

# Supplemental material for financial results for the 3rd quarter of fiscal year 2022

January 30, 2023  
Shionogi & Co., Ltd.

## 1. Revenue by segment

(Billions of yen)

	FY2022 2H forecast	FY2022 forecast	FY2022 3Q actual	FY2021 3Q actual	FY2022 1Q-3Q actual	FY2021 1Q-3Q actual	Progress % vs.FY2022 forecast
Prescription drugs	43.1	76.4	21.3	22.4	54.7	69.5	71.5
<i>change %</i>	2.6	(14.3)	(4.9)	(9.2)	(21.4)	(3.2)	
INTUNIV	10.5	20.0	5.3	4.5	14.8	12.1	74.0
VYVANSE	0.6	1.3	0.4	0.2	1.1	0.6	84.4
Infectious Disease Drugs	9.3	8.8	3.5	3.0	2.9	8.8	32.8
CYMBALTA	3.0	6.1	1.4	2.7	4.4	14.1	73.0
OXYCONTIN Franchise	2.2	4.5	1.2	1.3	3.5	3.8	78.3
SYMPROIC	1.8	3.4	1.0	0.7	2.6	2.0	76.4
ACTAIR	0.3	0.6	0.1	0.1	0.4	0.4	70.2
MULPLETA	0.1	0.1	0.0	0.0	0.1	0.1	68.9
PIRESPA	1.0	2.4	0.7	1.1	2.0	3.1	85.7
Others	14.2	29.4	7.7	8.7	22.9	24.6	77.8
CRESTOR	1.8	3.9	1.1	1.6	3.2	4.7	81.9
Overseas subsidiaries/Export	19.4	39.3	10.6	8.7	30.6	26.2	77.8
<i>change %</i>	14.3	14.4	21.7	35.1	16.9	49.7	
Shionogi Inc.	7.1	14.4	4.1	3.3	11.5	11.1	79.4
Ping An-Shionogi / C&O	4.8	10.4	2.7	2.5	8.4	7.2	80.5
Shionogi B.V.	4.3	8.6	2.3	1.6	6.6	3.8	77.4
Contract manufacturing	7.4	14.8	2.9	3.5	10.3	11.8	69.6
<i>change %</i>	(18.3)	(15.3)	(15.5)	(3.1)	(13.0)	15.3	
OTC and quasi-drugs	7.0	13.2	3.8	2.4	10.1	8.4	76.0
<i>change %</i>	36.3	18.7	60.8	(28.8)	19.8	(4.5)	
Royalty income	82.8	166.0	48.5	37.0	131.7	102.4	79.3
<i>change %</i>	(28.6)	(8.4)	31.0	(1.4)	28.7	(10.8)	
HIV Franchise	79.6	159.9	46.6	35.0	126.9	96.2	79.4
CRESTOR	1.3	1.3	1.3	1.2	1.3	1.2	100.0
Others	1.9	4.8	0.6	0.9	3.5	5.0	72.8
COVID-19 related products	110.0	110.0	100.0	—	100.0	—	90.9
<i>change %</i>	—	—	—	—	—	—	
Others	0.6	1.2	0.4	0.6	1.0	1.3	85.0
<i>change %</i>	(40.9)	(32.6)	(26.1)	37.3	(23.6)	8.7	
Total	270.2	421.0	187.6	74.5	338.3	219.6	80.4
<i>change %</i>	42.2	25.6	151.6	(1.9)	54.1	(2.1)	

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 Xocova and S-268019

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

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

## 2-2. 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 %	FY2022 3Q actual	Y on Y change %
Revenue	71.8	4.2	78.9	3.7	187.6	151.6
Cost of sales	18.0 (12.9)	5.0	18.3 (14.4)	(1.6)	9.2 (17.2)	33.6
Gross profit	58.9	4.0	64.5	5.0	170.4	176.3
SG & A expenses	31.2 (22.4)	3.2	30.5 (24.1)	7.0	12.9 (24.2)	8.4
R & D expenses	31.4 (22.5)	53.0	33.2 (26.2)	94.8	13.9 (26.1)	30.1
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
Other income & expenses	(0.5)		2.5		(0.9)	
Operating profit	17.3 12.4	(33.9)	20.0 15.8	(33.8)	63.0 118.2	565.9
Finance income & costs	27.9	572.5	11.9	195.1	12.6	102.7
Profit before tax	56.1 40.3	75.7	35.0 27.7	(0.8)	69.7 130.8	446.1
Income tax expense etc.	(5.6)	—	(5.1)	(26.8)	(30.3)	398.8
Profit attributable to owners of parent	48.3 34.7	7.7	28.6 22.5	7.9	53.6 100.5	462.2

### 3. Pipeline (as of January 30, 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)	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) Japan: Phase II/III Global: Phase III South Korea: NDA submission (Jan. 2023)	In-house	In-house
	F901318 (olorofim)	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G (UK)	SHIONOGI/ F2G
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-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
	GRT7039 (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 (Japan)	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: 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	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/GSK1265744 LAP*1 (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB*2 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: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	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	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	The Liver Company Inc.(USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	USA: Phase I	In-house	SHIONOGI-ViiV Healthcare LLC

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

Since Oct.31, 2022

Change of phase	S-649266: Taiwan: NDA submission (Dec. 2022)
	S-268019: Japan: Phase III → NDA submission (Nov. 2022)
	S-217622: Japan: NDA submission (Feb. 2022), Phase II/III, Global: Phase III → Japan: Approval under the Emergency Regulatory Approval System (Nov. 2022), Phase II/III, Global: Phase III, South Korea: NDA submission (Jan. 2023)
Code No.added to the list	resiniferatoxin → GRT7039 (resiniferatoxin)
Compound added to the list	S-365598: USA: Phase I