9	12.5	6.2	5.8
Ratio of profit before tax to total assets (ROA)	%	15.3	11.7	5.0	5.8
Ratio of operating profit to revenue	%	39.5	32.9	29.4	18.7
Ratio of profit before tax to revenue	%	48.1	37.7	35.0	45.1
Total assets turnover		0.32	0.31	0.14	0.13
Ratio of equity attributable to owners of parent to total assets	%	84.7	84.8	86.3	84.4
Dividend payout ratio	%	29.6	30.4	—	—
Ratio of dividends to equity attributable to owners of parent (DOE)	%	4.1	3.8	—	—
Basic earnings per share	yen	365.03	378.75	176.24	190.21
Diluted earnings per share	yen	364.89	378.63	176.18	190.15

4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2022 1H	FY2022 2H	FY2022	FY2021 1H	FY2021 2H	FY2021	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Investments in equipments	5.9	10.0	15.9	8.6	18.7	27.3	(2.7)	(8.7)	(11.4)
Depreciation and Amortization	8.6	8.5	17.1	7.8	8.5	16.4	0.8	(0.1)	0.7

5. R&D expenses

(Billions of yen)

	FY2022 1H	FY2022 2H	FY2022	FY2021 1H	FY2021 2H	FY2021	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
R&D expenses	48.7	46.3	95.0	28.2	44.8	73.0	20.6	1.4	22.0
<i>change %</i>	72.9	3.2	30.1	13.4	52.5	34.6			
% to revenue	32.3	17.8	23.2	19.4	23.6	21.8			

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

6. Employees

	End of FY2020	End of 2021 1H	End of FY2021	End of 2022 1H	End of FY2022	Y on Y change		
	actual	actual	actual	actual	forecast	1H	2H	full-year
Employees	5,485	5,561	5,693	5,729	5,693	36	(36)	—

7. Consolidated statement of profit or loss

(Millions of yen)

	FY2021 1H actual	FY2022 1H actual	Y on Y change	
Revenue	145,085	150,779	5,693	Increasing/(decreasing) in Prescription drugs: (13.8) billion yen Overseas subsidiaries/Export: 2.5 billion yen Contract manufacturing: (1.0) billion yen OTC and quasi-drugs: 0.2 billion yen Royalty income: 17.9 billion yen
Cost of sales	(26,984)	(27,367)	383	
Gross profit	118,101	123,412	5,310	
Selling, general and administrative expenses	(44,248)	(46,517)	2,268	
Research and development expenses	(28,175)	(48,729)	20,553	
Amortization of intangible assets associated with products	(1,641)	(1,951)	310	
Other income	1,606	3,490	1,884	Sale of investment property
Other expenses	(2,977)	(1,480)	(1,497)	(FY2021 1H) Loss on disposal of property, plant and equipment
Operating profit	42,664	28,224	(14,440)	
Finance income	8,338	39,834	31,495	Increasing in dividend income from ViiV • Receipt of dividends from ViiV which was scheduled to be received in 4th quarter of FY 2021 • Increased dividends due to ViiV receipt of lumpsum payment from the settlement with Gilead
Finance costs	(170)	(79)	(90)	
Profit before tax	50,832	67,978	17,146	
Income tax expense	2,191	(10,571)	12,762	(FY2021 1H) Refund received in relation to a favorable judgment of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau
Profit	53,023	57,407	4,383	
Profit attributable to				
Owners of parent	53,131	57,264	4,133	
Non-controlling interests	(107)	143	250	
Profit	53,023	57,407	4,383	

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

	<i>(Millions of yen)</i>		
	As of Mar. 31 2022	As of Sep. 30 2022	Y on Y change
Assets			
Non-Current assets			
Property, plant and equipment	108,893	109,789	895
Goodwill	9,638	10,077	438
Intangible assets	81,223	108,494	27,270
Right-of-use assets	3,524	3,738	214
Investment property	26,672	25,618	(1,053)
Other financial assets	242,479	240,739	(1,740)
Deferred tax assets	12,907	11,264	(1,643)
Other non-current assets	6,055	6,290	234
Total non-current assets	491,396	516,012	24,616
Current assets			
Inventories	45,892	56,069	10,176
Trade receivables	122,965	99,661	(23,303)
Other financial assets	210,757	290,520	79,762
Income taxes receivable	51	58	6
Other current assets	25,117	35,574	10,457
Cash and cash equivalents	254,420	198,043	(56,377)
Total current assets	659,205	679,927	20,722
Total assets	1,150,601	1,195,939	45,338

Increase due to in-process R&D assets, etc.

