



Consolidated Financial Results for the Third Quarter of Fiscal Year 2021 (IFRS)

January 31, 2022

Name of Listed Company: **SHIONOGI & CO., LTD.**

Listed Exchanges: Section I of Tokyo

Code: 4507

URL: <http://www.shionogi.co.jp>

Representative: Isao Teshirogi, President and CEO

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Scheduled date of quarterly securities report submission: February 10, 2022

Scheduled date of dividend payments: -

Preparation of supplemental material for the quarterly financial results: Yes

Holding of presentation for the quarterly financial results: Yes (for investment analysts)

(Note: All amounts are rounded down to the nearest million yen.)

1. Consolidated results for the period from April 1, 2021 to December 31, 2021

(1) Consolidated operating results

(% shows changes from the same period of the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended December 31, 2021	219,626	(2.1)	60,422	(42.5)	74,784	(37.6)	70,731	(20.6)	71,000	(20.3)	80,790	(16.3)
Nine months ended December 31, 2020	224,419	(11.9)	105,160	(1.4)	119,789	(3.1)	89,032	(5.6)	89,032	(5.5)	96,515	12.2

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Nine months ended December 31, 2021	235.51	235.43
Nine months ended December 31, 2020	289.52	289.41

Note: In the consolidated fiscal year ended March 2021, the provisional accounting for business combinations was finalized, and the consolidated financial statements for the Third quarter of fiscal year ended March 2021 have been retroactively adjusted.

(2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent to total assets
	Millions of yen	Millions of yen	Millions of yen	%
As of December 31, 2021	1,038,898	912,309	894,670	86.1
As of March 31, 2021	998,992	864,550	846,108	84.7

2. Dividends

(Date of record)	Dividends per share				
	End of first quarter	End of second quarter	End of third quarter	Year-end	Annual
	Yen	Yen	Yen	Yen	Yen
Year ended March 31, 2021	—	53.00	—	55.00	108.00
Year ending March 31, 2022	—	55.00	—		
Year ending March 31, 2022 (forecast)				55.00	110.00

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2022

(% shows changes from the same period of the previous fiscal year)

	Revenue		Operating profit		Profit before tax		Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Year ending March 31, 2022	294,000	(1.1)	90,000	(23.4)	115,000	(19.6)	100,000	(10.6)	331.71

Note: Revisions of the most recent consolidated financial forecast: None

※ Notes

(1) Significant changes in subsidiaries during the period (changes in specified subsidiaries involving changes in scope of consolidation): None

(2) Changes in accounting policies, changes/restatements of accounting estimates

- a) Changes in accounting policies required by IFRS: None
- b) Changes in accounting policies other than a) above: None
- c) Changes in accounting estimates: None

(3) Number of shares issued (common stock)

a) Number of shares issued (including treasury stock)

As of December 31, 2021:	311,586,165 shares
As of March 31, 2021:	311,586,165 shares

b) Number of treasury stock

As of December 31, 2021:	10,102,853 shares
As of March 31, 2021:	10,122,444 shares

c) Average number of shares issued during the period

Nine months ended December 31, 2021:	301,477,545 shares
Nine months ended December 31, 2020:	307,515,149 shares

※ This report of financial results is unaudited.

※ Explanation Concerning the Appropriate Use of Financial Results Forecasts and Other Special Instructions

(Cautionary note concerning forward-looking statements)

The forecast of financial results and forward-looking statements contained in this report are based on information currently available to the Company as well as certain assumptions that it judges to be reasonable. Actual results may differ materially due to a variety of factors.

For the assumptions used in forecasts and precautionary statements regarding the use of the forecasts, please refer to "1. Overview of Operating Results and Financial Position (4) Outlook" on page 3 of the accompanying materials.

