



Consolidated Financial Results for the First Quarter of Fiscal Year 2023 (IFRS)

July 31, 2023

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

Listed Exchanges: Tokyo

Code: 4507

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

Representative: Isao Teshirogi, Representative Director, President and CEO

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Scheduled date of quarterly securities report submission: August 9, 2023

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, 2023 to June 30, 2023

(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, 2023	109,312	52.2	46,585	275.0	55,704	38.2	42,214	22.6	42,562	22.6	92,600	63.6
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

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Three months ended June 30, 2023	144.62	144.57
Three months ended June 30, 2022	115.17	115.13

Note: Revenue includes Lump-sum income for transfer of ADHD drug

(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, 2023	1,363,776	1,192,178	1,170,421	85.8
As of March 31, 2023	1,311,800	1,121,878	1,100,046	83.9

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, 2023	—	60.00	—	75.00	135.00
Year ending March 31, 2024	—	—	—	—	—
Year ending March 31, 2024 (forecast)	—	75.00	—	75.00	150.00

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2024

(% 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, 2023	217,000	43.9	80,500	185.2	98,000	44.2	78,000	36.2	265.03
Year ending March 31, 2023	450,000	5.5	150,000	0.7	192,500	(12.6)	155,000	(16.2)	526.66

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 : Yes
 - 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, 2023: 307,386,165 shares
 - As of March 31, 2023: 307,386,165 shares
 - b) Number of treasury stock
 - As of June 30, 2023: 13,080,742 shares
 - As of March 31, 2023: 13,080,279 shares
 - c) Average number of shares issued during the period
 - Three months ended June 30, 2023: 294,305,575 shares
 - Three months ended June 30, 2022: 301,482,644 shares

Note: The average number of treasury shares during the period include the Company's shares held by the trust account of Sumitomo Mitsui Trust Bank, Limited. (Second-tier trustee: the trust account of Custody Bank of Japan, Ltd.) related to Shionogi Infectious Disease Research Promotion Foundation. (Q1 ended June 30, 2023 and Year ended March 31, 2023: 3,000,000 shares) The number of treasury shares deducted for calculation of the average number of shares during the period include these treasury shares. (Q1 ended June 30, 2023: 3,000,000 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, July 31, 2023. Plans are also in place to post explanatory details (Transcript) together with financial results explanatory materials distributed to analysts on July 31, 2023 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, 2024

For the Three months ended June 30, 2023 (April 1, 2023 to June 30, 2023), operating results were as follows.

Millions of yen

	Three months ended June 30, 2023	Three months ended June 30, 2022	Change	Percentage change (%)
Revenue*1	109,312	71,839	37,472	52.2
Operating profit	46,585	12,421	34,163	275.0
Core operating profit*2	46,914	12,662	34,251	270.5
Profit before tax	55,704	40,310	15,393	38.2
Profit attributable to owners of parent	42,562	34,722	7,839	22.6
EBITDA*3	51,300	16,963	34,336	202.4

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

*2 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.

*3 Earnings Before Interest, Taxes, Depreciation, and Amortization: Core operating profit added depreciation.

Revenue increased 52.2 percent year on year. Domestic sales of prescription drugs increased by 141.6 percent, reflecting a one-time payment received for the transfer of the license for co-development and co-commercialization of Intuniv and Vyvanse to Takeda Pharmaceutical Company Limited, as well as increased revenue from the market penetration of COVID-19 treatment Xocova.

Overseas subsidiary sales and exports increased 36.2 percent year on year, as 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. Royalty income increased 16.7 percent as a result of growth in sales of the HIV franchise licensed to ViiV (primarily Dovato, the long-acting treatment Cabenuva, and the prophylactic drug Apretude), as well as the impact of exchange rates.