Increased in time deposits over 3 months

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

	As of Mar. 31 2022	As of Sep. 30 2022	Y on Y change	
Equity and liabilities				
Equity				
Share capital	21,279	21,279	—	
Capital surplus	14,455	15,204	748	
Treasury shares	(57,857)	(63,263)	5,406	Purchase, Dispose for establishment of the "Shionogi Infectious Disease Research Promotion Foundation"
Retained earnings	832,958	853,614	20,656	
Other components of equity	164,824	182,744	17,919	Exchange rate fluctuations
Equity attributable to owners of parent	975,661	1,009,578	33,917	
Non-controlling interests	17,624	23,414	5,790	
Total equity	993,285	1,032,993	39,708	
Liabilities				
Non-current liabilities				
Lease liabilities	3,729	3,848	118	
Other financial liabilities	5,616	5,120	(495)	
Retirement benefit liability	15,412	16,754	1,342	
Deferred tax liabilities	7,807	8,877	1,070	
Other non-current liabilities	354	1,341	987	
Total non-current liabilities	32,920	35,942	3,022	
Current liabilities				
Lease liabilities	2,945	2,967	22	
Trade payables	16,372	17,844	1,471	
Other financial liabilities	22,027	17,222	(4,804)	
Income taxes payable	17,973	17,093	(879)	
Other current liabilities	65,078	71,875	6,796	
Total current liabilities	124,396	127,003	2,607	
Total liabilities	157,316	162,946	5,629	
Total equity and liabilities	1,150,601	1,195,939	45,338	

9-1. Quarterly trend for FY2021 and FY2022 (Revenue by segment)

Fiscal year ended March 31, 2022

(Billions of yen)

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)
Total	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)	115.5	58.8

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

Fiscal year ending March 31, 2023

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %
Prescription drugs	19.0	(19.0)	14.4	(39.3)
INTUNIV	4.7	29.5	4.8	19.7
VYVANSE	0.3	105.8	0.3	91.0
Infectious Disease Drugs	2.1	(2.3)	(2.6)	—
CYMBALTA	1.7	(75.6)	1.4	(70.3)
OXYCONTIN Franchise	1.2	(4.4)	1.1	(10.0)
SYMPROIC	0.8	31.7	0.8	27.2
ACTAIR	0.1	18.0	0.1	3.4
MULPLETA	0.0	(12.4)	0.0	(3.0)
PIRESPA	0.7	(29.0)	0.7	(33.2)
Others	7.5	(4.4)	7.7	(4.8)
CRESTOR	1.1	(25.7)	1.1	(34.3)
Overseas subsidiaries/Export	8.8	(5.3)	11.1	37.2
Shionogi Inc.	3.0	(36.2)	4.4	38.2
Ping An-Shionogi / C&O	2.5	7.4	3.1	30.7
Shionogi B.V.	1.9	108.6	2.4	75.3
Contract manufacturing	3.4	(10.2)	4.0	(13.4)
OTC and quasi-drugs	1.9	(21.2)	4.3	20.9
Royalty income	38.4	29.7	44.9	25.4
HIV Franchise	37.3	29.3	43.1	32.9
Others	1.1	42.6	1.8	(46.4)
Covid-19 related products	—	—	—	—
Others	0.3	(13.8)	0.3	(29.1)
Total	71.8	4.2	78.9	3.7

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

9-2. Quarterly trend for FY2021 and FY2022 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2022

(Billions of yen)

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)	(7.0)	(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