(Method of Obtaining Financial Results Supplementary Materials and Details of Results Briefing Meeting)

Financial results supplementary materials are posted via TDnet on the date of disclosure. The Company plans to hold a results briefing meeting for analysts on Tuesday, February 1, 2022. Plans are also in place to post explanatory details (Transcript) together with financial results explanatory materials distributed to analysts on February 1, 2022 on the Company's website in a timely manner after the results briefing.

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1. Overview of Operating Results and Financial Position

(1) Operating Results for the Third Quarter of the Fiscal Year Ending March 31, 2022

For the Nine months ended December 31, 2021 (April 1, 2021 to December 31, 2021), operating results were as follows.

Millions of yen

	Nine months ended December 31, 2021	Nine months ended December 31, 2020 *2	Change	Percentage change (%)
Revenue	219,626	224,419	(4,793)	(2.1)
Operating profit	60,422	105,160	(44,738)	(42.5)
Core operating profit *1	61,917	79,974	(18,057)	(22.6)
Profit before tax	74,784	119,789	(45,004)	(37.6)
Profit attributable to owners of parent	71,000	89,032	(18,031)	(20.3)

*1 The Company has established “core operating profit” as a profit indicator to present ordinary profitability. This has been adopted as the Company’s proprietary earnings management indicator. Core operating profit is an adjusted profit in which non-recurring items (impairment, gain on sales of property, plant, and equipment, etc.) are deducted from operating profit.

*2 In the consolidated fiscal year ended March 2021, the provisional accounting for business combinations about Tetra was finalized, and the consolidated financial statements for the third quarter of fiscal year ended March 2021 have been retroactively adjusted.

Revenue decreased 2.1 percent year on year. In domestic sales of prescription drugs, revenue for Intuniv expanded, but the entry of a generic version of Cymbalta reduced revenue, resulting in a 3.2 percent year-on-year decrease. In overseas subsidiary sales and exports, Cefiderocol (U.S. brand name: Fetroja, European brand name: Fetcroja), which has shown effectiveness against multidrug-resistant Gram-negative bacteria, performed well in the United States and Europe, and Shionogi received a one-time payment related to the transfer of marketing rights for FORTAMET in the United States. As a result, revenue from overseas subsidiary sales and exports increased 49.7 percent. Revenue from contract manufacturing increased 15.3 percent as a result of the acquisition of Nagase Medicals Co., Ltd., which is engaged in pharmaceutical contract manufacturing, as a consolidated subsidiary in the third quarter of the fiscal year ended March 31, 2021, in addition to an increase in orders from ViiV for dolutegravir. Regarding royalty income, ViiV’s continued strong global sales of anti-HIV drugs Tivicay, Triumeq, Juluca and Dovato resulted in a 1.2 percent increase in royalty income from ViiV. In addition, although Shionogi received a one-time payment from ViiV related to the out-licensing of S-365598, an HIV integrase inhibitor, the amount of royalty income received from AstraZeneca for Crestor decreased starting from the fourth quarter of the fiscal year ended March 31, 2021 based on the licensing agreement. As a result, total royalty income decreased 10.8 percent.

Gross profit decreased 4.6 percent year on year as a result of the increase in cost of sales exceeding the increase in revenue from sales at overseas subsidiaries, exports and contract manufacturing. Selling, general and administrative expenses and research and development expenses increased because of the increase in selling expenses for Cefiderocol, and because of research and development investments for key projects and priority issues such as treatments and vaccines for COVID-19. In addition, other revenue decreased due to the absence of the gain on exchange from redevelopment of the Shionogi Shibuya Building that occurred in the third quarter of the fiscal year ended March 31, 2021. As a result, operating profit decreased 42.5 percent year on year. Core operating profit decreased 22.6 percent as a result of the aforementioned gain on exchange from the Shionogi Shibuya Building, as well as a loss on disposal of property, plant and equipment and adjustment of interest on refund of income taxes. Profit before tax decreased 37.6 percent, reflecting the decrease in operating profit. Despite a refund received in relation to a favorable judgment of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau, profit attributable to owners of parent decreased 20.3 percent year on year, reflecting the decrease in profit before tax.