Regarding profit, research and development expenses increased because of investment in projects related to COVID-19 and other key projects, but operating profit increased 275.0 percent year on year, reflecting the increase in revenue. Dividends were impacted by dividend payments the SHIONOGI Group received from ViiV in the first quarter of fiscal 2022 that were originally scheduled to be received in the fourth quarter of fiscal 2021, and by the non-recurrence of the one-time payment the SHIONOGI Group received in connection with the settlement of litigation with Gilead Sciences, Inc. However, profit before tax increased 38.2 percent due to the increase in revenue. Profit attributable to owners of parent increased 22.6 percent.

(2) Financial Position for the First Quarter of the Fiscal Year Ending March 31, 2024

As of June 30, 2023, total assets were ¥1,363,776 million, an increase of ¥51,976 million from the end of the previous fiscal year.

Non-current assets were ¥580,498 million, an increase of ¥52,890 million from the end of the previous fiscal year, as other financial assets increased due to the impact of exchange rates and other non-current assets increased. Current assets were ¥783,278 million, a decrease of ¥914 million, mainly as a result of a decrease in cash and cash equivalents, changes in fixed-term deposits of more than three months and bonds (included in “Other financial assets” in current assets), and a decrease in other current assets.

Equity was ¥1,192,178 million, an increase of ¥70,300 million from the end of the previous fiscal year. This was due to recording of profit, payment of cash dividends, and an increase in exchange differences on translation of foreign operations (included in “Other components of equity”).

Liabilities totaled ¥171,598 million, a decrease of ¥18,323 million from the end of the previous fiscal year.

Non-current liabilities were ¥31,477 million, an increase of ¥108 million from the end of the previous fiscal year. Current liabilities were ¥140,120 million, a decrease of ¥18,431 million from the end of the previous fiscal year, mainly because of a decrease in income taxes payable.

(3) Cash Flows for the First Quarter of the Fiscal Year Ending March 31, 2024

Net cash provided by operating activities during the first quarter of the fiscal year ending March 31, 2024 was ¥31,384 million, a decrease of ¥6,865 million year on year. Factors included recording of profit before tax, an increase in dividends received from ViiV, an increase in trade receivables, and an increase in income taxes paid.

Net cash used in investing activities was ¥34,755 million, a decrease in cash used of ¥47,718 million year on year. Factors included a decrease in purchase of intangible assets and changes in time deposits.

Net cash used in financing activities was ¥23,073 million, an increase in cash used of ¥8,852 million year on year, mainly due to an increase in dividends paid and because there was a capital increase through third-party allotment at a subsidiary in the previous fiscal year.

As a result, cash and cash equivalents at June 30, 2023 totaled ¥289,076 million, a decrease of ¥20,147 million from the end of the previous fiscal year.

(4) Outlook

There are no revisions to the consolidated financial forecast for the year ending March 31, 2024 announced on May 10, 2023.

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, 2022	Three months ended June 30, 2023
Revenue	71,839	84,303
Profit from license transfer	—	25,008
Cost of sales	(12,945)	(13,119)
Gross profit	58,893	96,192
Selling, general and administrative expenses	(22,447)	(23,191)
Research and development expenses	(22,530)	(24,997)
Amortization of intangible assets associated with products	(956)	(849)
Other income	165	92
Other expenses	(702)	(660)
Operating profit	12,421	46,585
Finance income	27,913	10,073
Finance costs	(24)	(954)
Profit before tax	40,310	55,704
Income tax expense	(5,884)	(13,490)
Profit	34,426	42,214
Profit attributable to		
Owners of parent	34,722	42,562
Non-controlling interests	(295)	(347)
Profit	34,426	42,214
Earnings per share		
Basic earnings per share	115.17	144.62
Diluted earnings per share	115.13	144.57

Consolidated statement of comprehensive income

Millions of yen

	Three months ended June 30, 2022	Three months ended June, 2023
Profit	34,426	42,214
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	1,125	2,989
Remeasurements of defined benefit plans	(365)	418
Total of items that will not be reclassified to profit or loss	760	3,408
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	22,580	52,313
Effective portion of cash flow hedges	(1,160)	(5,335)
Total of items that may be reclassified to profit or loss	21,420	46,978
Total other comprehensive income, net of tax	22,180	50,386
Comprehensive income	56,607	92,600
Comprehensive income attributable to		
Owners of parent	56,042	92,675
Non-controlling interests	564	(74)
Comprehensive income	56,607	92,600