Fiscal year ending March 31, 2023

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %
Revenue	71.8	4.2	78.9	3.7
Cost of sales	18.0 (12.9)	5.0	18.3 (14.4)	(1.6)
Gross profit	58.9	4.0	64.5	5.0
SG & A expenses	31.2 (22.4)	3.2	30.5 (24.1)	7.0
R & D expenses	31.4 (22.5)	53.0	33.2 (26.2)	94.8
Amortization of intangible assets associated with products	1.3 (1.0)	16.9	1.3 (1.0)	20.9
Other income & expenses	(0.5)		2.5	
Operating profit	17.3 12.4	(33.9)	20.0 15.8	(33.8)
Finance income & costs	27.9	572.5	11.9	195.1
Profit before tax	56.1 40.3	75.7	35.0 27.7	(0.8)
Income tax expense etc.	(5.6)	—	(5.1)	(26.8)
Profit attributable to owners of parent	48.3 34.7	7.7	28.6 22.5	7.9

10. Group companies

<Consolidated affiliated companies (as of September 30, 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 Business Partner Co., Ltd.	Osaka, Japan	JPY 10 million	Insurance agency, shared services, and real estate rental	Apr. 3, 2017	Mar. 31	100
5	Shionogi Pharmacovigilance Center Co., Ltd.	Osaka, Japan	JPY 10 million	Pharmacovigilance activity for the group companies	Apr. 3, 2017	Mar. 31	100
6	UMN Pharma Inc.	Akita, Japan	JPY 90 million	Research, development, mfg., and marketing of biopharmaceuticals	Apr. 20, 2004	Mar. 31	100
7	Pharmira Co., Ltd.	Hyogo, Japan	JPY 85 million	Mfg., and analytical testing of APIs and intermediates for medicinal drugs investigational drugs	Nov. 25, 2021	Mar. 31	*50.05
8	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg., sale and development of pharmaceuticals	Aug. 25, 2008	Mar. 31	100
9	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
10	Shionogi B.V.	Amsterdam, Netherlands	GBP 630 thousand	Mfg., sale and development of pharmaceuticals	Nov. 29, 2018	Mar. 31	100
11	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg., and sale of pharmaceuticals	Dec. 26, 1963	Mar. 31	100
12	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	Mar. 29, 2013	Dec. 31	100
13	Ping An-Shionogi (Hong Kong) Ltd.	Hong Kong, China	HKD 361,794 thousand	Sale of pharmaceuticals	Aug. 24, 2020	Mar. 31	* 51
14	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 consolidated affiliated companies are not shown on this table as the scale of their business is very small.

11. Pipeline (as of October 31, 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-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Children, 5 to 11 years)	Japan: Phase I/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	F901318 (olorofim)	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G (UK)	SHIONOGI/ F2G
	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-600918 (sivopixant)	P2X ₃ receptor antagonist (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-600918 (sivopixant)	P2X ₃ receptor antagonist (oral)	Refractory/unexplained chronic cough	Global: Phase II	In-house	In-house
	S-812217 (zuranolone)	GABA _A 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
(Resiniferatoxin)	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal	
Metabolic disorder Areas	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto	SHIONOGI/ Rohto
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: Phase I	In-house	In-house

	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	StemRIM(Japan)	In-house
	S-531011	anti-CCR8 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 for prevention) Global: PhaseIII	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:Xofluza™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA: NDA submission (pediatric, >1 year old) (Mar. 2020) Global: PhaseIII (pediatric,< 1 year old) Global: PhaseIII (transmission)	In-house	SHIONOGI/Roche (Switzerland)
S-555739 (asapiprant)	Prostaglandin D2 DP1 receptor antagonist (oral)	Control of the aggravation of COVID-19	USA: PhaseII	In-house	BioAge Labs, Inc. (USA)
S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	The Liver Company Inc.(USA)

*1 Long acting parenteral formulation,*2 Cabotegravir

Since Aug. 1, 2022

Compound added to the list	Resiniferatoxin: Global: Phase III
Compound erased from the list	S-010887 (Neuropathic pain) : Closed
	S-120083 (Inflammatory pain) : Closed
	S-117957 (Insomnia) : Closed
	S-237648 (Obesity) : Closed