

Financial results for the second quarter
of fiscal year 2023

< Supplement >

October 31, 2023



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1. Financial results and forecast

(Billions of yen)

	FY2023 1H actual	FY2023 2H forecast	FY2023 forecast	FY2022 1H actual	FY2022 2H actual	FY2022 actual	Y on Y change		
							1H	2H	full-year
Revenue	230.5	219.5	450.0	150.8	275.9	426.7	79.8	(56.4)	23.3
<i>change %</i>	52.9	(20.5)	5.5	3.9	45.2	27.3			
Operating profit	98.1	51.9	150.0	28.2	120.8	149.0	69.9	(68.9)	1.0
<i>change %</i>	247.6	(57.0)	0.7	(33.8)	78.5	35.1			
Profit before tax	115.6	76.9	192.5	68.0	152.4	220.3	47.6	(75.5)	(27.8)
<i>change %</i>	70.1	(49.5)	(12.6)	33.7	102.0	74.5			
Profit attributable to owners of parent	90.6	64.4	155.0	57.3	127.7	185.0	33.3	(63.3)	(30.0)
<i>change %</i>	58.2	(49.6)	(16.2)	7.8	109.2	62.0			

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

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

2. Revenue by segment

(Billions of yen)

	FY2023 1H	FY2023 2H	FY2023	FY2022 1H	FY2022 2H	FY2022	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Prescription drugs	96.4	70.6	167.0	33.4	146.4	179.7	63.0	(75.7)	(12.7)
<i>change %</i>	188.8	(51.7)	(7.1)	(29.2)	248.6	101.7			
Infectious Disease Drugs	49.0	48.5	97.5	(0.6)	112.7	112.1	49.6	(64.2)	(14.6)
CYMBALTA	2.1	2.1	4.2	3.0	2.4	5.4	(1.0)	(0.3)	(1.3)
OXYCONTIN Franchise	2.2	2.1	4.3	2.3	2.1	4.4	(0.1)	(0.0)	(0.2)
SYMPROIC	2.1	2.8	4.9	1.6	1.8	3.4	0.5	1.1	1.5
ACTAIR	0.3	0.7	1.0	0.3	0.3	0.5	0.1	0.4	0.5
MULPLETA	0.0	0.1	0.1	0.1	0.0	0.1	(0.0)	0.0	0.0
PIRESPA	1.0	0.9	1.9	1.4	1.2	2.5	(0.3)	(0.3)	(0.6)
Others	39.6	13.5	53.1	25.3	25.9	51.2	14.3	(12.4)	1.9
Overseas subsidiaries/Export	22.9	26.2	49.2	19.9	22.6	42.5	3.0	3.7	6.7
<i>change %</i>	15.1	16.2	15.7	14.5	33.0	23.7			
Shionogi Inc.	8.1	8.8	17.0	7.4	8.1	15.4	0.8	0.7	1.5
Shionogi B.V.	6.1	6.9	13.0	4.3	4.8	9.1	1.8	2.1	4.0
Ping An-Shionogi / C&O	5.2	6.8	12.1	5.6	6.4	12.0	(0.4)	0.4	0.1
Others	3.4	3.7	7.1	2.7	3.4	6.0	0.8	0.4	1.1
Contract manufacturing	7.9	8.4	16.4	7.4	8.0	15.3	0.6	0.5	1.0
<i>change %</i>	7.8	5.7	6.7	(12.0)	(12.1)	(12.0)			
OTC and quasi-drugs	7.1	7.7	14.8	6.3	6.9	13.1	0.8	0.8	1.6
<i>change %</i>	13.1	11.7	12.4	3.7	34.2	17.7			
Royalty income	95.6	105.7	201.2	83.3	91.4	174.7	12.3	14.2	26.5
<i>change %</i>	14.8	15.5	15.2	27.4	(21.1)	(3.6)			
HIV Franchise	94.5	102.0	196.5	80.4	88.1	168.5	14.1	13.9	28.1
CRESTOR	—	—	—	—	1.3	1.3	—	(1.3)	(1.3)
Others	1.1	3.6	4.7	2.9	2.0	4.9	(1.8)	1.6	(0.2)
Others	0.6	0.8	1.5	0.6	0.7	1.3	0.0	0.1	0.2
<i>change %</i>	5.6	22.0	14.2	(21.9)	(34.2)	(28.8)			
Total	230.5	219.5	450.0	150.8	275.9	426.7	79.8	(56.4)	23.3
<i>change %</i>	52.9	(20.5)	5.5	3.9	45.2	27.3			