(2) Consolidated statement of financial position

Millions of yen

	As of March 31, 2023	As of June 30, 2023
Assets		
Non-current assets		
Property, plant and equipment	112,085	111,005
Goodwill	9,819	9,894
Intangible assets	96,309	99,902
Right-of-use assets	6,482	6,540
Investment property	26,382	26,380
Other financial assets	247,711	276,777
Deferred tax assets	22,100	21,178
Other non-current assets	6,716	28,819
Total non-current assets	527,607	580,498
Current assets		
Inventories	57,919	62,600
Trade receivables	109,774	115,359
Other financial assets	254,131	287,309
Income taxes receivable	68	151
Other current assets	53,074	28,779
Cash and cash equivalents	309,224	289,076
Total current assets	784,192	783,278
Total assets	1,311,800	1,363,776

Millions of yen

	As of March 31, 2023	As of June 30, 2023
Equity and liabilities		
Equity		
Share capital	21,279	21,279
Capital surplus	15,204	15,204
Treasury shares	(63,074)	(63,076)
Retained earnings	940,606	961,288
Other components of equity	186,030	235,725
Equity attributable to owners of parent	1,100,046	1,170,421
Non-controlling interests	21,832	21,757
Total equity	1,121,878	1,192,178
Liabilities		
Non-current liabilities		
Lease liabilities	6,397	6,472
Other financial liabilities	4,844	4,834
Retirement benefit liability	12,867	12,042
Deferred tax liabilities	5,916	6,287
Other non-current liabilities	1,343	1,841
Total non-current liabilities	31,369	31,477
Current liabilities		
Lease liabilities	3,014	3,079
Trade payables	14,005	15,300
Other financial liabilities	29,720	34,511
Income taxes payable	42,217	17,512
Other current liabilities	69,595	69,717
Total current liabilities	158,552	140,120
Total liabilities	189,921	171,598
Total equity and liabilities	1,311,800	1,363,776

(3) Consolidated statement of changes in equity
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

Three months ended June 30, 2023

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, 2023	21,279	15,204	(63,074)	940,606	186,030	1,100,046	21,832	1,121,878
Profit				42,562		42,562	(347)	42,214
Total other comprehensive income, net of tax					50,113	50,113	272	50,386
Comprehensive income	—	—	—	42,562	50,113	92,675	(74)	92,600
Purchase of treasury shares			(2)			(2)		(2)
Dividends				(22,297)		(22,297)		(22,297)
Transfer from other components of equity to retained earnings				418	(418)	—		—
Balance as of June 30, 2023	21,279	15,204	(63,076)	961,288	235,725	1,170,421	21,757	1,192,178

(4) Consolidated statement of cash flows

Millions of yen

	Three months ended June 30, 2022	Three months ended June 30, 2023
Cash flows from operating activities		
Profit before tax	40,310	55,704
Depreciation and amortization	4,300	4,385
Impairment Losses	—	100
Finance income and finance costs	(27,091)	(4,519)
Decrease (increase) in trade and other receivables	25,898	(4,988)
Decrease (increase) in inventories	(5,785)	(4,263)
Increase (decrease) in trade and other payables	2,937	(2,312)
Other	(2,879)	4,927
Subtotal	37,689	49,033
Interest and dividends received	12,718	19,621
Interest paid	(26)	(14)
Income taxes paid	(12,132)	(37,255)
Net cash provided by (used in) operating activities	38,249	31,384
Cash flows from investing activities		
Payments into time deposits	(181,608)	(105,291)
Proceeds from withdrawal of time deposits	118,742	68,502
Purchase of property, plant and equipment	(5,040)	(2,895)
Purchase of intangible assets	(13,290)	(3,425)
Purchase of investments	(51,716)	(28,477)
Proceeds from sale and redemption of investments	50,436	36,549
Other	1	281
Net cash provided by (used in) investing activities	(82,474)	(34,755)