(2) Financial Position for the Third Quarter of the Fiscal Year Ending March 31, 2022

As of December 31, 2021, total assets were ¥1,038,898 million, an increase of ¥39,905 million from the end of the previous

fiscal year.

Non-current assets were ¥452,221 million, an increase of ¥9,466 million from the end of the previous fiscal year, mainly due to an increase in property, plant and equipment. Current assets were ¥586,677 million, an increase of ¥30,439 million, mainly reflecting increases and decreases in cash and cash equivalents and in time deposits and bonds of more than three months (included in "Other financial assets" in current assets).

Equity was ¥912,309 million, an increase of ¥47,759 million from the end of the previous fiscal year, mainly due to recording of profit and cash dividends paid.

Liabilities totaled ¥126,588 million, a decrease of ¥7,853 million from the end of the previous fiscal year.

Non-current liabilities were ¥32,094 million, a decrease of ¥2,166 million. Current liabilities were ¥94,493 million, a decrease of ¥5,686 million from the end of the previous fiscal year, mainly because income taxes payable decreased due to payment of income taxes.

(3) Cash Flows for the Third Quarter of the Fiscal Year Ending March 31, 2022

Net cash provided by operating activities during the nine months ended December 31, 2021 was ¥76,709 million, an increase of ¥18,069 million year on year. Factors included a decrease in profit before tax and an increase in cash due to a refund received in relation to a favorable judgment of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau.

Net cash used in investing activities was ¥117,964 million, an increase of ¥69,991 million year on year. Factors included increases and decreases of time deposits and acquisition of securities for investment of surplus.

Net cash used in financing activities was ¥35,733 million, an increase of ¥22,390 million year on year, mainly because of the absence of the purchase of treasury shares and of cash provided by the disposal of treasury shares by third-party allotment and the issuance of shares in connection with the establishment of a subsidiary with Ping An Insurance (Group) Company of China, Ltd. in the same period of the fiscal year ended March 31, 2021.

As a result, cash and cash equivalents at the end of the third quarter totaled ¥201,282 million, a decrease of ¥74,890 million from the end of the previous fiscal year.

(4) Outlook

There are no revisions to the consolidated financial forecast announced on November 1, 2021.

2. Consolidated Financial Statements and Notes

(1) Consolidated statement of profit or loss and Consolidated statement of comprehensive income

Consolidated statement of profit or loss

Millions of yen

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Revenue	224,419	219,626
Cost of sales	(35,947)	(39,853)
Gross profit	188,471	179,772
Selling, general and administrative expenses	(66,232)	(66,542)
Research and development expenses	(39,234)	(48,219)
Amortization of intangible assets associated with products	(2,406)	(2,479)
Other income	26,273	1,741
Other expenses	(1,712)	(3,850)
Operating profit	105,160	60,422
Finance income	15,884	15,017
Finance costs	(1,256)	(655)
Profit before tax	119,789	74,784
Income tax expense	(30,756)	(4,052)
Profit	89,032	70,731
Profit attributable to		
Owners of parent	89,032	71,000
Non-controlling interests	(0)	(269)
Profit	89,032	70,731
Earnings per share		
Basic earnings per share	289.52	235.51
Diluted earnings per share	289.41	235.43

Consolidated statement of comprehensive income

Millions of yen

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Profit	89,032	70,731
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	(1,190)	(6,106)
Remeasurements of defined benefit plans	2,293	828
Total of items that will not be reclassified to profit or loss	1,102	(5,278)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	9,459	12,500
Effective portion of cash flow hedges	(3,079)	2,836
Total of items that may be reclassified to profit or loss	6,380	15,337
Total other comprehensive income, net of tax	7,483	10,058
Comprehensive income	96,515	80,790
Comprehensive income attributable to		
Owners of parent	96,515	80,642
Non-controlling interests	(0)	147
Comprehensive income	96,515	80,790

