Financial Results for the 3rd Quarter of FY2024 Supplement

January 31, 2025
SHIONOGI & CO., LTD.

1. Consolidated statement of profit or loss

(Billions of yen)

	FY2023 Apr.-Dec.	FY2024 Apr.-Dec.	Change	Change(%)	Comment	FY2024 forecast	Progress(%)
Revenue	336.8	333.6	(3.2)	(1.0)	Increasing/(decreasing) in Prescription drugs (48.6) billion Overseas subsidiaries/Export 6.9billion Royalty income 37.7billion	460.0	72.5
Cost of sales	(42.4)	(46.0)	3.6	8.6		(67.0)	68.7
Gross profit	294.4	287.6	(6.9)	(2.3)		393.0	73.2
SG&A expenses	(71.7)	(73.2)	1.5	2.1		(104.7)	69.9
R&D expenses	(72.6)	(79.4)	6.8	9.4	Investments in major development projects and foreign exchange effects	(116.0)	68.5
Amortization of intangible assets associated with products	(2.6)	(3.3)	0.6	24.1		(4.3)	75.7
Other income	0.4	0.5	0.1	39.9			
Other expenses	(9.1)	(3.0)	(6.2)	(67.6)	FY2023 : Expenses related to implementation of early retirement program	(3.0)	81.7
Operating profit	138.7	129.2	(9.5)	(6.9)		165.0	78.3
Finance income	29.8	33.0	3.3	11.0		41.0	65.0
Finance costs	(4.0)	(6.4)	2.4	59.0			
Profit before tax	164.5	155.9	(8.6)	(5.2)		206.0	75.7
Income tax expense	(38.0)	(22.5)	(15.5)	(40.8)			
Profit	126.4	133.3	6.9	5.5			
Profit attributable to							
Owners of parent	127.2	133.8	6.6	5.2		171.0	78.2
Non-controlling interests	(0.8)	(0.5)	(0.3)	(40.5)			
Profit	126.4	133.3	6.9	5.5			

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

Reconciliation from operating profit to EBITDA

(Billions of yen)

	FY2023 Apr.-Dec.	FY2024 Apr.-Dec.
Operating profit	138.7	129.2
Other income	(0.1)	(0.2)
Other expenses	8.1	1.6
Core operating profit *1	146.7	130.6
Depreciation and amortization	13.4	15.7
EBITDA *2	160.2	146.4

*1. Core operating profit: An adjusted profit in which non-recurring items (impairment, gain on sales of property, plant, and equipment, etc.) are deducted from operating profit.
2. Earnings Before Interest, Taxes, Depreciation and Amortization: Core operating profit added depreciation and amortization.

2. Revenue by segment

(Billions of yen)

	FY2023 Apr.-Dec.	FY2024 Apr.-Dec.	Change	Change(%)	FY2024 forecast	Progress(%)
Prescription drugs	127.5	78.9	(48.6)	(38.1)	124.7	63.3
Infectious Disease Drugs	69.0	50.0	(19.0)	(27.5)	83.4	60.0
COVID-19 related products + Influenza Franchise	62.0	43.3	(18.7)	(30.2)	72.3	59.9
SYMPROIC	3.3	3.8	0.5	15.5	5.9	65.0
OXYCONTIN Franchise	3.3	3.3	(0.0)	(0.4)	5.0	66.2
ACTAIR	0.5	0.7	0.1	27.6	1.3	51.1
CYMBALTA	3.1	1.9	(1.3)	(40.3)	3.3	56.4
Others	48.2	19.2	(29.0)	(60.1)	25.8	74.4
QUVIVIQ	—	0.5	0.5	—	3.0	16.5
Overseas subsidiaries/Export	36.5	43.4	6.9	18.8	57.6	75.3
Shionogi Inc. (US)	13.1	17.5	4.4	33.6	22.6	77.4
Shionogi B.V. (EU)	10.1	12.9	2.9	28.5	16.7	77.5
Ping An-Shionogi / C&O	8.3	6.3	(2.0)	(24.4)	9.1	68.9
Others	5.1	6.7	1.6	32.1	9.2	72.5
Contract manufacturing	11.7	10.7	(1.0)	(8.9)	16.5	64.8
OTC and quasi-drugs	10.6	12.7	2.1	20.0	16.6	76.5
Royalty income	149.1	186.8	37.7	25.3	242.8	76.9
HIV Franchise	146.1	183.5	37.4	25.6	234.9	78.1
Others	3.0	3.3	0.2	7.7	7.9	41.2
Others	1.4	1.1	(0.2)	(18.2)	1.8	62.1
Total	336.8	333.6	(3.2)	(1.0)	460.0	72.5