Millions of yen

	Three months ended June 30, 2022	Three months ended June 30, 2023
Cash flows from financing activities		
Repayments of lease liabilities	(843)	(779)
Purchase of treasury shares	(1)	(2)
Dividends paid	(18,089)	(22,292)
Capital contribution from non-controlling interests	4,714	—
Net cash provided by (used in) financing activities	(14,221)	(23,073)
Effect of exchange rate changes on cash and cash equivalents	8,654	6,297
Net increase (decrease) in cash and cash equivalents	(49,791)	(20,147)
Cash and cash equivalents at beginning of period	254,420	309,224
Cash and cash equivalents at end of period	204,629	289,076

(5) Notes

Going concern assumption

None

Change in accounting policies

The SHIONOGI Group has applied the following standard from the first quarter of the fiscal year ending March 31, 2024. The adoption does not have a significant impact on the consolidated financial statements.

Standards	Name	Overview of new standards and revisions
IAS 12	Income Taxes	Clarification of deferred tax related to assets and liabilities arising from a single transaction

Segment information

The SHIONOGI Group has a single business segment related to prescription drugs. We operate 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.

Additional information

(Profit from License Transfer)

With the transfer of the licenses for Intuniv and Vyvanse to Takeda Pharmaceutical Company Limited, the difference of ¥25,008 million between the compensation received and the derecognized intangible assets was stated in "Profit from License Transfer" in the consolidated statement of profit or loss, and included in gross profit. This profit is not revenue based on IFRS 15 Revenue from Contracts with Customers. Regarding the method of recovering investments in intangible assets such as in-process research and development assets and marketing rights, the SHIONOGI Group uses the procedure that is optimal at the time of the transaction, such as obtaining revenue from manufacture or sale by the SHIONOGI Group, or receiving one-time payments and royalty income from out-licensing to other companies. This transaction was one of those investment recovery methods. Therefore, the SHIONOGI Group judged that including it in gross profit will aid in providing useful information to readers of the financial statements.

Subsequent events

(Business Combinations)

The SHIONOGI Group signed an agreement on June 25, 2023 to acquire Qpex Biopharma, Inc. ("Qpex") and make it a wholly owned subsidiary. Qpex became a subsidiary on July 5, 2023.

1. Purpose of the Business Combinations

Qpex, which the SHIONOGI Group signed an agreement to acquire, is a pharmaceutical company that focuses on discovery and development of novel antimicrobial drugs targeting antimicrobial-resistant bacteria. Qpex has discovered xeruborbactam, a novel boronic acid β -lactamase inhibitor with a broad inhibitory spectrum against β -lactamases. Xeruborbactam is being clinically developed as the IV OMNIvance in combination with meropenem, a carbapenem antibiotic, and as the oral agent ORAvance in combination with ceftibuten, a cephem antibiotic, for infections caused by drug-resistant Gram-negative bacteria. In addition to its proven track record in the discovery and clinical development of novel antimicrobial agents, Qpex has also built an extensive external network with regulatory agencies in the United States, including the Biomedical Advanced Research and Development Authority (BARDA).

Development projects for compounds with very high efficacy against antimicrobial resistance (AMR), antimicrobial research and development capabilities, and external network in the United States are in alignment with the SHIONOGI Group's business direction, and the expected synergy led to the Group's decision to acquire Qpex.

2. Outline of the Business Combinations

Name of acquired company: Qpex Biopharma, Inc.

Business of acquired company: Research and development of pharmaceuticals in the area of infectious diseases

Acquisition date: July 5, 2023

3. Voting Equity Interest Acquired

Percentage of voting rights immediately before the acquisition:	0%
Percentage of voting rights acquired on the acquisition date:	100.00%
Percentage of voting rights after the acquisition:	100.00%

4. Cost of Acquisition of Acquired Company and Cost Breakdown

A one-time payment of \$113 million was made for the acquired company.

