Financial results for the year ended March 31, 2024

< Supplement >

May 13, 2024

SHIONOGI

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 FY2022 and FY2023

10 Group Companies

11 Pipeline (as of May 13, 2024)

1. Financial results and forecast

(Billions of yen)

	FY2022 actual	FY2023 actual	FY2024 forecast	Change FY2023	Change FY2024	FY2024 1H forecast
Revenue	426.7	435.1	455.0	8.4	19.9	210.0
change %	*27.3*	*2.0*	*4.6*			*(8.9)*
Operating profit	149.0	153.3	160.0	4.3	6.7	69.0
change %	*35.1*	*2.9*	*4.4*			*(29.7)*
Profit before tax	220.3	198.3	200.0	(22.0)	1.7	82.5
change %	*74.5*	*(10.0)*	*0.9*			*(28.6)*
Profit attributable to owners of parent	185.0	162.0	163.0	(22.9)	1.0	66.5
change %	*62.0*	*(12.4)*	0.6			*(26.6)*

Note: Change % shows changes from the same period of the previous fiscal year.
Revenue for FY2023 includes Lump-sum income for transfer of ADHD drug.

2. Revenue by segment

(Billions of yen)

	FY2022 actual	FY2023 actual	FY2024 forecast	Change FY2023	Change FY2024	FY2024 1H forecast
Prescription drugs	179.7	151.1	134.9	(28.6)	(16.2)	58.0
change %	*101.7*	*(15.9)*	*(10.7)*			*(39.8)*
Infectious Disease Drugs	112.1	82.9	91.2	(29.2)	8.2	37.6
CYMBALTA	5.4	3.8	3.3	(1.6)	(0.5)	1.8
OXYCONTIN Franchise	4.4	4.2	5.0	(0.3)	0.8	2.3
SYMPROIC	3.4	4.5	6.5	1.1	2.0	2.9
ACTAIR	0.5	0.7	1.4	0.2	0.7	0.5
MULPLETA	0.1	0.1	—	(0.0)	—	—
PIRESPA	2.5	1.9	—	(0.6)	—	—
Others	51.2	53.0	27.5	1.8	(27.4)	12.8
Overseas subsidiaries/Export	42.5	49.9	53.7	7.4	3.8	24.7
change %	*23.7*	*17.4*	*7.6*			*7.7*
Shionogi Inc.	15.4	17.9	20.6	2.4	2.7	10.0
Shionogi B.V.	9.1	13.6	14.4	4.5	0.8	6.8
Ping An-Shionogi / C&O	12.0	10.6	11.2	(1.4)	0.6	4.7
Others	6.0	7.8	7.5	1.8	(0.3)	3.2
Contract manufacturing	15.3	17.6	15.5	2.3	(2.1)	6.5
change %	*(12.0)*	*14.8*	*(12.0)*			*(18.0)*
OTC and quasi-drugs	13.1	14.6	16.6	1.5	2.0	8.0
change %	*17.7*	*11.6*	*13.3*			*12.9*
Royalty income	174.7	200.4	232.5	25.7	32.1	112.2
change %	*(3.6)*	*14.7*	*16.0*			*17.4*
HIV Franchise	168.5	195.8	224.6	27.3	28.8	111.2
Others	6.2	4.6	7.9	(1.7)	3.3	1.0
Others	1.3	1.4	1.8	0.2	0.4	0.6
change %	*(28.8)*	*12.6*	*25.3*			*(7.1)*
Total	426.7	435.1	455.0	8.4	19.9	210.0
change %	*27.3*	*2.0*	*4.6*			*(8.9)*

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.
・Xocova ・COVID-19 vaccines ・Xofluza ・Rapiacta ・Brightpoc Flu Neo ・Finibax ・Flumarin ・Flomox ・Shiomarin ・Baktar ・Flagyl ・Isodine ・Fetroja
Others in prescription drugs for FY2023 include Lump-sum income for transfer of ADHD drug.
Others in prescription drugs for FY2024 include revenue from MULPLETA and PIRESPA.