*1. Sales of prescription drugs are shown on non-consolidated basis.
2. Products included in Infectious Disease Drugs: Xocova, Xofluza, Rapiacta, Brightpoc Flu Neo, Finibax, Flumarin, Flomox, Shiomarin, Baktar, Flagyl, Isodine, Fetroja
3. Others in prescription drugs for FY2023 include Lump-sum income for transfer of ADHD drug.

3. Quarterly trend (Consolidated statement of profit or loss)

(Billions of yen)

	FY2023				FY2024							
	1Q	2Q	3Q	4Q	1Q	Y on Y change (%)	2Q	Y on Y change (%)	3Q	Y on Y change (%)	4Q	Y on Y change (%)
Revenue	109.3	121.2	106.3	98.3	97.6	(10.7)	116.4	(4.0)	119.6	12.6		
Cost of sales	(13.1)	(14.8)	(14.5)	(15.2)	(14.4)	10.1	(15.7)	6.3	(15.9)	9.5		
Gross profit	96.2	106.5	91.8	83.1	83.1	(13.6)	100.7	(5.4)	103.7	13.0		
SG&A expenses	(23.2)	(24.3)	(24.1)	(28.0)	(24.0)	3.7	(23.7)	(2.6)	(25.5)	5.4		
R&D expenses	(25.0)	(22.2)	(25.4)	(30.0)	(29.4)	17.7	(27.4)	23.4	(22.6)	(11.0)		
Amortization of intangible assets associated with products	(0.8)	(0.9)	(0.9)	(1.1)	(1.1)	28.9	(1.1)	21.6	(1.1)	22.0		
Other income	0.1	0.1	0.2	5.8	0.1	(16.6)	0.4	330.4	0.0	(90.5)		
Other expenses	(0.7)	(7.6)	(0.8)	(15.2)	(0.5)	(18.0)	(1.2)	(84.5)	(1.2)	46.6		
Operating profit	46.6	51.5	40.6	14.6	28.1	(39.7)	47.8	(7.3)	53.4	31.3		
Finance income	10.1	10.6	11.4	21.9	11.3	11.7	13.9	31.4	10.2	(10.5)		
Finance costs	(1.0)	(2.2)	(3.1)	(2.7)	(2.8)	197.5	(4.4)	97.3	(1.5)	(52.3)		
Profit before tax	55.7	59.9	48.9	33.8	36.5	(34.4)	57.3	(4.3)	62.0	26.9		
Income tax expense	(13.5)	(11.9)	(12.6)	0.3	(6.2)	(53.9)	(4.7)	(60.2)	(11.6)	(8.4)		
Profit	42.2	48.0	36.2	34.1	30.3	(28.2)	52.6	9.5	50.5	39.2		
Profit attributable to												
Owners of parent	42.6	48.0	36.6	34.8	30.6	(28.0)	52.5	9.3	50.7	38.3		
Non-controlling intersts	(0.3)	(0.0)	(0.4)	(0.7)	(0.3)	(5.0)	0.1	-	(0.2)	(47.2)		
Profit	42.2	48.0	36.2	34.1	30.3	(28.2)	52.6	9.5	50.5	39.2		

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

4. Quarterly trend (Revenue by segment)

(Billions of yen)