(2) Consolidated statement of financial position

Millions of yen

	As of March 31, 2021	As of December 31, 2021
Assets		
Non-current assets		
Property, plant and equipment	90,883	102,442
Goodwill	9,357	9,494
Intangible assets	76,558	78,373
Right-of-use assets	4,827	3,918
Investment property	26,759	27,001
Other financial assets	217,437	214,728
Deferred tax assets	11,729	9,882
Other non-current assets	5,200	6,378
Total non-current assets	442,754	452,221
Current assets		
Inventories	38,003	41,751
Trade receivables	78,047	80,414
Other financial assets	142,151	240,760
Income taxes receivable	164	85
Other current assets	21,697	22,381
Cash and cash equivalents	276,173	201,282
Total current assets	556,238	586,677
Total assets	998,992	1,038,898

Millions of yen

	As of March 31, 2021	As of December 31, 2021
Equity and liabilities		
Equity		
Share capital	21,279	21,279
Capital surplus	13,733	14,683
Treasury shares	(57,989)	(57,853)
Retained earnings	752,248	790,909
Other components of equity	116,836	125,650
Equity attributable to owners of parent	846,108	894,670
Non-controlling interests	18,442	17,639
Total equity	864,550	912,309
Liabilities		
Non-current liabilities		
Lease liabilities	4,608	3,911
Other financial liabilities	5,242	4,578
Retirement benefit liability	16,318	15,420
Deferred tax liabilities	7,749	7,866
Other non-current liabilities	341	317
Total non-current liabilities	34,261	32,094
Current liabilities		
Lease liabilities	3,379	3,173
Trade payables	9,902	11,139
Other financial liabilities	21,383	18,305
Income taxes payable	28,033	5,427
Other current liabilities	37,481	56,448
Total current liabilities	100,180	94,493
Total liabilities	134,442	126,588
Total equity and liabilities	998,992	1,038,898

(3) Consolidated statement of changes in equity

Nine months ended December 31, 2020

Millions of yen

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	Equity attributable to owners of parent	Non-controlling interests	Total equity
Balance as of April 1, 2020	21,279	21,025	(77,292)	708,291	91,848	765,152	51	765,203
Profit				89,032		89,032	(0)	89,032
Total other comprehensive income, net of tax					7,483	7,483		7,483
Comprehensive income	—	—	—	89,032	7,483	96,515	(0)	96,515
Purchase of treasury shares			(20,446)			(20,446)		(20,446)
Disposal of treasury shares		(4,705)	38,404			33,698		33,698
Cancellation of treasury shares		(30,912)	30,912			—		—
Dividends				(32,543)		(32,543)		(32,543)
Change in scope of consolidation						—	10,696	10,696
Transfer from other components of equity to retained earnings				2,292	(2,292)	—		—
Other		35,919		(35,430)	(488)	(0)		(0)
Balance as of December 31, 2020	21,279	21,326	(28,422)	731,643	96,549	842,376	10,747	853,124

Nine months ended December 31, 2021

Millions of yen

	Share capital	Capital surplus	Treasury shares	Retained earnings	Other components of equity	Equity attributable to owners of parent	Non-controlling interests	Total equity
Balance as of April 1, 2021	21,279	13,733	(57,989)	752,248	116,836	846,108	18,442	864,550
Profit				71,000		71,000	(269)	70,731
Total other comprehensive income, net of tax					9,642	9,642	416	10,058
Comprehensive income	—	—	—	71,000	9,642	80,642	147	80,790
Purchase of treasury shares			(10)			(10)		(10)
Disposal of treasury shares		(5)	147			141		141
Dividends				(33,162)		(33,162)		(33,162)
Transfer from other components of equity to retained earnings				828	(828)	—		—
Other		955		(5)		949	(949)	—
Balance as of December 31, 2021	21,279	14,683	(57,853)	790,909	125,650	894,670	17,639	912,309