3. Management index

(Management index trend)

		FY2021	FY2022	FY2023
Return on equity attributable to owners of parent (ROE)	%	12.5	17.8	13.9
Ratio of profit before tax to total assets (ROA)	%	11.7	17.9	14.5
Ratio of operating profit to revenue	%	32.9	34.9	35.2
Ratio of profit before tax to revenue	%	37.7	51.6	45.6
Total assets turnover		0.31	0.35	0.32
Ratio of equity attributable to owners of parent to total assets	%	84.8	83.9	87.2
Dividend payout ratio	%	30.4	21.7	28.6
Ratio of dividends to equity attributable to owners of parent (DOE)	%	3.8	3.9	4.0
Basic earnings per share	yen	378.75	621.31	558.51
Diluted earnings per share	yen	378.63	621.10	558.32

4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2022 actual	FY2023 actual	FY2024 forecast	Change FY2023	Change FY2024	FY2024 1H forecast
Investments in equipments	12.6	14.9	13.0	2.3	(1.9)	7.7
Depreciation and Amortization	17.2	18.3	21.5	1.2	3.2	8.9

5. R&D expenses

(Billions of yen)

	FY2022 actual	FY2023 actual	FY2024 forecast	Change FY2023	Change FY2024	FY2024 1H forecast
R&D expenses	102.4	102.6	120.0	0.2	17.4	59.0
change %	*40.3*	*0.2*	*16.9*			*25.0*
% to revenue	24.0	23.6	26.4			28.1

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

6. Employees

	FY2022 actual	FY2023 actual	FY2024 forecast	Change FY2023	Change FY2024	FY2024 1H forecast
Employees	5,680	4,959	4,913	(721)	(46)	4,940

Note: The decrease in FY2023 is mainly due to the fact that Shionogi Business Partner Co., Ltd. is no longer part of the Shionogi Group following the formation of a joint venture with Accenture Japan Ltd. in July 2023 and the implementation of a special early retirement program with a retirement date of October 31, 2023.

7. Consolidated statement of profit or loss

(Millions of yen)

	FY2022 actual	FY2023 actual	Y on Y change
Revenue	426,684	435,081	8,396
Cost of sales	(62,246)	(57,602)	(4,644)
Gross profit	364,437	377,479	13,041
Selling, general and administrative expenses	(97,775)	(99,651)	1,875
Research and development expenses	(102,392)	(102,640)	247
Amortization of intangible assets associated with products	(3,720)	(3,728)	8
Other income	3,899	6,194	2,295
Oher expenses	(15,445)	(24,342)	8,897
Operating profit	149,003	153,310	4,307
Finance income	75,829	51,674	(24,155)
Finance costs	(4,500)	(6,701)	2,200
Profit before tax	220,332	198,283	(22,048)
Income tax expense	(35,836)	(37,708)	1,872
Profit	184,496	160,575	(23,920)
Profit attributable to			
Owners of parent	184,965	162,030	(22,935)
Non-controlling intersts	(469)	(1,455)	(985)
Profit	184,496	160,575	(23,920)

Increasing/(decreasing) in
Prescription drugs *: (28.6)billion yen
Overseas subsidiaries/Export: 7.4billion yen
Contract manufacturing: 2.3billion yen
OTC and quasi-drugs: 1.5billion yen
Royalty income: 25.7billion yen

* Due to the purchase of XOCOVA, a COVID-19 treatment drug, by the Japanese government in FY2022

FY2023: Impairment losses on in-process research and development assets and expenses relating to the implementation of a special early retirement program

FY2022: 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 settlemnt with Gilead

Note:Revenue for FY2023 includes Lump-sum income for transfer of ADHD drug.