	FY2023				FY2024							
	1Q	2Q	3Q	4Q	1Q	Y on Y change (%)	2Q	Y on Y change (%)	3Q	Y on Y change (%)	4Q	Y on Y change (%)
Prescription drugs	45.9	50.4	31.2	23.6	15.4	(66.4)	32.3	(36.0)	31.2	0.2		
Infectious Disease Drugs	9.3	39.8	20.0	13.9	6.1	(34.4)	23.1	(41.8)	20.8	4.0		
COVID-19 related products + Influenza Franchise	7.1	37.3	17.6	11.4	3.9	(44.9)	21.0	(43.9)	18.5	4.8		
SYMPROIC	1.0	1.1	1.2	1.2	1.1	6.0	1.3	19.4	1.5	19.9		
OXYCONTIN Franchise	1.1	1.1	1.1	0.8	1.0	(6.7)	1.0	(4.4)	1.2	9.5		
ACTAIR	0.1	0.2	0.2	0.2	0.2	43.9	0.2	24.9	0.3	19.0		
CYMBALTA	1.1	1.0	1.0	0.7	0.8	(27.0)	0.7	(32.7)	0.4	(61.9)		
Others	33.3	7.4	7.5	6.8	6.2	(81.3)	6.0	(19.2)	7.1	(6.6)		
QUVIVIQ	–	–	–	–	–	–	–	–	0.5	–		
Overseas subsidiaries/Export	12.0	10.9	13.6	13.4	15.0	24.9	13.4	22.0	15.0	10.8		
Shionogi Inc. (US)	4.0	4.1	5.0	4.8	6.0	48.6	5.2	27.4	6.3	26.6		
Shionogi B.V. (EU)	3.0	3.1	4.0	3.5	4.0	34.2	4.3	37.1	4.6	17.3		
Ping An-Shionogi / C&O	3.1	2.2	3.0	2.3	2.3	(25.8)	1.9	(11.6)	2.1	(32.0)		
Others	1.9	1.6	1.6	2.8	2.7	42.9	1.9	23.9	2.1	27.4		
Contract manufacturing	4.0	3.9	3.8	5.9	3.6	(10.4)	4.2	6.3	2.9	(22.9)		
OTC and quasi-drugs	2.3	4.8	3.5	4.1	2.4	6.6	5.7	19.1	4.5	30.0		
Royalty income	44.8	50.8	53.5	51.3	61.0	36.1	60.5	19.2	65.3	22.0		
HIV Franchise	44.3	50.2	51.6	49.7	59.8	35.1	59.8	19.1	63.9	23.9		
Others	0.6	0.5	1.9	1.6	1.2	109.6	0.7	27.3	1.4	(28.9)		
Others	0.3	0.3	0.7	0.1	0.2	(44.1)	0.4	0.8	0.6	(16.8)		
Total	109.3	121.2	106.3	98.3	97.6	(10.7)	116.4	(4.0)	119.6	12.6		

*1. Sales of prescription drugs are shown on non-consolidated basis.
2. Products included in Infectious Disease Drugs: Xocova, Xofluza, Rapiacta, Brightpoc Flu Neo, Finibax, Flumarin, Flomox, Shiomarin, Baktar, Flagyl, Isodine, Fetroja
3. Others in prescription drugs for FY2023 include Lump-sum income for transfer of ADHD drug.

5. Consolidated statement of financial position

(Billions of yen)

	As of Mar. 31 2024	As of Dec. 31 2024	Y on Y change	Comment
Assets				
Non-current assets				
Property, plant and equipment	114.6	110.6	(4.0)	
Goodwill	15.3	15.8	0.5	
Intangible assets	117.6	144.7	27.1	Increase due to acquisition of in-process research and development assets
Right-of-use assets	9.4	20.5	11.0	Increase in right-of-use assets relating to the new Head Office
Investment property	27.8	27.8	0.1	
Other financial assets	292.3	312.9	20.6	ViiV shares: Increase due to an increase in foreign exchange effects
Deferred tax assets	13.5	14.1	0.6	
Other non-current assets	42.2	41.5	(0.7)	
Total non-current assets	632.7	687.9	55.2	
Current assets				
Inventories	64.9	67.9	3.0	
Trade receivables	122.8	144.0	21.2	Increase in accounts receivable due to HIV royalty revenue, etc.
Other financial assets	215.8	286.0	70.2	Increase in time deposits over 3 months
Other current assets	22.6	25.2	2.6	
Cash and cash equivalents	358.1	305.6	(52.5)	
Total current assets	784.2	828.7	44.5	
Total assets	1,416.9	1,516.6	99.7	