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 • Xofluz • Rapiacta • Brightpoc Flu Neo • Finibax • Flumarin • Flomox
• Shiomarin • Baktar • Flagyl • Isodine

Others in prescription drugs include Lump-sum income for transfer of ADHD drug.

3. Management index

(Management index trend)

		FY2021	FY2022	FY2022 1H	FY2023 1H
Return on equity attributable to owners of parent (ROE)	%	12.5	17.8	5.8	7.8
Ratio of profit before tax to total assets (ROA)	%	11.7	17.9	5.8	8.5
Ratio of operating profit to revenue	%	32.9	34.9	18.7	42.6
Ratio of profit before tax to revenue	%	37.7	51.6	45.1	50.1
Total assets turnover		0.31	0.35	0.13	0.17
Ratio of equity attributable to owners of parent to total assets	%	84.8	83.9	84.4	85.8
Dividend payout ratio	%	30.4	21.7	—	—
Ratio of dividends to equity attributable to owners of parent (DOE)	%	3.8	3.9	—	—
Basic earnings per share	yen	378.75	621.31	190.21	308.65
Diluted earnings per share	yen	378.63	621.10	190.15	308.54

4. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2023 1H	FY2023 2H	FY2023	FY2022 1H	FY2022 2H	FY2022	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
Investments in equipments	7.9	7.6	15.5	5.9	6.7	12.6	2.0	0.9	3.0
Depreciation and Amortization	8.9	9.0	17.8	8.6	8.5	17.2	0.2	0.4	0.7

5. R&D expenses

(Billions of yen)

	FY2023 1H	FY2023 2H	FY2023	FY2022 1H	FY2022 2H	FY2022	Y on Y change		
	actual	forecast	forecast	actual	actual	actual	1H	2H	full-year
R&D expenses	47.2	64.8	112.0	48.7	53.7	102.4	(1.5)	11.1	9.6
change %	(3.1)	20.7	9.4	72.9	19.7	40.3			
% to revenue	20.5	29.5	24.9	32.3	19.5	24.0			

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

6. Employees

	End of FY2021	End of 2022 1H	End of FY2022	End of 2023 1H	End of FY2023	Y on Y change		
	actual	actual	actual	actual	forecast	1H	2H	full-year
Employees	5,693	5,729	5,680	5,325	4,960	(355)	(365)	(720)

Note: The number of employees at the end of the fiscal year ending March 31, 2024 is expected to be lower than at the end of the previous fiscal year.

The main factors are as follows.

Shionogi Business Partner Co., Ltd. is no longer included in the SHIONOGI Group as a result of the formation of a joint venture with Accenture Co., Ltd. in July 2023.

Shionogi carried out a special early retirement program with a retirement date of October 31, 2023.