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

(Millions of yen)

	As of Mar. 31 2023	As of Mar. 31 2024	Y on Y change	
Assets				
Non-Current assets				
Property, plant and equipment	112,085	114,586	2,501	
Goodwill	9,819	15,287	5,468	Due to the aquisition of Qpex Biopharma, Inc.
Intangible assets	96,309	117,621	21,312	Increase due to acquisition of in-process research and development assets and decrease due to impairment losses
Right-of-use assets	6,482	9,440	2,957	
Investment property	26,382	27,768	1,385	
Other financial assets	247,711	292,321	44,610	ViiV shares: Increase due to an increase in fair value and foreign exchange effects
Deferred tax assets	22,100	13,526	(8,574)	
Other non-current assets	6,716	42,158	35,441	
Total non-current assets	527,607	632,712	105,104	
Current assets				
Inventories	57,919	64,916	6,997	
Trade receivables	109,774	122,830	13,056	Increase in accounts receivable from ViiV
Other financial assets	254,131	215,761	(38,370)	Decrease in time deposits over 3 months and increase in bonds
Other current assets	53,142	22,607	(30,535)	
Cash and cash equivalents	309,224	358,090	48,866	
Total current assets	784,192	784,205	13	
Total assets	1,311,800	1,416,918	105,117	

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

(Millions of yen)

	As of Mar. 31 2023	As of Mar. 31 2024	Y on Y change	
Equity and liabilities				
Equity				
Share capital	21,279	21,279	—	
Capital surplus	15,204	14,242	(961)	
Treasury shares	(63,074)	(137,889)	74,814	Due to purchase
Retained earnings	940,606	1,065,913	125,307	
Other components of equity	186,030	271,778	85,748	Exchange rate fluctuations
Equity attributable to owners of parent	1,100,046	1,235,325	135,279	
Non-controlling interests	21,832	17,236	(4,595)	
Total equity	1,121,878	1,252,562	130,684	
Liabilities				
Non-current liabilities				
Lease liabilities	6,397	8,753	2,355	
Other financial liabilities	4,844	7,649	2,804	
Retirement benefit liability	12,867	7,994	(4,873)	
Deferred tax liabilities	5,916	4,360	(1,555)	
Other non-current liabilities	1,343	1,691	347	
Total non-current liabilities	31,369	30,448	(921)	
Current liabilities				
Lease liabilities	3,014	2,867	(146)	
Trade payables	14,005	14,808	803	
Other financial liabilities	29,720	31,118	1,398	
Income taxes payable	42,217	20,844	(21,372)	
Other current liabilities	69,595	64,267	(5,327)	
Total current liabilities	158,552	133,907	(24,645)	
Total liabilities	189,921	164,355	(25,566)	
Total equity and liabilities	1,311,800	1,416,918	105,117	

9-1. Quarterly trend for FY2022 and FY2023 (Revenue by segment)

Fiscal year ended March 31, 2023

(Billions of yen)

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %	FY2022 3Q actual	Y on Y change %	FY2022 4Q actual	Y on Y change %
Prescription drugs	19.0	(19.0)	14.4	(39.3)	21.3	(4.9)	20.4	4.0
INTUNIV	4.7	29.5	4.8	19.7	5.3	17.2	4.4	3.6
VYVANSE	0.3	105.8	0.3	91.0	0.4	80.1	0.4	58.6
Infectious Disease Drugs	2.1	(2.3)	(2.6)	—	3.5	15.9	4.5	49.6
CYMBALTA	1.7	(75.6)	1.4	(70.3)	1.4	(47.5)	1.0	(43.5)
OXYCONTIN Franchise	1.2	(4.4)	1.1	(10.0)	1.2	(6.9)	0.9	(9.5)
SYMPROIC	0.8	31.7	0.8	27.2	1.0	31.0	0.8	22.6
ACTAIR	0.1	18.0	0.1	3.4	0.1	11.5	0.1	4.2
MULPLETA	0.0	(12.4)	0.0	(3.0)	0.0	(23.2)	0.0	(29.1)
PIRESPA	0.7	(29.0)	0.7	(33.2)	0.7	(38.3)	0.5	(33.4)
Others	7.5	(4.4)	7.7	(4.8)	7.7	(11.7)	7.7	(0.4)
CRESTOR	1.1	(25.7)	1.1	(34.3)	1.1	(31.5)	0.9	(30.6)
Overseas subsidiaries/Export	8.8	(5.3)	11.1	37.2	10.6	21.7	11.9	45.1
Shionogi Inc.	3.0	(36.2)	4.4	38.2	4.1	25.2	4.0	50.4
Ping An-Shionogi / C&O	2.5	7.4	3.1	30.7	2.7	10.6	3.6	21.5
Shionogi B.V.	1.9	108.6	2.4	75.3	2.3	50.4	2.4	109.9
Contract manufacturing	3.4	(10.2)	4.0	(13.4)	2.9	(15.5)	5.1	(10.0)
OTC and quasi-drugs	1.9	(21.2)	4.3	20.9	3.8	60.8	3.1	11.3
Royalty income	38.4	29.7	44.9	25.4	48.5	31.0	43.0	(45.5)
HIV Franchise	37.3	29.3	43.1	32.9	46.6	33.2	41.5	(46.6)
CRESTOR	—	—	—	—	1.3	15.4	—	—
Others	1.1	42.6	1.8	(46.4)	0.6	(35.7)	1.4	28.4
COVID-19 related products	—	—	—	—	100.0	—	4.7	—
Others	0.3	(13.8)	0.3	(29.1)	0.4	(26.1)	0.2	(44.3)
Total	71.8	4.2	78.9	3.7	187.6	151.6	88.3	(23.5)