In addition, further payments up to a maximum of \$40 million may be due depending on future research and development achievements.

The acquired assets, assumed liabilities, goodwill and other details are not presented as the initial accounting procedures of this business combination were not yet completed by the date of the release of the consolidated financial statements.

(Transfer of Shares of Subsidiary)

The Shionogi Group sold a portion of the shares of Shionogi Business Partner Co., Ltd. ("Shionogi Business Partner") to Accenture Co., Ltd. ("Accenture") and formed a joint venture on July 3, 2023.

1. Purpose of the Share Transfer

In the corporate reorganization of July 2022, the SHIONOGI Group merged four companies, with Shionogi Business Partner as the surviving company, in order to boost the efficiency of indirect functions, and has since improved the efficiency of operations including human resources, administration and accounting and finance. Subsequently, the SHIONOGI Group has considered measures to enhance the expertise of employees while further accelerating business reforms. As a result, Shionogi sold 80 percent of the shares of Shionogi Business Partner to Accenture and formed a joint venture on July 3, 2023. In addition, prior to the formation of this joint venture, Shionogi Pharmacovigilance Center Co., Ltd., which handles some of the SHIONOGI Group's safety management and post-marketing operations as required by the Pharmaceuticals and Medical Devices Act, was absorbed into Shionogi Business Partner on July 1, 2023, and became part of the joint venture for the purpose of synergy with Accenture's business process managed services related to safety management operations.

By forming these joint ventures, the SHIONOGI Group will utilize Accenture's strength in indirect business standardization and IT investment to thoroughly improve efficiency. Furthermore, by utilizing Accenture's know-how, the SHIONOGI Group will create opportunities for the professional growth of the employees of Shionogi Business Partner and Shionogi Pharmacovigilance Center to support the joint ventures in providing services in a competitive market, thereby contributing to the SHIONOGI Group's further business development.

2. Outline of the Share Transfer

Name:	Shionogi Business Partner Company Limited
Business:	Shared services (Contracted services related to the SHIONOGI Group's following operations: personnel, administration, public relations, facility management, database management, accounting, finance, procurement, sales support, marketing support, education and training, career development support) Safety management and post-marketing operations of the SHIONOGI Group as required by the Pharmaceuticals and Medical Devices Act and other regulations
Date of share transfer:	July 3, 2023

3. Name of Recipient of Share Transfer: Accenture Co., Ltd.

4. Voting Equity Interest

Percentage of voting rights immediately before the share transfer:	100.00%
Percentage of voting rights transferred on the transfer date:	80.00%
Percentage of voting rights after the share transfer:	20.00%

5. Impact on Financial Results

The impact of the share transfer on the SHIONOGI Group's financial results is currently being evaluated.

Supplemental material for financial results for the 1st quarter of fiscal year 2023

