

Supplemental material for financial results for the 1st quarter of fiscal year 2021

August 2, 2021
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2021 1H forecast	FY2021 forecast	FY2021 1Q actual	FY2020 1Q actual	Change	Progress% vs. FY2020 1H forecast
Prescription drugs	46.1	94.4	23.5	22.4	1.1	50.9
<i>change %</i>	<i>(2.2)</i>	<i>(0.3)</i>	<i>5.1</i>	<i>(15.1)</i>		
CYMBALTA	10.0	15.1	6.8	6.9	(0.1)	68.1
INTUNIV	8.5	18.2	3.6	2.6	1.0	42.0
VYVANSE	0.4	1.0	0.1	0.0	0.1	37.3
Infectious Disease Drugs	4.8	17.0	2.1	2.1	(0.0)	43.9
OXYCONTIN Franchise	2.6	5.0	1.3	1.4	(0.1)	48.1
SYMPROIC	1.3	3.1	0.6	0.5	0.1	46.1
ACTAIR	0.2	0.4	0.1	0.1	0.0	58.8
MULPLETA	0.1	0.1	0.0	0.0	0.0	46.0
PIRESPA	1.8	3.5	1.0	1.4	(0.5)	54.2
Others	16.4	30.9	7.9	7.3	0.6	47.8
CRESTOR	3.8	6.5	1.4	1.5	(0.1)	37.8
IRBETAN Franchise	1.7	3.1	0.8	0.8	(0.1)	47.1
Overseas subsidiaries/Export	12.2	31.1	9.3	5.5	3.8	76.2
<i>change %</i>	<i>10.9</i>	<i>26.2</i>	<i>70.0</i>	<i>(49.1)</i>		
Shionogi Inc.	4.2	8.4	4.7	1.7	3.0	111.5
Ping An-Shionogi / C&O	3.9	14.3	2.4	2.4	0.0	60.8
Shionogi B.V.	1.4	3.5	0.9	0.4	0.5	63.7
Contract manufacturing	7.4	17.8	3.7	2.9	0.9	50.5
<i>change %</i>	<i>11.0</i>	<i>(9.7)</i>	<i>30.2</i>	<i>17.6</i>		
OTC and quasi-drugs	6.9	15.4	2.5	2.3	0.2	36.0
<i>change %</i>	<i>25.1</i>	<i>31.8</i>	<i>9.0</i>	<i>26.1</i>		
Royalty income	61.7	129.8	29.6	38.0	(8.4)	48.0
<i>change %</i>	<i>(20.2)</i>	<i>(10.3)</i>	<i>(22.1)</i>	<i>(2.4)</i>		
HIV Franchise	60.8	125.2	28.8	31.0	(2.1)	47.5
CRESTOR	-	1.1	-	5.6	(5.6)	-
Others	0.9	3.5	0.8	1.5	(0.7)	84.4
Others	0.7	1.4	0.4	0.4	(0.1)	51.4
<i>change %</i>	<i>(12.8)</i>	<i>(18.2)</i>	<i>(17.3)</i>	<i>(17.2)</i>		
Total	135.0	290.0	69.0	71.4	(2.4)	51.1
<i>change %</i>	<i>(9.1)</i>	<i>(2.4)</i>	<i>(3.4)</i>	<i>(11.6)</i>		

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

Revenue of prescription drugs are shown on non-consolidated basis.

Products included in infectious disease drugs are below.

•Xofluza •Rapiacta •Brightpoc Flu Neo •Finibax •Flumarin •Flomox •Shiomarin •Vancomycin •Baktar
•Flagyl •Fluconazole •Isodine

2 - 1. Quarterly trend for FY2020 and FY2021 (Revenue by segment)

Fiscal year ended March 31, 2021

(Billions of yen)

