



Consolidated Financial Results for the First Quarter of Fiscal Year 2022 (IFRS)

August 1, 2022

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

Listed Exchanges: Section I of Tokyo

Code: 4507 URL: <https://www.shionogi.com>

Representative: Isao Teshirogi, Ph.D., Chairman of the Board and Representative Director, President and CEO

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Scheduled date of quarterly securities report submission: August 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, 2022 to June 30, 2022

(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	%
Three months ended June 30, 2022	71,839	4.2	12,421	(33.9)	40,310	75.7	34,426	6.9	34,722	7.7	56,607	66.8
Three months ended June 30, 2021	68,965	(3.4)	18,794	(34.2)	22,941	(30.5)	32,198	31.4	32,238	31.6	33,935	47.9

	Basic earnings per share		Diluted earnings per share	
	Yen		Yen	
Three months ended June 30, 2022	115.17		115.13	
Three months ended June 30, 2021	106.94		106.91	

(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 June 30, 2022	1,200,957	1,036,516	1,014,361	84.5
As of March 31, 2022	1,150,601	993,285	975,661	84.8

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, 2022	—	55.00	—	60.00	115.00
Year ending March 31, 2023	—				
Year ending March 31, 2023 (forecast)		60.00	—	60.00	120.00

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2023

(% 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
Six months ending September 30, 2022	180,000	24.1	57,000	33.6	86,000	69.2	71,500	34.6	237.16
Year ending March 31, 2023	400,000	19.4	120,000	8.8	168,000	33.0	136,000	19.1	451.10

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 June 30 2022:	311,586,165 shares
As of March 31 2022:	311,586,165 shares

b) Number of treasury stock

As of June 30 2022:	10,103,658 shares
As of March 31 2022:	10,103,385 shares

c) Average number of shares issued during the period

Three months ended June 30, 2022:	301,482,644 shares
Three months ended June 30, 2021:	301,463,533 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 Monday, August 1, 2022. Plans are also in place to post explanatory details (Transcript) together with financial results explanatory materials distributed to analysts on August 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 First Quarter of the Fiscal Year Ending March 31, 2023

For the three months ended June 30, 2022 (April 1, 2022 to June 30, 2022), operating results were as follows.

	<i>Millions of yen</i>			
	Three months ended June 30, 2022	Three months ended June 30, 2021	Change	Percentage change (%)
Revenue	71,839	68,965	2,873	4.2
Operating profit	12,421	18,794	(6,372)	(33.9)
Core operating profit *	12,662	19,384	(6,721)	(34.7)
Profit before tax	40,310	22,941	17,369	75.7
Profit attributable to owners of parent	34,722	32,238	2,483	7.7

* 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.

Revenue increased 4.2 percent year on year. In domestic sales of prescription drugs, revenue for Intuniv expanded, but revenue for Cymbalta decreased due to the market entry of a generic version, resulting in a 19.0 percent decrease in revenue. 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; however, revenue from overseas subsidiary sales and exports decreased 5.3 percent, reflecting the absence of a one-time payment Shionogi group received in the first quarter of the previous fiscal year in connection with the transfer of marketing rights for FORTAMET in the United States. Royalty income increased 29.7 percent due to growth in sales of the HIV franchise out-licensed to ViiV, centered on Dovato, Cabenuva and other products as well as the impact of exchange rates.

Research and development expenses increased because of investment in key projects and priority issues such as potential treatments and vaccines for COVID-19. As a result, operating profit decreased 33.9 percent year on year. Core operating profit decreased 34.7 percent, basically in line with the decrease in operating profit, as a result of adjustment of non-recurring items. Profit before tax increased 75.7 percent due to an increase in dividends because Shionogi group received dividends from ViiV in the current fiscal year that were originally scheduled to be received in the fourth quarter of fiscal 2021, and because ViiV received a one-time payment in connection with the settlement of litigation with Gilead Sciences, Inc. Profit attributable to owners of parent increased only 7.7 percent year on year, reflecting the refund received in the first quarter of fiscal 2021 in connection with a favorable judgement of the complaint for the rescission of tax reassessment by the Osaka Regional Taxation Bureau.

(2) Financial Position for the First Quarter of the Fiscal Year Ending March 31, 2023

As of June 30, 2022, total assets were ¥1,200,957 million, an increase of ¥50,355 million from the end of the previous fiscal year.

Non-current assets were ¥517,035 million, an increase of ¥25,639 million from the end of the previous fiscal year, due to increases in in-process R&D assets (included in "Intangible assets") and financial assets measured at fair value (included in "Other financial assets") through other comprehensive income. Current assets were ¥683,921 million, an increase of ¥24,716 million, due to an increase in inventories and receivables (included in "Other financial assets").