July 31, 2023
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2023 1H forecast	FY2023 forecast	FY2023 1Q actual	FY2022 1Q actual	Change	Progress% vs.FY2023 1H forecast
Prescription drugs	87.4	134.1	45.9	19.0	26.9	52.5
<i>change %</i>	<i>162.1</i>	<i>78.7</i>	<i>141.6</i>	<i>(19.0)</i>		
Infectious Disease Drugs	40.0	65.7	9.3	2.1	7.2	23.1
CYMBALTA	2.1	4.2	1.1	1.7	(0.5)	52.6
OXYCONTIN Franchise	2.1	4.1	1.1	1.2	(0.1)	52.7
SYMPROIC	2.3	4.9	1.0	0.8	0.2	45.2
ACTAIR	0.4	1.0	0.1	0.1	0.0	35.0
MULPLETA	0.1	0.1	0.0	0.0	0.0	44.2
PIRESPA	1.1	1.9	0.5	0.7	(0.2)	47.9
Others	39.3	52.1	32.7	12.5	20.3	83.2
Overseas subsidiaries/Export	28.0	96.6	12.0	8.8	3.2	42.8
<i>change %</i>	<i>40.5</i>	<i>127.3</i>	<i>36.2</i>	<i>(5.3)</i>		
Shionogi Inc.	6.7	13.6	4.0	3.0	1.0	60.3
Shionogi B.V.	5.4	11.5	3.0	1.9	1.1	54.9
Ping An-Shionogi / C&O	13.2	58.0	3.1	2.5	0.6	23.4
Others	2.7	13.4	1.9	1.4	0.5	69.9
Contract manufacturing	7.3	13.8	4.0	3.4	0.6	54.7
<i>change %</i>	<i>(0.4)</i>	<i>(10.1)</i>	<i>19.1</i>	<i>(10.2)</i>		
OTC and quasi-drugs	6.8	15.0	2.3	1.9	0.3	33.3
<i>change %</i>	<i>8.6</i>	<i>14.2</i>	<i>16.6</i>	<i>(21.2)</i>		
Royalty income	86.9	189.5	44.8	38.4	6.4	51.6
<i>change %</i>	<i>4.4</i>	<i>8.5</i>	<i>16.7</i>	<i>29.7</i>		
HIV Franchise	86.0	185.0	44.3	37.3	7.0	51.4
Others	0.9	4.5	0.6	1.1	(0.5)	65.5
Others	0.5	1.0	0.3	0.3	(0.0)	58.6
<i>change %</i>	<i>(17.4)</i>	<i>(21.6)</i>	<i>(7.3)</i>	<i>(13.8)</i>		
Total	217.0	450.0	109.3	71.8	37.5	50.4
<i>change %</i>	<i>43.9</i>	<i>5.5</i>	<i>52.2</i>	<i>4.2</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.

• Xocova • COVID-19 vaccines • Xofluza • Rapiacta • Brightpoc Flu Neo • Finibax • Flumarin • Flomox
• Shiomarin • Baktar • Flagyl • Isodine

Others in prescription drugs include Lump-sum income for transfer of ADHD drug.

2-1. Quarterly trend for FY2022 and FY2023 (Revenue by segment)

Fiscal year ended March 31, 2023

(Billions of yen)

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %	FY2022 3Q actual	Y on Y change %	FY2022 4Q actual	Y on Y change %
Prescription drugs	19.0	(19.0)	14.4	(39.3)	21.3	(4.9)	20.4	4.0
INTUNIV	4.7	29.5	4.8	19.7	5.3	17.2	4.4	3.6
VYVANSE	0.3	105.8	0.3	91.0	0.4	80.1	0.4	58.6
Infectious Disease Drugs	2.1	(2.3)	(2.6)	—	3.5	15.9	4.5	49.6
CYMBALTA	1.7	(75.6)	1.4	(70.3)	1.4	(47.5)	1.0	(43.5)
OXYCONTIN Franchise	1.2	(4.4)	1.1	(10.0)	1.2	(6.9)	0.9	(9.5)
SYMPROIC	0.8	31.7	0.8	27.2	1.0	31.0	0.8	22.6
ACTAIR	0.1	18.0	0.1	3.4	0.1	11.5	0.1	4.2
MULPLETA	0.0	(12.4)	0.0	(3.0)	0.0	(23.2)	0.0	(29.1)
PIRESPA	0.7	(29.0)	0.7	(33.2)	0.7	(38.3)	0.5	(33.4)
Others	7.5	(4.4)	7.7	(4.8)	7.7	(11.7)	7.7	(0.4)
CRESTOR	1.1	(25.7)	1.1	(34.3)	1.1	(31.5)	0.9	(30.6)
Overseas subsidiaries/Export	8.8	(5.3)	11.1	37.2	10.6	21.7	11.9	45.1
Shionogi Inc.	3.0	(36.2)	4.4	38.2	4.1	25.2	4.0	50.4
Ping An-Shionogi / C&O	2.5	7.4	3.1	30.7	2.7	10.6	3.6	21.5
Shionogi B.V.	1.9	108.6	2.4	75.3	2.3	50.4	2.4	109.9
Contract manufacturing	3.4	(10.2)	4.0	(13.4)	2.9	(15.5)	5.1	(10.0)
OTC and quasi-drugs	1.9	(21.2)	4.3	20.9	3.8	60.8	3.1	11.3
Royalty income	38.4	29.7	44.9	25.4	48.5	31.0	43.0	(45.5)
HIV Franchise	37.3	29.3	43.1	32.9	46.6	33.2	41.5	(46.6)
CRESTOR	—	—	—	—	1.3	15.4	—	—
Others	1.1	42.6	1.8	(46.4)	0.6	(35.7)	1.4	28.4
COVID-19 related products	—	—	—	—	100.0	—	4.7	—
Others	0.3	(13.8)	0.3	(29.1)	0.4	(26.1)	0.2	(44.3)
Total	71.8	4.2	78.9	3.7	187.6	151.6	88.3	(23.5)