Fiscal year ended March 31, 2024

FY2023	FY2023 1Q actual	Y on Y change %	FY2023 2Q actual	Y on Y change %	FY2023 3Q actual	Y on Y change %	FY2023 4Q actual	Y on Y change %
Prescription drugs	45.9	141.6	50.4	251.4	31.2	(74.3)	23.6	(5.9)
Infectious Disease Drugs	9.3	348.9	39.8	—	20.0	(80.7)	13.9	50.4
CYMBALTA	1.1	(32.4)	1.0	(29.7)	1.0	(25.9)	0.7	(28.2)
OXYCONTIN Franchise	1.1	(6.8)	1.1	(3.6)	1.1	(5.5)	0.8	(9.8)
SYMPROIC	1.0	29.7	1.1	28.0	1.2	25.4	1.2	47.5
ACTAIR	0.1	13.9	0.2	26.0	0.2	42.5	0.2	33.2
MULPLETA	0.0	5.8	0.0	(19.7)	0.0	(45.6)	0.0	(50.4)
PIRESPA	0.5	(25.7)	0.5	(25.3)	0.5	(18.9)	0.4	(25.2)
Others	32.7	162.5	6.8	(46.6)	7.0	(47.9)	6.4	(48.7)
Overseas subsidiaries/Export	12.0	36.2	10.9	(1.6)	13.6	27.5	13.4	12.5
Shionogi Inc.	4.0	34.5	4.1	(6.2)	5.0	20.8	4.8	20.9
Shionogi B.V.	3.0	61.3	3.1	29.1	4.0	68.3	3.5	44.1
Ping An-Shionogi / C&O	3.1	22.2	2.2	(30.0)	3.0	10.9	2.3	(35.7)
Others	1.9	31.7	1.6	24.5	1.6	11.7	2.8	45.8
Contract manufacturing	4.0	19.1	3.9	(1.7)	3.8	30.2	5.9	15.9
OTC and quasi-drugs	2.3	16.6	4.8	11.5	3.5	(8.0)	4.1	32.7
Royalty income	44.8	16.7	50.8	13.2	53.5	10.4	51.3	19.3
HIV Franchise	44.3	18.7	50.2	16.6	51.6	10.8	49.7	19.7
Others	0.6	(47.6)	0.5	(70.1)	1.9	0.0	1.6	8.2
Others	0.3	(7.3)	0.3	19.8	0.7	73.9	0.1	(72.1)
Total	109.3	52.2	121.2	53.6	106.3	(43.3)	98.3	11.2

Note: Sales of prescription drugs are shown on non-consolidated basis.
Infectious Disease Drugs in prescription drugs include COVID-19 related products.
Others in prescription drugs include Intuniv, Vyvanse and Lump-sum income for transfer of ADHD drug.
Others in royalty income include Crestor royalty income.
The year-on-year change is calculated based on the products for the fiscal year ending March 2024.