Equity was ¥1,036,516 million, an increase of ¥43,230 million from the end of the previous fiscal year. This was due to recording of profit, payment of cash dividends, an increase in exchange differences on translation of foreign operations (included in "Other components of equity"), and an increase in non-controlling interests resulting from a third-party allotment at a subsidiary.

Liabilities totaled ¥164,441 million, an increase of ¥7,124 million from the end of the previous fiscal year.

Non-current liabilities were ¥34,604 million, an increase of ¥1,684 million from the end of the previous fiscal year. Current liabilities were ¥129,836 million, an increase of ¥5,440 million from the end of the previous fiscal year.

(3) Cash Flows for the First Quarter of the Fiscal Year Ending March 31, 2023

Net cash provided by operating activities during the first quarter of the fiscal year ending March 31, 2023 was ¥38,249 million, an increase of ¥17,982 million year on year. Factors included profit before tax and collection of trade receivables.

Net cash used in investing activities was ¥82,474 million, an increase of ¥9,061 million year on year. Factors included increases and decreases of time deposits and purchase of intangible assets.

Net cash used in financing activities was ¥14,221 million, a decrease of ¥3,236 million year on year, mainly because an increase in cash dividends paid was offset by a capital increase through third-party allotment at a subsidiary in the first quarter.

As a result, cash and cash equivalents at the end of the first quarter totaled ¥204,629 million, a decrease of ¥49,791 million from the end of the previous fiscal year.

(4) Outlook

There are no revisions to the consolidated financial forecast announced on May 11, 2022. Shionogi group will promptly announce any revision to the consolidated financial forecast resulting.

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

	Three months ended June 30, 2021	Three months ended June 30, 2022
Revenue	68,965	71,839
Cost of sales	(12,331)	(12,945)
Gross profit	56,634	58,893
Selling, general and administrative expenses	(21,750)	(22,447)
Research and development expenses	(14,729)	(22,530)
Amortization of intangible assets associated with products	(818)	(956)
Other income	1,282	165
Other expenses	(1,824)	(702)
Operating profit	18,794	12,421
Finance income	4,229	27,913
Finance costs	(82)	(24)
Profit before tax	22,941	40,310
Income tax expense	9,256	(5,884)
Profit	32,198	34,426
Profit attributable to		
Owners of parent	32,238	34,722
Non-controlling interests	(40)	(295)
Profit	32,198	34,426
Earnings per share		
Basic earnings per share	106.94	115.17
Diluted earnings per share	106.91	115.13

Consolidated statement of comprehensive income

Millions of yen

	Three months ended June 30, 2021	Three months ended June 30, 2022
Profit	32,198	34,426
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	(4,685)	1,125
Remeasurements of defined benefit plans	460	(365)
Total of items that will not be reclassified to profit or loss	(4,224)	760
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	5,448	22,580
Effective portion of cash flow hedges	513	(1,160)
Total of items that may be reclassified to profit or loss	5,962	21,420
Total other comprehensive income, net of tax	1,737	22,180
Comprehensive income	33,935	56,607
Comprehensive income attributable to		
Owners of parent	33,847	56,042
Non-controlling interests	88	564
Comprehensive income	33,935	56,607

(2) Consolidated statement of financial position

Millions of yen

	As of March 31, 2022	As of June 30, 2022
Assets		
Non-current assets		
Property, plant and equipment	108,893	111,243
Goodwill	9,638	9,864
Intangible assets	81,223	97,125
Right-of-use assets	3,524	3,529
Investment property	26,672	26,659
Other financial assets	242,479	250,470
Deferred tax assets	12,907	11,928
Other non-current assets	6,055	6,214
Total non-current assets	491,396	517,035
Current assets		
Inventories	45,892	52,061
Trade receivables	122,965	97,928
Other financial assets	210,757	298,175
Income taxes receivable	51	610
Other current assets	25,117	30,516
Cash and cash equivalents	254,420	204,629
Total current assets	659,205	683,921
Total assets	1,150,601	1,200,957

Millions of yen

	As of March 31, 2022	As of June 30, 2022
Equity and liabilities		
Equity		
Share capital	21,279	21,279
Capital surplus	14,455	15,204
Treasury shares	(57,857)	(57,858)
Retained earnings	832,958	849,226
Other components of equity	164,824	186,510
Equity attributable to owners of parent	975,661	1,014,361
Non-controlling interests	17,624	22,154
Total equity	993,285	1,036,516
Liabilities		
Non-current liabilities		
Lease liabilities	3,729	3,675
Other financial liabilities	5,616	5,027
Retirement benefit liability	15,412	16,092
Deferred tax liabilities	7,807	8,456
Other non-current liabilities	354	1,352
Total non-current liabilities	32,920	34,604
Current liabilities		
Lease liabilities	2,945	2,971
Trade payables	16,372	15,579
Other financial liabilities	22,027	22,947
Income taxes payable	17,973	12,255
Other current liabilities	65,078	76,083
Total current liabilities	124,396	129,836
Total liabilities	157,316	164,441
Total equity and liabilities	1,150,601	1,200,957