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

Fiscal year ending March 31, 2024

FY2023	FY2023 1Q actual	Y on Y change %
Prescription drugs	45.9	141.6
Infectious Disease Drugs	9.3	348.9
CYMBALTA	1.1	(32.4)
OXYCONTIN Franchise	1.1	(6.8)
SYMPROIC	1.0	29.7
ACTAIR	0.1	13.9
MULPLETA	0.0	5.8
PIRESPA	0.5	(25.7)
Others	32.7	162.5
Overseas subsidiaries/Export	12.0	36.2
Shionogi Inc.	4.0	34.5
Shionogi B.V.	3.0	61.3
Ping An-Shionogi / C&O	3.1	22.2
Others	1.9	31.7
Contract manufacturing	4.0	19.1
OTC and quasi-drugs	2.3	16.6
Royalty income	44.8	16.7
HIV Franchise	44.3	18.7
Others	0.6	(47.6)
Others	0.3	(7.3)
Total	109.3	52.2

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

Others in prescription drugs include Intuniv, Vyvanse and Lump-sum income for transfer of ADHD drug.

2-2. Quarterly trend for FY2022 and FY2023 (Consolidated statement of profit or loss)

Fiscal year ended March 31, 2023

(Billions of yen)

FY2022	FY2022 1Q actual	Y on Y change %	FY2022 2Q actual	Y on Y change %	FY2022 3Q actual	Y on Y change %	FY2022 4Q actual	Y on Y change %
Revenue	71.8	4.2	78.9	3.7	187.6	151.6	88.3	(23.5)
Cost of sales	18.0 (12.9)	5.0	18.3 (14.4)	(1.6)	9.2 (17.2)	33.6	20.0 (17.7)	13.6
Gross profit	58.9	4.0	64.5	5.0	170.4	176.3	70.7	(29.3)
SG & A expenses	31.2 (22.4)	3.2	30.5 (24.1)	7.0	12.9 (24.2)	8.4	30.7 (27.1)	7.4
R & D expenses	31.4 (22.5)	53.0	33.2 (26.2)	94.8	13.9 (26.1)	30.1	31.2 (27.6)	11.3
Amortization of intangible assets associated with products	1.3 (1.0)	16.9	1.3 (1.0)	20.9	0.5 (0.9)	10.2	1.0 (0.8)	(15.2)
Other income & expenses	(0.5)		2.5		(0.9)		(12.6)	
Operating profit	17.3 12.4	(33.9)	20.0 15.8	(33.8)	63.0 118.2	565.9	2.9 2.5	(94.9)
Finance income & costs	27.9	572.5	11.9	195.1	12.6	102.7	19.0	—
Profit before tax	56.1 40.3	75.7	35.0 27.7	(0.8)	69.7 130.8	446.1	24.4 21.5	(58.2)
Income tax expense etc.	(5.6)	—	(5.1)	(26.8)	(30.3)	398.8	5.7	—
Profit attributable to owners of parent	48.3 34.7	7.7	28.6 22.5	7.9	53.6 100.5	462.2	30.8 27.2	(36.9)