	As of Mar. 31 2024	As of Dec. 31 2024	Y on Y change	Comment
Equity and liabilities				
Equity				
Share capital	21.3	21.3	–	
Capital surplus	14.2	14.2	(0.0)	
Treasury shares	(137.9)	(65.9)	(72.0)	Cancellation of treasury shares
Retained earnings	1,065.9	1,079.0	13.1	
Other components of equity	271.8	296.9	25.2	Increase in exchange differences on translation of foreign operations
Equity attributable to owners of parent	1,235.3	1,345.6	110.3	
Non-controlling interests	17.2	17.0	(0.2)	
Total equity	1,252.6	1,362.6	110.0	
Liabilities				
Non-current liabilities				
Lease liabilities	8.8	19.4	10.7	Increase in lease liabilities relating to the new Head Office
Other financial liabilities	7.6	7.8	0.2	
Retirement benefit liability	8.0	9.2	1.2	
Deferred tax liabilities	4.4	4.6	0.2	
Other non-current liabilities	1.7	4.5	2.8	
Total non-current liabilities	30.4	45.5	15.0	
Current liabilities				
Lease liabilities	2.9	3.6	0.8	
Trade payables	14.8	13.1	(1.7)	
Other financial liabilities	31.1	15.5	(15.7)	Decrease in other payable
Income taxes payable	20.8	14.8	(6.0)	
Other current liabilities	64.3	61.5	(2.8)	
Total current liabilities	133.9	108.5	(25.4)	
Total liabilities	164.4	154.0	(10.4)	
Total equity and liabilities	1,416.9	1,516.6	99.7	

6. Management index

		FY2023				FY2024			
		Apr.-Jun.	Apr.-Sep.	Apr.-Dec.	Apr.-Mar.	Apr.-Jun.	Apr.-Sep.	Apr.-Dec.	Apr.-Mar.
STS2030 Revision Growth									
Revenue *1	Billions of yen	109.3	230.5	336.8	435.1	97.6	214.0	333.6	
Overseas sales CAGR *2	%	-	-	-	17.4	-	-	-	
EBITDA	Billions of yen	51.3	114.2	160.2	188.7	33.1	86.7	146.4	
STS2030 Revision Shareholder return									
Basic earnings per share *3	yen	48.21	102.88	145.30	186.17	36.02	97.74	157.30	
Diluted earnings per share *3	yen	48.19	102.85	145.25	186.11	36.01	97.70	157.25	
Ratio of dividends to equity attributable to owners of parent (DOE)	%	-	-	-	4.0	-	-	-	
Return on equity attributable to owners of parent (ROE)	%	3.7	7.8	11.1	13.9	2.4	6.6	10.4	
Others									
Ratio of profit before tax to total assets (ROA)	%	4.2	8.5	12.3	14.5	2.5	6.5	10.6	
Ratio of operating profit to revenue	%	42.6	42.6	41.2	35.2	28.8	35.5	38.7	
Ratio of equity attributable to owners of parent to total assets	%	85.8	85.8	87.7	87.2	87.9	88.7	88.7	
Dividend payout ratio	%	-	-	-	28.6	-	-	-	

*1. Revenue for FY2023 includes Lump-sum income for transfer of ADHD drug.
2. Excluding royalty income, starting from FY2022
3. The Company conducted a 3-for-1 stock split of shares of common stock, effective October 1, 2024. Basic earnings per share and Diluted earnings per share were calculated under the assumption that the stock split had been conducted at the beginning of FY2023.

7. Employees

		FY2023				FY2024			
		As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Mar. 31
Employees	Persons	5,719	5,325	4,957	4,959	5,001	4,990	4,944	

* The decrease in FY2023 is mainly due to the fact that Shionogi Business Partner Co., Ltd. is no longer a consolidated subsidiary 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.

8. Capital investments and Depreciation and Amortization

(Billions of yen)

	FY2023 Apr.-Dec.	FY2024 Apr.-Dec.	Change	Change(%)	FY2024 forecast	Progress(%)
Investments in equipments	10.4	5.1	(5.3)	(50.6)	12.5	41.2
Depreciation and Amortization	13.4	15.7	2.3	17.0	20.6	76.5
Property, plant andequipment	7.6	8.8	1.1	14.5		
Intangible assets	4.2	4.7	0.5	11.6		
Right-of-use assets	1.6	2.0	0.5	28.8		
Investment property	0.0	0.2	0.2	-		

9. Exchange rate

	FY2023 Apr.-Dec.		FY2023		FY2024 Apr.-Dec.		FY2024 forecast
	CR	AR	CR	AR	CR	AR	AR
USD	141.83	143.33	151.33	144.59	158.15	152.64	148
GBP	180.66	179.59	191.13	181.72	198.94	195.50	190
EUR	157.08	155.33	163.24	156.76	164.86	164.89	161