(3) Consolidated statement of changes in equity

Three months ended June 30, 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				32,238		32,238	(40)	32,198
Total other comprehensive income, net of tax					1,608	1,608	129	1,737
Comprehensive income	—	—	—	32,238	1,608	33,847	88	33,935
Purchase of treasury shares			(1)			(1)		(1)
Dividends				(16,580)		(16,580)		(16,580)
Transfer from other components of equity to retained earnings				460	(460)	—		—
Other		798		(8)		789	(798)	(8)
Balance as of June 30, 2021	21,279	14,531	(57,990)	768,358	117,984	864,163	17,732	881,896

Three months ended June 30, 2022

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, 2022	21,279	14,455	(57,857)	832,958	164,824	975,661	17,624	993,285
Profit				34,722		34,722	(295)	34,426
Total other comprehensive income, net of tax					21,320	21,320	860	22,180
Comprehensive income	—	—	—	34,722	21,320	56,042	564	56,607
Purchase of treasury shares			(1)			(1)		(1)
Dividends				(18,088)		(18,088)		(18,088)
Changes in ownership interest in subsidiaries		748				748	3,965	4,714
Transfer from other components of equity to retained earnings				(365)	365	—		—
Balance as of June 30, 2022	21,279	15,204	(57,858)	849,226	186,510	1,014,361	22,154	1,036,516

(4) Consolidated statement of cash flows

Millions of yen

	Three months ended June 30, 2021	Three months ended June 30, 2022
Cash flows from operating activities		
Profit before tax	22,941	40,310
Depreciation and amortization	3,746	4,300
Impairment Losses	125	—
Finance income and finance costs	(4,063)	(27,091)
Decrease (increase) in trade and other receivables	3,682	25,898
Decrease (increase) in inventories	(2,324)	(5,785)
Increase (decrease) in trade and other payables	(2,745)	2,937
Other	(1,960)	(2,879)
Subtotal	19,402	37,689
Interest and dividends received	10,755	12,718
Interest paid	(24)	(26)
Income taxes paid	(21,968)	(12,132)
Income taxes refund	12,102	—
Net cash provided by (used in) operating activities	20,266	38,249
Cash flows from investing activities		
Payments into time deposits	(78,021)	(181,608)
Proceeds from withdrawal of time deposits	24,557	118,742
Purchase of property, plant and equipment	(1,699)	(5,040)
Purchase of intangible assets	(300)	(13,290)
Purchase of investments	(39,976)	(51,716)
Proceeds from sale of investments	22,000	50,436
Other	26	1
Net cash provided by (used in) investing activities	(73,413)	(82,474)

Millions of yen

	Three months ended June 30, 2021	Three months ended June 30, 2022
Cash flows from financing activities		
Repayments of lease liabilities	(879)	(843)
Purchase of treasury shares	(1)	(1)
Dividends paid	(16,577)	(18,089)
Capital contribution from non-controlling interests	—	4,714
Net cash provided by (used in) financing activities	(17,457)	(14,221)
Effect of exchange rate changes on cash and cash equivalents	750	8,654
Net increase (decrease) in cash and cash equivalents	(69,853)	(49,791)
Cash and cash equivalents at beginning of period	276,173	254,420
Cash and cash equivalents at end of period	206,319	204,629

(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 1st quarter of fiscal year 2022