FY2020	FY2020 1Q actual	Y on Y change %	FY2020 2Q actual	Y on Y change %	FY2020 3Q actual	Y on Y change %	FY2020 4Q actual	Y on Y change%
Prescription drugs	22.4	(15.1)	24.8	(1.2)	24.7	(14.4)	22.9	(12.1)
CYMBALTA	6.9	2.9	6.6	6.8	7.0	(4.2)	6.0	(1.0)
INTUNIV	2.6	42.2	3.4	30.1	3.6	36.3	3.5	(2.3)
VYVANSE	0.0	-	0.1	-	0.1	1,586.9	0.1	1,827.2
Infectious Disease Drugs	2.1	(40.7)	2.7	(26.5)	2.7	(50.4)	2.2	(32.4)
OXYCONTIN Franchise	1.4	(17.3)	1.4	(1.5)	1.3	(19.9)	1.2	11.2
SYMPROIC	0.5	(7.9)	0.6	9.2	0.6	22.3	0.6	4.7
ACTAIR	0.1	3.4	0.1	40.1	0.1	44.3	0.1	14.6
MULPLETA	0.0	(26.3)	0.0	(19.8)	0.0	(28.6)	0.0	(16.1)
PIRESPA	1.4	(17.1)	1.4	(18.2)	1.2	(22.1)	1.1	(38.8)
Others	7.3	(28.4)	8.5	(3.5)	8.1	(16.2)	8.1	(15.9)
CRESTOR	1.5	(35.3)	2.1	4.7	1.4	(34.2)	1.6	(22.0)
IRBETAN Franchise	0.8	(30.5)	0.9	(11.4)	0.9	(17.8)	0.8	(23.1)
Overseas subsidiaries/Export	5.5	(49.1)	5.5	(18.5)	6.5	0.1	7.2	5.5
Shionogi Inc.	1.7	(68.6)	1.7	11.1	2.1	20.9	2.1	26.6
C&O	2.4	(37.5)	1.9	(44.1)	2.7	(11.5)	3.1	6.6
Contract manufacturing	2.9	17.6	3.8	(50.1)	3.6	88.0	9.5	68.9
OTC and quasi-drugs	2.3	26.1	3.2	23.4	3.3	27.3	2.9	8.3
Royalty income	38.0	(2.4)	39.3	(2.1)	37.5	(26.0)	29.8	(19.7)
HIV Franchise	31.0	(2.4)	33.0	(0.7)	31.1	(5.2)	28.3	(6.7)
CRESTOR	5.6	(1.6)	5.6	(0.8)	5.4	(0.4)	(0.0)	(100.0)
Others	1.5	(3.6)	0.8	(40.7)	0.9	(92.5)	1.5	24.1
Others	0.4	(17.2)	0.4	(36.0)	0.4	(33.0)	0.5	26.2
Total	71.4	(11.6)	77.1	(7.0)	76.0	(16.6)	72.8	(7.5)

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

Fiscal year ending March 31, 2022

FY2021	FY2021 1Q actual	Y on Y change%
Prescription drugs	23.5	5.1
CYMBALTA	6.8	(1.5)
INTUNIV	3.6	37.3
VYVANSE	0.1	436.2
Infectious Disease Drugs	2.1	(1.6)
OXYCONTIN Franchise	1.3	(8.9)
SYMPROIC	0.6	24.8
ACTAIR	0.1	79.1
MULPLETA	0.0	18.0
PIRESPA	1.0	(32.2)
Others	7.9	8.1
CRESTOR	1.4	(7.7)
IRBETAN Franchise	0.8	(7.3)
Overseas subsidiaries/Export	9.3	70.0
Shionogi Inc.	4.7	182.7
Ping An-Shionogi / C&O	2.4	0.2
Shionogi B.V.	0.9	144.1
Contract manufacturing	3.7	30.2
OTC and quasi-drugs	2.5	9.0
Royalty income	29.6	(22.1)
HIV Franchise	28.8	(6.8)
CRESTOR	-	-
Others	0.8	(47.4)
Others	0.4	(17.3)
Total	69.0	(3.4)

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

2 - 2. Quarterly trend for FY2020 and FY2021 (Consolidated statements of profit or loss)

Fiscal year ended March 31, 2021

(Billions of yen)