(4) Consolidated statement of cash flows

Millions of yen

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Cash flows from operating activities		
Profit before tax	119,789	74,784
Depreciation and amortization	10,987	12,029
Impairment Losses	—	135
Finance income and finance costs	(14,951)	(14,626)
Decrease (increase) in trade and other receivables	(2,830)	(1,283)
Decrease (increase) in inventories	(6,491)	(3,195)
Increase (decrease) in trade and other payables	(1,255)	6,152
Other	(38,874)	10,324
Subtotal	66,372	84,319
Interest and dividends received	24,785	18,972
Interest paid	(71)	(131)
Income taxes paid	(32,446)	(39,715)
Income taxes refund	—	13,264
Net cash provided by (used in) operating activities	58,640	76,709
Cash flows from investing activities		
Payments into time deposits	(170,592)	(256,331)
Proceeds from withdrawal of time deposits	139,070	188,901
Purchase of property, plant and equipment	(10,077)	(17,579)
Purchase of intangible assets	(4,329)	(3,890)
Payments for acquisition of subsidiaries	(3,636)	—
Purchase of investments	(86,349)	(89,796)
Proceeds from sale of investments	91,576	61,300
Other	(3,634)	(566)
Net cash provided by (used in) investing activities	(47,973)	(117,964)

Millions of yen

	Nine months ended December 31, 2020	Nine months ended December 31, 2021
Cash flows from financing activities		
Repayments of lease liabilities	(2,688)	(2,556)
Purchase of treasury shares	(20,468)	(10)
Proceeds from disposal of treasury shares	33,534	—
Dividends paid	(32,545)	(33,166)
Capital contribution from non-controlling interests	10,401	—
Payments for acquisition of interests in subsidiaries from non-controlling interests	(1,575)	—
Other	(0)	—
Net cash provided by (used in) financing activities	(13,342)	(35,733)
Effect of exchange rate changes on cash and cash equivalents	(1,396)	2,097
Net increase (decrease) in cash and cash equivalents	(4,072)	(74,890)
Cash and cash equivalents at beginning of period	208,861	276,173
Cash and cash equivalents at end of period	204,788	201,282

(5) Notes

Going concern assumption

None

Segment information

Shionogi group has a single business segment related to prescription drugs. The group operates research, development, purchase, manufacturing, and distributing prescription drugs and related businesses. While analysis of each product sales and profits or expenses of each subsidiary are made, decision of business strategy and allocation of the management resources, especially allocation of R&D expenses, are made on a company-wide basis. Therefore disclosure of segment information is omitted.

Supplemental material for financial results for the 3rd quarter of fiscal year 2021