Fiscal year ending March 31, 2024

FY2023	FY2023 1Q actual	Y on Y change %
Revenue	109.3	52.2
Cost of sales	12.0 (13.1)	1.3
Gross profit	96.2	63.3
SG & A expenses	21.2 (23.2)	3.3
R & D expenses	22.9 (25.0)	10.9
Amortization of intangible assets associated with products	0.8 (0.8)	(11.1)
Other income & expenses	(0.6)	
Operating profit	42.6 46.6	275.0
Finance income & costs	9.1	(67.3)
Profit before tax	51.0 55.7	38.2
Income tax expense etc.	(13.1)	135.2
Profit attributable to owners of parent	38.9 42.6	22.6

Note: Revenue includes Lump-sum income for transfer of ADHD drug.

3. Pipeline (as of July 31, 2023)

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Infectious disease	S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja®] [EU:Fetroja®]	Cell-wall synthesis inhibition (injection)	USA:Complicated urinary tract infections, including pyelonephritis and nosocomial pneumonia Europe:Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options Japan:Various infectious diseases caused by Gram-negative bacteria that are resistant to carbapenem antibiotics Taiwan: Infections due to aerobic Gram-negative bacteria in adult patients with limited treatment options	Global: Phase III (pediatric) Japan: NDA submission (Mar. 2022) Taiwan: NDA submission (Dec. 2022)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral, granule)	Influenza virus infection	Japan: NDA submission (body weight <20kg) (Aug. 2018) Taiwan: sNDA submission (5 to 11 years old) (Jul. 2023)	In-house	SHIONOGI/Roche (Switzerland)
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19	Japan: NDA submission (Nov. 2022) Japan: Phase III Global: Phase III	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Adolescent)	Japan: Phase II/III	In-house	In-house
	S-268019	Vaccine (muscular injection)	Prevention of COVID-19 (Children, 5 to 11 years)	Japan: Phase I/II/III	In-house	In-house
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Treatment of COVID-19	Japan: Approval under the Emergency Regulatory Approval System (Nov. 2022) Normal NDA submission (June 2023) Japan:Phase II/III Global: Phase III South Korea: NDA submission (Jan. 2023)	In-house	In-house
	S-217622 (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
	S-217622 (Ensitrelvir Fumaric Acid) [Japan:Xocova®]	3CL protease inhibitor (oral)	Prevention of COVID-19	Global: Phase III	In-house	In-house
	F901318 (Olorofim)	Dihydroorotate dehydrogenase (DHODH) inhibition (oral)	Invasive aspergillosis	Global: Phase III	F2G (UK)	SHIONOGI/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	In-house/UBE	SHIONOGI/UBE
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-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
	GRT7039 (Resiniferatoxin)	TRPV1 agonist (Intra-articular injection)	Pain associated with osteoarthritis of knee	Global: Phase III	Grünenthal (Germany)	Grünenthal
S-151128	New mechanism of action	Chronic pain	Japan: Phase I	In-house	In-house	

	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Frontier	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto(Japan)	SHIONOGL/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
	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)	SHIONOGL/FunPep
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Global: Phase IIb	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-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	SHIONOGL/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 (TLC-3595)	Acetyl-CoA carboxylase 2 inhibitor (oral)	Type 2 diabetes	New Zealand: PhaseIIa	In-house	OrsoBio, Inc.(USA)
S-365598	Integrase inhibitor (ultra long-acting injection)	HIV infection	USA: Phase I	In-house	SHIONOGL-ViiV Healthcare LLC

Note: S-0373: Withdrawal of NDA submission, feasibility of additional clinical trials under consideration.

Since May10, 2023

Change	S-033188 : Taiwan: sNDA submission (5 to 11 years old) (Jul. 2023)
	S-217622: Taiwan: Plan to switch to normal NDA submission
	S-0373 : Japan: withdraw NDA submission
	S-723595: New Zealand: PhaseIIa started and indication changed (NASH⇒Type 2 diabetes)