10. Pipeline (as of January 31, 2025)

Areas	Generic name/Code No. [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja®] [EU:Fetcroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	Global: Phase III (pediatric)	In-house	In-house
	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja®] [EU:Fetcroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	China: NDA submission (Aug. 2024) China: Phase III	In-house	Ping An-Shionogi (China)
	Cefiderocol Tosilate Sulfate Hydrate [US, Japan: Fetroja®] [EU:Fetcroja®]	Cell-wall synthesis inhibition (injection)	Gram-negative infection	Australia: MAA submission (Dec. 2024)	In-house	In-house
	Baloxavir marboxil [USA:Xofluza™] [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: NDA submission (body weight <20kg) (Aug. 2018)	In-house	In-house/ Roche (Switzerland)
	S-268019 [Japan:Covgoze®]	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Approval (Jun. 2024) Japan: Phase III	In-house	In-house
	S-268019 [Japan:Covgoze®]	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Japan: Phase II/III	In-house	In-house
	S-268019 [Japan:Covgoze®]	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
	Ensitrelvir Fumaric Acid [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19 (12 years old and older)	Japan: Phase III Global: Phase III South Korea: NDA withdrawal Taiwan: NDA submission (Jan. 2025) Singapore: NDA submission (Dec. 2023)	In-house	Japan, global, Taiwan In-house South Korea: In-house/Ildong Singapore: In-house/Juniper
	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
	Ensitrelvir Fumaric Acid [Japan:Xocova®]	3CL protease inhibitor (oral)	Prevention of COVID-19	Global: Phase III	In-house	In-house
	Olorofim	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G(UK)	In-house/ 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	In-house/ UBE
	S-743229	Cell-wall synthesis inhibition (oral)	Complicated urinary tract infections, including pyelonephritis	USA: Phase I Australia: Phase I	In-house/ Qpex	In-house/ Qpex
	S-649228	Cell-wall synthesis inhibition (injection)	Gram-negative infection	USA: Phase I	In-house/ Qpex	In-house/ Qpex
QOL Diseases	Naldemedine tosilate [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, powder)	Opioid-induced constipation (pediatric)	Europe: Phase I/II	In-house	In-house
	Naldemedine tosilate [Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	China: Phase III	In-house	Ping An-Shionogi (China)
	Zuranolone	$GABA_A$ receptor positive allosteric modulator (oral)	Depression	Japan: NDA submission (Sep. 2024)	Sage (USA)	In-house/ Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Treatment of ADHD (pediatric)	Japan: NDA submission (Feb. 2024)	Akili (USA)	In-house/ Akili
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Fragile X syndrome	USA: Phase II/III	Tetra (USA)	In-house/ Tetra
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Jordan syndrome	USA: Phase II	Tetra (USA)	In-house/ Tetra
	Zatolmilast	PDE4D negative allosteric modulator (oral)	Alzheimer's disease	USA: Phase II Japan: Phase II	Tetra (USA)	In-house/ Tetra
	Resiniferatoxin	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal
	S-151128	Nav1.7 inhibitor (injection)	Chronic pain	Japan: Phase I	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto (Japan)	In-house/ 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

Areas	Generic name/Code No. [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
QOL Diseases	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)	In-house/ FunPep
	Redasemtide Trifluoroacetate	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Global: Phase IIb	StemRIM (Japan)	In-house
	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
	S-740792	New mechanism of action (oral)	Walking impairment associated with multiple sclerosis	USA: Phase I	In-house	In-house
	SASS-001 (S-600918+Concomitant drug X)	P2X3 receptor inhibitor (oral) + Mechanism of Concomitant drug	Sleep Apnea Syndrome	USA: Phase II	S-600918: In-house	Shionogi-Apnimed Sleep Science, LLC (USA)
	S-606001	Glycogen synthase 1 (GYS1) inhibitor	Pompe disease	Japan: Phase I	Maze (USA)	In-house

<Out-Licensing Activity>

Generic name/Code No. [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Baloxavir marboxil [USA:Xofluza™] [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection	EU: NDA Submission (pediatric, < 1 year old) (Jun. 2024) USA: NDA submission (Nov.2024) (transmission)	In-house	In-house/ Roche (Switzerland)
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 October 28, 2024

Change	Baloxavir marboxil (transmission): Global Phase III→USA: NDA submission (Nov.2024)
	Ensitrelvir Fumaric Acid: South Korea: NDA submissionm→NDA withdrawal
Add	Cefiderocol Tosilate Sulfate Hydrate: Australiz: MAA
	Ensitrelvir Fumaric Acid: Taiwan: NDA submissionm
	Zatolmilast(Jordan syndrome): USA: Phase II