9-2. Quarterly trend for FY2022 and FY2023 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2023

(Billions of yen)

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %	FY2022 3Q actual	Y on Y change %	FY2022 4Q actual	Y on Y change %
Revenue	71.8	4.2	78.9	3.7	187.6	151.6	88.3	(23.5)
Cost of sales	18.0 (12.9)	5.0	18.3 (14.4)	(1.6)	9.2 (17.2)	33.6	20.0 (17.7)	13.6
Gross profit	58.9	4.0	64.5	5.0	170.4	176.3	70.7	(29.3)
SG & A expenses	31.2 (22.4)	3.2	30.5 (24.1)	7.0	12.9 (24.2)	8.4	30.7 (27.1)	7.4
R & D expenses	31.4 (22.5)	53.0	33.2 (26.2)	94.8	13.9 (26.1)	30.1	31.2 (27.6)	11.3
Amortization of intangible assets associated with products	1.3 (1.0)	16.9	1.3 (1.0)	20.9	0.5 (0.9)	10.2	1.0 (0.8)	(15.2)
Other income & expenses	(0.5)		2.5		(0.9)		(12.6)	
Operating profit	17.3 12.4	(33.9)	20.0 15.8	(33.8)	63.0 118.2	565.9	2.9 2.5	(94.9)
Finance income & costs	27.9	572.5	11.9	195.1	12.6	102.7	19.0	—
Profit before tax	56.1 40.3	75.7	35.0 27.7	(0.8)	69.7 130.8	446.1	24.4 21.5	(58.2)
Income tax expense etc.	(5.6)	—	(5.1)	(26.8)	(30.3)	398.8	5.7	—
Profit attributable to owners of parent	48.3 34.7	7.7	28.6 22.5	7.9	53.6 100.5	462.2	30.8 27.2	(36.9)

Fiscal year ended March 31, 2024

FY2023	FY2023 1Q actual	Y on Y change %	FY2023 2Q actual	Y on Y change %	FY2023 3Q actual	Y on Y change %	FY2023 4Q actual	Y on Y change %
Revenue	109.3	52.2	121.2	53.6	106.3	(43.3)	98.3	11.2
Cost of sales	12.0 (13.1)	1.3	12.2 (14.8)	2.4	13.7 (14.5)	(15.6)	15.5 (15.2)	(14.0)
Gross profit	96.2	63.3	106.5	65.0	91.8	(46.1)	83.1	17.6
SG & A expenses	21.2 (23.2)	3.3	20.1 (24.3)	1.1	22.7 (24.1)	(0.1)	28.5 (28.0)	3.3
R & D expenses	22.9 (25.0)	10.9	18.3 (22.2)	(15.2)	23.9 (25.4)	(2.5)	30.5 (30.0)	8.8
Amortization of intangible assets associated with products	0.8 (0.8)	(11.1)	0.7 (0.9)	(11.5)	0.8 (0.9)	(3.2)	1.1 (1.1)	30.7
Other income & expenses	(0.6)		(7.5)		(0.7)		(9.4)	
Operating profit	42.6 46.6	275.0	42.5 51.5	226.0	38.2 40.6	(65.6)	14.8 14.6	476.1
Finance income & costs	9.1	(67.3)	8.4	(29.4)	8.3	(34.3)	19.2	1.1
Profit before tax	51.0 55.7	38.2	49.4 59.9	116.5	46.0 48.9	(62.6)	34.4 33.8	56.9
Income tax expense etc.	(13.1)	135.2	(11.9)	131.5	(12.3)	(59.6)	1.0	(82.2)
Profit attributable to owners of parent	38.9 42.6	22.6	39.6 48.0	113.1	34.5 36.6	(63.5)	35.4 34.8	27.8

Note:Revenue includes Lump-sum income for transfer of ADHD drug.