August 1, 2022
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2022 1H forecast	FY2022 forecast	FY2022 1Q actual	FY2021 1Q actual	Change	Progress% vs. FY2022 1H forecast
Prescription drugs	35.5	78.6	19.0	23.5	(4.5)	53.5
<i>change %</i>	<i>(24.6)</i>	<i>(11.8)</i>	<i>(19.0)</i>	<i>5.1</i>		
INTUNIV	9.0	19.5	4.7	3.6	1.1	51.6
VYVANSE	0.5	1.1	0.3	0.1	0.2	65.0
Infectious Disease Drugs	4.3	13.4	2.1	2.1	(0.0)	47.8
CYMBALTA	3.1	6.1	1.7	6.8	(5.2)	53.8
OXYCONTIN Franchise	2.3	4.5	1.2	1.3	(0.1)	52.0
SYMPROIC	1.5	3.3	0.8	0.6	0.2	51.9
ACTAIR	0.3	0.6	0.1	0.1	0.0	45.5
MULPLETA	0.1	0.1	0.0	0.0	(0.0)	46.5
PIRESPA	1.2	2.4	0.7	1.0	(0.3)	57.5
Others	13.3	27.6	7.5	7.9	(0.3)	56.4
CRESTOR	1.7	3.3	1.1	1.4	(0.4)	62.5
Overseas subsidiaries/Export	18.1	41.6	8.8	9.3	(0.5)	48.7
<i>change %</i>	<i>3.7</i>	<i>21.2</i>	<i>(5.3)</i>	<i>70.0</i>		
Shionogi Inc.	6.0	13.0	3.0	4.7	(1.7)	50.1
Ping An-Shionogi / C&O	6.3	14.8	2.5	2.4	0.2	40.1
Shionogi B.V.	3.4	8.4	1.9	0.9	1.0	55.0
Contract manufacturing	6.3	14.8	3.4	3.7	(0.4)	53.7
<i>change %</i>	<i>(25.0)</i>	<i>(15.3)</i>	<i>(10.2)</i>	<i>30.2</i>		
OTC and quasi-drugs	6.3	13.4	1.9	2.5	(0.5)	30.8
<i>change %</i>	<i>4.5</i>	<i>20.0</i>	<i>(21.2)</i>	<i>9.0</i>		
Royalty income	68.2	140.4	38.4	29.6	8.8	56.3
<i>change %</i>	<i>4.4</i>	<i>(22.5)</i>	<i>29.7</i>	<i>(22.1)</i>		
HIV Franchise	67.0	133.9	37.3	28.8	8.5	55.7
CRESTOR	-	-	-	-	-	-
Others	1.2	6.5	1.1	0.8	0.3	91.5
COVID-19 related products	45.0	110.0	-	-	-	-
<i>change %</i>	<i>-</i>	<i>-</i>	<i>-</i>	<i>-</i>		
Others	0.6	1.2	0.3	0.4	(0.1)	51.6
<i>change %</i>	<i>(21.0)</i>	<i>(32.7)</i>	<i>(13.8)</i>	<i>(17.3)</i>		
Total	180.0	400.0	71.8	69.0	2.9	39.9
<i>change %</i>	<i>24.1</i>	<i>19.4</i>	<i>4.2</i>	<i>(3.4)</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.

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

COVID-19 related products : Revenue from Ensitrelvir Fumaric Acid (S-217622) 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)
Total	69.0	(3.4)	76.1	(1.2)	74.5	(1.9)	115.5	58.8

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

Fiscal year ending March 31, 2023

FY2022	FY2022 1Q actual	Y on Y change %
Prescription drugs	19.0	(19.0)
INTUNIV	4.7	29.5
VYVANSE	0.3	105.8
Infectious Disease Drugs	2.1	(2.3)
CYMBALTA	1.7	(75.6)
OXYCONTIN Franchise	1.2	(4.4)
SYMPROIC	0.8	31.7
ACTAIR	0.1	18.0
MULPLETA	0.0	(12.4)
PIRESPA	0.7	(29.0)
Others	7.5	(4.4)
CRESTOR	1.1	(25.7)
Overseas subsidiaries/Export	8.8	(5.3)
Shionogi Inc.	3.0	(36.2)
Ping An-Shionogi / C&O	2.5	7.4
Shionogi B.V.	1.9	108.6
Contract manufacturing	3.4	(10.2)
OTC and quasi-drugs	1.9	(21.2)
Royalty income	38.4	29.7
HIV Franchise	37.3	29.3
CRESTOR	-	-
Others	1.1	42.6
Covid-19 related products	-	-
Others	0.3	(13.8)
Total	71.8	4.2

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

2 - 2. Quarterly trend for FY2021 and FY2022 (Consolidated statements 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)	(0.7)	(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 %
Revenue	71.8	4.2
Cost of sales	18.0 (12.9)	5.0
Gross profit	58.9	4.0
SG & A expenses	31.2 (22.4)	3.2
R & D expenses	31.4 (22.5)	53.0
Amortization of intangible assets associated with products	1.3 (1.0)	16.9
Other income & expenses	(0.5)	
Operating profit	17.3 12.4	(33.9)
Finance income & costs	27.9	572.5
Profit before tax	56.1 40.3	75.7
Income tax expense etc.	(5.6)	-
Profit attributable to owners of parent	48.3 34.7	7.7

3. Pipeline (as of August 1, 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 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	Global: Phase III (pediatric) Japan: NDA submission (Mar. 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: 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)	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: NDA submission (Feb. 2022), Phase II/III Global: Phase III	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-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-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	
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-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: 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 (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	Acetyl-CoA carboxylase 2 inhibitor (oral)	NASH	Japan: Phase I	In-house	The Liver Company Inc. (USA)

*1 Long acting parenteral formulation, *2 Cabotegravir

Since May 11, 2022

Phase added to the list	S-268019(Children, 5 to 11 years): Japan: Phase I/II/III
	F901318: Global: Phase III
Change of phase	S-723595: Pipeline → Out-Licensing