FY2020	FY2020 1Q actual	Y on Y change %	FY2020 2Q actual	Y on Y change %	FY2020 3Q actual	Y on Y change %	FY2020 4Q actual	Y on Y change %
Revenue	71.4	(11.6)	77.1	(7.0)	76.0	(16.6)	72.8	(7.5)
Cost of sales	16.1 (11.5)	(9.3)	14.8 (11.4)	(24.4)	17.2 (13.1)	0.6	22.8 (16.6)	3.1
Gross profit	59.9	(12.0)	65.7	(3.1)	62.9	(19.5)	56.2	(10.2)
SG & A expenses	29.2 (20.9)	(9.5)	28.9 (22.3)	(5.5)	30.4 (23.1)	(3.9)	35.3 (25.7)	5.1
R & D expenses	17.0 (12.2)	4.2	16.5 (12.7)	8.9	18.9 (14.4)	24.8	20.6 (15.0)	14.7
Amortization of intangible assets associated with products	1.1 (0.8)	(0.1)	1.0 (0.8)	(0.8)	1.0 (0.8)	(2.9)	1.1 (0.8)	(1.9)
Other income & expenses	2.5		(0.2)		22.3		(2.4)	
Operating profit	40.0 28.6	(9.8)	38.5 29.7	(5.8)	61.7 46.9	7.8	16.9 12.3	(48.7)
Finance income & costs	4.4	21.1	7.4	96.3	2.7	(71.0)	11.0	0.1
Profit before tax	46.2 33.0	(6.6)	48.2 37.1	5.1	65.3 49.6	(6.3)	31.9 23.2	(33.4)
Income tax expense etc.	(8.5)	3.8	(9.3)	15.2	(12.9)	(1.2)	(0.4)	(94.2)
Profit attributable to owners of parent	34.3 24.5	(9.7)	36.1 27.8	2.2	48.3 36.7	(8.0)	31.4 22.8	(18.3)

Fiscal year ending March 31, 2022

FY2021	FY2021 1Q actual	Y on Y change %
Revenue	69.0	(3.4)
Cost of sales	17.9 (12.3)	7.3
Gross profit	56.6	(5.5)
SG & A expenses	31.5 (21.8)	4.2
R & D expenses	21.4 (14.7)	21.1
Amortization of intangible assets associated with products	1.2 (0.8)	1.2
Other income & expenses	(0.5)	
Operating profit	27.3 18.8	(34.2)
Finance income & costs	4.1	(6.7)
Profit before tax	33.3 22.9	(30.5)
Income tax expense etc.	9.3	(209.0)
Profit attributable to owners of parent	46.7 32.2	31.6

3. Pipeline (as of August 2, 2021)

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 with no or limited treatment options Europe: Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options	Global: Phase III (pediatric) USA: Approval (cUTI) (Nov. 2019) Approval (Nosocomial pneumonia) (Sep. 2020) Europe: Approval (Apr. 2020)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan: Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: Approval (body weight >20kg) (Sep. 2018) Japan: NDA submission (body weight <20kg) (Aug. 2018)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Not disclosed (oral)	HIV infection	USA, Japan: Phase I	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Phase I/II	In-house	In-house
	S-217622	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Phase I	In-house	In-house
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-120083	Not disclosed (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Not disclosed (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-117957	Not disclosed (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	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-600918 (sivopixant)	P2X ₃ receptor antagonist (oral)	Sleep Apnea Syndrome	Japan: Phase II	In-house	In-house
	S-637880	Not disclosed (oral)	Neuropathic Low Back Pain	Japan: Phase II	In-house	In-house
	S-812217 (zuranolone)	GABA _A receptor positive allosteric modulator (oral)	Depression	Japan: Phase II	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan: Phase II	Akili (USA)	Shionogi/Akili
	BPN14770 (zatolmilast)	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: Phase II	Tetra (USA)	Shionogi/Tetra
	BPN14770 (zatolmilast)	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA: Phase II Japan: Phase II	Tetra (USA)	Shionogi/Tetra
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto	Shionogi/Rohto
	S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	In-house

Areas	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 (preparing NDA submission)	StemRIM (Japan)	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+RPV*3 LAP 2-drug regimen for treatment) Canada: Approval (Mar. 2020) USA: Approval (Jan. 2021) Europe: Approval (Dec. 2020) (CAB LAP for prevention) Global: PhaseIII	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc.(USA)for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan: PhaseIII (preparing NDA submission)	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA:Xofluzax™]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	USA: Approval (Oct. 2018) USA: Approval (high risk patients) (Oct. 2019) USA: NDA submission (pediatric, >1 year old) (Mar. 2020) USA: Approval (granule, >12 years old) (Nov. 2020) USA: Approval (prophylaxis, >12 years old) (Nov. 2020) Europe: Approval (treatment, >12 years old) (prophylaxis, >12 years old) (Jan. 2021) 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)

*1 Long acting parenteral formulation, *2 Cabotegravir, *3 Rilpivirine

Since May 10, 2021

Change of phase	SR-0379(Cutaneous ulcer) : Japan : PhaseII→PhaseIII
Compound added to the list	S-217622(Treatment of COVID-19) : Japan : PhaseI