January 31, 2022
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2021 2H forecast	FY2021 forecast	FY2021 3Q actual	FY2020 3Q actual	FY2021 1Q-3Q actual	FY2020 1Q-3Q actual	Progress %vs.FY2021 forecast
Prescription drugs	47.3	94.4	22.4	24.7	69.5	71.8	73.7
<i>change %</i>	<i>(0.6)</i>	<i>(0.3)</i>	<i>(9.2)</i>	<i>(14.4)</i>	<i>(3.2)</i>	<i>(10.5)</i>	
CYMBALTA	5.6	17.1	2.7	7.0	14.1	20.5	82.6
INTUNIV	9.0	16.6	4.5	3.6	12.1	9.6	73.0
VYVANSE	0.7	1.0	0.2	0.1	0.6	0.2	53.7
Infectious Disease Drugs	10.9	16.6	3.0	2.7	8.8	7.6	52.7
OXYCONTIN Franchise	2.5	5.0	1.3	1.3	3.8	4.1	75.5
SYMPROIC	1.9	3.1	0.7	0.6	2.0	1.7	64.5
ACTAIR	0.1	0.4	0.1	0.1	0.4	0.2	95.8
MULPLETA	0.1	0.1	0.0	0.0	0.1	0.1	75.1
PIRESPA	1.5	3.5	1.1	1.2	3.1	4.0	88.0
Others	14.9	30.8	8.7	8.1	24.6	23.9	79.8
CRESTOR	2.6	5.7	1.6	1.4	4.7	5.1	82.0
IRBETAN Franchise	1.5	3.1	0.9	0.9	2.4	2.6	78.5
Overseas subsidiaries/Export	17.5	35.0	8.7	6.5	26.2	17.5	74.8
<i>change %</i>	<i>28.6</i>	<i>41.8</i>	<i>35.1</i>	<i>0.1</i>	<i>49.7</i>	<i>(27.2)</i>	
Shionogi Inc.	4.8	12.7	3.3	2.1	11.1	5.4	87.6
Ping An-Shionogi / C&O	7.6	12.3	2.5	2.7	7.2	6.9	58.5
Shionogi B.V.	2.7	5.0	1.6	0.6	3.8	1.3	76.7
Contract manufacturing	9.5	17.8	3.5	3.6	11.8	10.3	66.3
<i>change %</i>	<i>(27.6)</i>	<i>(9.7)</i>	<i>(3.1)</i>	<i>88.0</i>	<i>15.3</i>	<i>(14.3)</i>	
OTC and quasi-drugs	7.4	13.4	2.4	3.3	8.4	8.8	62.5
<i>change %</i>	<i>18.7</i>	<i>14.8</i>	<i>(28.8)</i>	<i>27.3</i>	<i>(4.5)</i>	<i>25.5</i>	
Royalty income	66.6	132.0	37.0	37.5	102.4	114.8	77.6
<i>change %</i>	<i>(1.1)</i>	<i>(8.8)</i>	<i>(1.4)</i>	<i>(26.0)</i>	<i>(10.8)</i>	<i>(11.5)</i>	
HIV Franchise	64.0	125.2	35.0	31.1	96.2	95.1	76.8
CRESTOR	-	-	1.2	5.4	1.2	16.6	-
Others	2.6	6.7	0.9	0.9	5.0	3.2	74.8
Others	0.7	1.4	0.6	0.4	1.3	1.2	93.3
<i>change %</i>	<i>(29.6)</i>	<i>(18.2)</i>	<i>37.3</i>	<i>(33.0)</i>	<i>8.7</i>	<i>(29.1)</i>	
Total	148.9	294.0	74.5	76.0	219.6	224.4	74.7
<i>change %</i>	<i>0.1</i>	<i>(1.1)</i>	<i>(1.9)</i>	<i>(16.6)</i>	<i>(2.1)</i>	<i>(11.9)</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.

• Xofluzza • Rapiacta • Brightpoc Flu Neo • Finibax • Flumarin • Flomox
• Shiomarin • Vancomycin • Baktar • Flagyl • 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: Sales of prescription drugs are shown on non-consolidated basis.