10. Group companies

<Consolidated affiliated companies (as of March 31, 2024)>

№	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	UMN Pharma Inc.	Akita, Japan	JPY 90 million	Research, development, mfg., and marketing of biopharmaceuticals	Apr. 20, 2004	Mar. 31	100
5	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	*100
6	Shionogi Inc.	New Jersey, U.S.A.	USD 12	Mfg., sale and development of pharmaceuticals	Aug. 25, 2008	Mar. 31	100
7	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
8	Shionogi B.V.	Amsterdam, Netherlands	GBP 630 thousand	Mfg., sale and development of pharmaceuticals	Nov. 29, 2018	Mar. 31	100
9	Taiwan Shionogi & Co., Ltd.	Taipei, Taiwan, R.O.C.	TWD 92 million	Mfg., and sale of pharmaceuticals	Dec. 26, 1963	Mar. 31	100
10	Beijing Shionogi Pharmaceutical Technology Limited	Beijing, China	JPY 30 million	Support services for sales	Mar. 29, 2013	Dec. 31	100
11	Ping An-Shionogi (Hong Kong) Ltd.	Hong Kong, China	HKD 361,794 thousand	Sale of pharmaceuticals	Aug. 24, 2020	Mar. 31	* 51
12	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 13, 2024)

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:Fetcroja®]	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 Taiwan: Iinfections due to aerobic Gram-negative bacteria in adult patients with limited treatment options	Global: Phase III (pediatric) Taiwan: Approval (Feb. 2024)	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) Taiwan: Approval (5 to 11 years old, treatment and prevention) (Apr. 2024)	In-house	SHIONOGI/ Roche (Switzerland)
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: NDA submission (Nov. 2022) 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-268023	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Phase III	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Approval under the Emergency Regulatory Approval System (Nov. 2022) Normal Approval (Mar. 2024) Phase III Global: Phase III South Korea: NDA submission Singapore: NDA submission (Dec. 2023)	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (Children, 5 to 11 years)	Japan: Phase III	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Prevention of COVID-19	Global: Phase III	In-house	In-house
	F901318 (Olorofim)	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G (UK)	SHIONOGI/ F2G
	S-892216	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Phase I	In-house	In-house
	S-337395	RNA dependent RNA polymerase inhibitor (Oral)	Treatment of RSV infection	Japan: Phase I Europe: Phase II	In-house/UBE	SHIONOGI/ UBE
	S-743229	Cell-wall synthesis inhibition (oral)	Complicated urinary tract infections, including pyelonephritis	USA: Phase I Australia: Phase I	In-house/Qpex	SHIONOGI/ Qpex

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Pain/CNS	S-297995 (naldemedine tosilate) [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation (pediatric)	Europe: Phase I/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	Treatment of ADHD (pediatric)	Japan: NDA submission(Feb. 2024)	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
	GRT7039 (Resiniferatoxin)	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal
	S-151128	New mechanism of action	Chronic pain	Japan: Phase I	In-house	In-house
Frontier	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto (Japan)	SHIONOGI/ Rohto
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: Phase II	In-house	In-house
	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
	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	Global: Phase IIb	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	anti-CCR8 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-033188 (Baloxavir marboxil) [USA:Xofluza™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA: Approved (pediatric, 5 years old and older) (Mar. 2024) 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)
S-723595 (TLC-3595)	Acetyl-CoA carboxylase 2 inhibitor (oral)	Type 2 diabetes	New Zealand: Phase IIa	In-house	OrsoBio, Inc.(USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	Global: Phase IIa	In-house	SHIONOGI-ViiV Healthcare LLC

Since Jan.31, 2024

Change	S-649266: Taiwan: Submission (Dec. 2022)→ Approval (Feb. 2024)
	S-033188: Taiwan: Submission (Jul. 2023)→Approval (5 to 11 years old, treatment and prevention) (Apr. 2024)
	S-217622: Japan: Normal NDA submission (Jun. 2023)→Normal Approval (Mar.2024)
	SDT-001: Japan: Phase III→ NDA submission (Feb. 2024)
	S-033188: USA: NDA submission (pediatric, >1 year old) (Mar. 2020)→Approved (pediatric, 5 years old and older) (Mar. 2024)
	S-365598: USA: Phase I→Global: Phase IIa