

Supplemental material for financial results for the 1st quarter of fiscal year 2023

July 31, 2023
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2023 1H forecast	FY2023 forecast	FY2023 1Q actual	FY2022 1Q actual	Change	Progress% vs.FY2023 1H forecast
Prescription drugs	87.4	134.1	45.9	19.0	26.9	52.5
<i>change %</i>	<i>162.1</i>	<i>78.7</i>	<i>141.6</i>	<i>(19.0)</i>		
Infectious Disease Drugs	40.0	65.7	9.3	2.1	7.2	23.1
CYMBALTA	2.1	4.2	1.1	1.7	(0.5)	52.6
OXYCONTIN Franchise	2.1	4.1	1.1	1.2	(0.1)	52.7
SYMPROIC	2.3	4.9	1.0	0.8	0.2	45.2
ACTAIR	0.4	1.0	0.1	0.1	0.0	35.0
MULPLETA	0.1	0.1	0.0	0.0	0.0	44.2
PIRESPA	1.1	1.9	0.5	0.7	(0.2)	47.9
Others	39.3	52.1	32.7	12.5	20.3	83.2
Overseas subsidiaries/Export	28.0	96.6	12.0	8.8	3.2	42.8
<i>change %</i>	<i>40.5</i>	<i>127.3</i>	<i>36.2</i>	<i>(5.3)</i>		
Shionogi Inc.	6.7	13.6	4.0	3.0	1.0	60.3
Shionogi B.V.	5.4	11.5	3.0	1.9	1.1	54.9
Ping An-Shionogi / C&O	13.2	58.0	3.1	2.5	0.6	23.4
Others	2.7	13.4	1.9	1.4	0.5	69.9
Contract manufacturing	7.3	13.8	4.0	3.4	0.6	54.7
<i>change %</i>	<i>(0.4)</i>	<i>(10.1)</i>	<i>19.1</i>	<i>(10.2)</i>		
OTC and quasi-drugs	6.8	15.0	2.3	1.9	0.3	33.3
<i>change %</i>	<i>8.6</i>	<i>14.2</i>	<i>16.6</i>	<i>(21.2)</i>		
Royalty income	86.9	189.5	44.8	38.4	6.4	51.6
<i>change %</i>	<i>4.4</i>	<i>8.5</i>	<i>16.7</i>	<i>29.7</i>		
HIV Franchise	86.0	185.0	44.3	37.3	7.0	51.4
Others	0.9	4.5	0.6	1.1	(0.5)	65.5
Others	0.5	1.0	0.3	0.3	(0.0)	58.6
<i>change %</i>	<i>(17.4)</i>	<i>(21.6)</i>	<i>(7.3)</i>	<i>(13.8)</i>		
Total	217.0	450.0	109.3	71.8	37.5	50.4
<i>change %</i>	<i>43.9</i>	<i>5.5</i>	<i>52.2</i>	<i>4.2</i>		

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

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

2-1. 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 %
Prescription drugs	45.9	141.6
Infectious Disease Drugs	9.3	348.9
CYMBALTA	1.1	(32.4)
OXYCONTIN Franchise	1.1	(6.8)
SYMPROIC	1.0	29.7
ACTAIR	0.1	13.9
MULPLETA	0.0	5.8
PIRESPA	0.5	(25.7)
Others	32.7	162.5
Overseas subsidiaries/Export	12.0	36.2
Shionogi Inc.	4.0	34.5
Shionogi B.V.	3.0	61.3
Ping An-Shionogi / C&O	3.1	22.2
Others	1.9	31.7
Contract manufacturing	4.0	19.1
OTC and quasi-drugs	2.3	16.6
Royalty income	44.8	16.7
HIV Franchise	44.3	18.7
Others	0.6	(47.6)
Others	0.3	(7.3)
Total	109.3	52.2

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.

2-2. 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 %
Revenue	109.3	52.2
Cost of sales	12.0 (13.1)	1.3
Gross profit	96.2	63.3
SG & A expenses	21.2 (23.2)	3.3
R & D expenses	22.9 (25.0)	10.9
Amortization of intangible assets associated with products	0.8 (0.8)	(11.1)
Other income & expenses	(0.6)	
Operating profit	42.6 46.6	275.0
Finance income & costs	9.1	(67.3)
Profit before tax	51.0 55.7	38.2
Income tax expense etc.	(13.1)	135.2
Profit attributable to owners of parent	38.9 42.6	22.6

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

3. Pipeline (as of July 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
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-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	

	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Frontier	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto(Japan)	SHIONOGL/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)	SHIONOGL/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 (Asapirant)	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 May10, 2023

Change	S-033188 : Taiwan: sNDA submission (5 to 11 years old) (Jul. 2023)
	S-217622: Taiwan: Plan to switch to normal NDA submission
	S-0373 : Japan: withdraw NDA submission
	S-723595: New Zealand: PhaseIIa started and indication changed (NASH⇒Type 2 diabetes)