Fiscal year ending March 31, 2022

FY2021	FY2021 1Q actual	Y on Y change %	FY2021 2Q actual	Y on Y change %	FY2021 3Q actual	Y on Y change %
Prescription drugs	23.5	5.1	23.7	(4.6)	22.4	(9.2)
CYMBALTA	6.8	(1.5)	4.7	(29.0)	2.7	(62.0)
INTUNIV	3.6	37.3	4.0	18.2	4.5	27.4
VYVANSE	0.1	436.2	0.2	223.0	0.2	170.0
Infectious Disease Drugs	2.1	(1.6)	3.7	34.4	3.0	9.3
OXYCONTIN Franchise	1.3	(8.9)	1.2	(12.0)	1.3	(1.1)
SYMPROIC	0.6	24.8	0.7	11.8	0.7	26.5
ACTAIR	0.1	79.1	0.1	56.2	0.1	36.2
MULPLETA	0.0	18.0	0.0	(4.3)	0.0	21.0
PIRESPA	1.0	(32.2)	1.0	(27.6)	1.1	(8.5)
Others	7.9	8.1	8.1	(5.6)	8.7	7.4
CRESTOR	1.4	(7.7)	1.6	(22.4)	1.6	12.9
IRBETAN Franchise	0.8	(7.3)	0.8	(10.7)	0.9	0.4
Overseas subsidiaries/Export	9.3	70.0	8.1	46.7	8.7	35.1
Shionogi Inc.	4.7	182.7	3.2	89.2	3.3	58.6
Ping An-Shionogi / C&O	2.4	0.2	2.4	24.1	2.5	(7.4)
Shionogi B.V.	0.9	144.1	1.4	267.6	1.6	180.6
Contract manufacturing	3.7	30.2	4.6	21.3	3.5	(3.1)
OTC and quasi-drugs	2.5	9.0	3.6	11.1	2.4	(28.8)
Royalty income	29.6	(22.1)	35.8	(9.1)	37.0	(1.4)
HIV Franchise	28.8	(6.8)	32.4	(1.7)	35.0	12.3
CRESTOR	-	-	-	-	1.2	(78.9)
Others	0.8	(47.4)	3.3	328.6	0.9	(3.4)
Others	0.4	(17.3)	0.4	8.6	0.6	37.3
Total	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)

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

2-2. Quarterly trend for FY2020 and FY2021 (Consolidated statement 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 %	FY2021 2Q actual	Y on Y change %	FY2021 3Q actual	Y on Y change %
Revenue	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)
Cost of sales	17.9 (12.3)	7.3	19.2 (14.7)	28.9	17.3 (12.9)	(1.7)
Gross profit	56.6	(5.5)	61.5	(6.4)	61.7	(1.9)
SG & A expenses	31.5 (21.8)	4.2	29.6 (22.5)	0.9	29.9 (22.3)	(3.4)
R & D expenses	21.4 (14.7)	21.1	17.7 (13.4)	6.0	26.9 (20.0)	39.4
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
Other income & expenses	(0.5)		(0.8)		(0.7)	
Operating profit	27.3 18.8	(34.2)	31.4 23.9	(19.6)	23.8 17.8	(62.1)
Finance income & costs	4.1	(6.7)	4.0	(45.9)	6.2	125.4
Profit before tax	33.3 22.9	(30.5)	36.6 27.9	(24.9)	32.1 24.0	(51.7)
Income tax expense etc.	9.3	(209.0)	(7.0)	(24.6)	(6.1)	(53.0)
Profit attributable to owners of parent	46.7 32.2	31.6	27.4 20.9	(25.0)	24.0 17.9	(51.3)

3. Pipeline (as of January 31, 2022)

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-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: Phase III Global: Phase III	In-house	In-house
	S-217622	3CL protease inhibitor (oral)	Treatment of COVID-19	Global: Phase II/III	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-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 III	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 (Japan)	Shionogi/Rohto
	S-723595	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	In-house
	S-309309	Monoacylglycerol acyltransferase 2 inhibitor (oral)	Obesity	USA: 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	StemRIM (Japan)	In-house
	S-531011	CCR8-specific monoclonal antibody (injection)	Solid tumor	Japan,USA: PhaseIb/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+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: NDA submission(Dec. 2021)	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA: Xofluza TM]	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 (asapirant)	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 Nov 1, 2021

Change of phase	S-268019 : Japan : PhaseII/III→Japan: Phase III、 Global: PhaseIII
	S-217622 : Japan : PhaseII/III→Global: PhaseII/III
	S-812217 : Japan: PhaseII→ Japan: Phase III
	S-0373 : Japan: PhaseIII (preparing NDA submission)→ NDA submission(Dec. 2021)
Compound erased from the list	S-600918(Sleep Apnea Syndrome) : Closed (Dec. 2021)