7. Consolidated statement of profit or loss

(Millions of yen)

	FY2022 1H actual	FY2023 1H actual	Y on Y change	
Revenue	150,779	230,542	79,762	Increasing/(decreasing) in Prescription drugs*: 63.0 billion yen Overseas subsidiaries/Export: 3.0 billion yen Contract manufacturing: 0.6 billion yen OTC and quasi-drugs: 0.8 billion yen Royalty income: 12.3 billion yen
Cost of sales	(27,367)	(27,885)	518	
Gross profit	123,412	202,656	79,244	
Selling, general and administrative expenses	(46,517)	(47,517)	1,000	
Research and development expenses	(48,729)	(47,205)	(1,523)	
Amortization of intangible assets associated with products	(1,951)	(1,730)	(221)	
Other income	3,490	187	(3,303)	(FY2022 1H) Sale of investment property
Other expenses	(1,480)	(8,283)	6,803	Expenses related to implementation of early retirement program
Operating profit	28,224	98,106	69,882	
Finance income	39,834	20,111	(19,722)	(FY 2022 1H) Increase in dividends received from ViiV (delayed from previous fiscal year, and one-time payment related to ViiV's settlement with Gilead)
Finance costs	(79)	(2,614)	2,534	
Profit before tax	67,978	115,603	47,624	
Income tax expense	(10,571)	(25,405)	14,833	
Profit	57,407	90,198	32,790	
Profit attributable to				
Owners of parent	57,264	90,593	33,329	
Non-controlling interests	143	(395)	(538)	
Profit	57,407	90,198	32,790	

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

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

	<i>(Millions of yen)</i>		
	As of Mar. 31 2023	As of Sep. 30 2023	Y on Y change
Assets			
Non-Current assets			
Property, plant and equipment	112,085	112,328	242
Goodwill	9,819	26,800	16,981
Intangible assets	96,309	99,832	3,523
Right-of-use assets	6,482	6,720	237
Investment property	26,382	26,378	(4)
Other financial assets	247,711	282,158	34,447
Deferred tax assets	22,100	17,539	(4,561)
Other non-current assets	6,716	31,778	25,062
Total non-current assets	527,607	603,536	75,928
Current assets			
Inventories	57,919	64,155	6,236
Trade receivables	109,774	153,124	43,350
Other financial assets	254,131	301,074	46,943
Income taxes receivable	68	13	(54)
Other current assets	53,074	35,317	(17,757)
Cash and cash equivalents	309,224	252,371	(56,852)
Total current assets	784,192	806,057	21,864
Total assets	1,311,800	1,409,593	97,793

Increase due to acquisition of Qpex

Fluctuation of ViiV stock due to exchange rates

Increase in trade receivables associated with the start of regular distribution of Xocova

Use of surplus funds

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

	<i>(Millions of yen)</i>		
	As of Mar. 31 2023	As of Sep. 30 2023	Y on Y change
Equity and liabilities			
Equity			
Share capital	21,279	21,279	—
Capital surplus	15,204	15,204	—
Treasury shares	(63,074)	(82,313)	19,239
Retained earnings	940,606	1,009,805	69,199
Other components of equity	186,030	245,402	59,372
Equity attributable to owners of parent	1,100,046	1,209,378	109,332
Non-controlling interests	21,832	22,054	222
Total equity	1,121,878	1,231,433	109,555
Liabilities			
Non-current liabilities			
Lease liabilities	6,397	6,272	(124)
Other financial liabilities	4,844	5,038	193
Retirement benefit liability	12,867	11,106	(1,761)
Deferred tax liabilities	5,916	6,459	543
Other non-current liabilities	1,343	1,837	494
Total non-current liabilities	31,369	30,715	(654)
Current liabilities			
Lease liabilities	3,014	3,165	150
Trade payables	14,005	14,685	680
Other financial liabilities	29,720	35,859	6,138
Income taxes payable	42,217	29,159	(13,058)
Other current liabilities	69,595	64,576	(5,018)
Total current liabilities	158,552	147,444	(11,107)
Total liabilities	189,921	178,160	(11,761)
Total equity and liabilities	1,311,800	1,409,593	97,793

Purchase of treasury shares

Exchange rate fluctuations

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)

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

Fiscal year ending March 31, 2024

FY2023	FY2023 1Q actual	Y on Y change %	FY2023 2Q actual	Y on Y change %
Prescription drugs	45.9	141.6	50.4	251.4
Infectious Disease Drugs	9.3	348.9	39.8	—
CYMBALTA	1.1	(32.4)	1.0	(29.7)
OXYCONTIN Franchise	1.1	(6.8)	1.1	(3.6)
SYMPROIC	1.0	29.7	1.1	28.0
ACTAIR	0.1	13.9	0.2	26.0
MULPLETA	0.0	5.8	0.0	(19.7)
PIRESPA	0.5	(25.7)	0.5	(25.3)
Others	32.7	162.5	6.8	(46.6)
Overseas subsidiaries/Export	12.0	36.2	10.9	(1.6)
Shionogi Inc.	4.0	34.5	4.1	(6.2)
Shionogi B.V.	3.0	61.3	3.1	29.1
Ping An-Shionogi / C&O	3.1	22.2	2.2	(30.0)
Others	1.9	31.7	1.6	24.5
Contract manufacturing	4.0	19.1	3.9	(1.7)
OTC and quasi-drugs	2.3	16.6	4.8	11.5
Royalty income	44.8	16.7	50.8	13.2
HIV Franchise	44.3	18.7	50.2	16.6
Others	0.6	(47.6)	0.5	(70.1)
Others	0.3	(7.3)	0.3	19.8
Total	109.3	52.2	121.2	53.6

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

Others in prescription drugs include Intuniv, Vyvanse and Lump-sum income for transfer of ADHD drug.

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 ending March 31, 2024

FY2023	FY2023 1Q actual	Y on Y change %	FY2023 2Q actual	Y on Y change %
Revenue	109.3	52.2	121.2	53.6
Cost of sales	12.0 (13.1)	1.3	12.2 (14.8)	2.4
Gross profit	96.2	63.3	106.5	65.0
SG & A expenses	21.2 (23.2)	3.3	20.1 (24.3)	1.1
R & D expenses	22.9 (25.0)	10.9	18.3 (22.2)	(15.2)
Amortization of intangible assets associated with products	0.8 (0.8)	(11.1)	0.7 (0.9)	(11.5)
Other income & expenses	(0.6)		(7.5)	
Operating profit	42.6 46.6	275.0	42.5 51.5	226.0
Finance income & costs	9.1	(67.3)	8.4	(29.4)
Profit before tax	51.0 55.7	38.2	49.4 59.9	116.5
Income tax expense etc.	(13.1)	135.2	(11.9)	131.5
Profit attributable to owners of parent	38.9 42.6	22.6	39.6 48.0	113.1

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

10. Group companies

<Consolidated affiliated companies (as of September 30, 2023)>

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	UMN Pharma Inc.	Akita, Japan	JPY 90 million	Research, development, mfg., and marketing of biopharmaceuticals	Apr. 20, 2004	Mar. 31	100
5	Phamira 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
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 October 31, 2023)

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 Taiwan: Infections due to aerobic Gram-negative bacteria in adult patients with limited treatment options	Global: Phase III (pediatric) Japan: NDA submission (Mar. 2022) Taiwan: NDA submission (Dec. 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) Taiwan: sNDA submission (5 to 11 years old) (Jul. 2023)	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-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 NDA submission (June 2023) Japan:Phase II/III Global: Phase III South Korea: NDA submission (Jan. 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	In-house/UBE	SHIONOGI/ UBE
	S-743229	Cell-wall synthesis inhibition (oral)	Complicated urinary tract infections, including pyelonephritis	USA: 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	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
	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: NDA submission (pediatric, >1 year old) (Mar. 2020) Global: Phase III (pediatric, < 1 year old) Global: Phase III (transmission)	In-house	SHIONOGL/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: PhaseIIa	In-house	OrsoBio, Inc.(USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	USA: Phase I	In-house	SHIONOGL-ViiV Healthcare LLC

Note: S-0373: Withdrawal of NDA submission, feasibility of additional clinical trials under consideration.

Since July. 31, 2023

Change	S-743229:USA: Phase I (Compound added to the list)
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