



Consolidated Financial Results for the First Quarter of Fiscal Year 2020 (IFRS)

July 31, 2020

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: August 13, 2020

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, 2020 to June 30, 2020

(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, 2020	71,402	(11.6)	25,617	(19.1)	30,063	(14.9)	21,539	(20.7)	21,536	(20.6)	19,981	165.2
Three months ended June 30, 2019	80,778	—	31,671	—	35,343	—	27,157	—	27,128	—	7,533	—

	Basic earnings per share	Diluted earnings per share
	Yen	Yen
Three months ended June 30, 2020	70.88	70.85
Three months ended June 30, 2019	87.14	87.02

(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, 2020	864,573	768,490	768,436	88.9
As of March 31, 2020	871,526	764,611	764,560	87.7

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, 2020	—	50.00	—	53.00	103.00
Year ending March 31, 2021	—	—	—	—	—
Year ending March 31, 2021 (forecast)	—	53.00	—	53.00	106.00

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2021

(% 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, 2020	155,600	—	53,800	—	61,600	—	44,900	—	147.80
Year ending March 31, 2021	323,500	(3.0)	110,300	(15.6)	136,300	(14.0)	103,600	(15.2)	341.03

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, 2020:	311,586,165 shares
As of March 31, 2020:	316,786,165 shares
 - b) Number of treasury stock

As of June 30, 2020:	7,722,192 shares
As of March 31, 2020:	13,002,082 shares
 - c) Average number of shares issued during the period

Three months ended June 30, 2020:	303,833,023 shares
Three months ended June 30, 2019:	311,329,640 shares

※ This report of financial results is unaudited.

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

(Adoption of International Financial Reporting Standards (IFRS))

The Shionogi Group has voluntarily applied International Financial Reporting Standards (IFRS) starting from the consolidated financial statements for the previous fiscal year (fiscal year ended March 31, 2020). The consolidated financial statements for the first quarter of the previous fiscal year are also restated in accordance with IFRS.

(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 Friday, July 31, 2020. Plans are also in place to post explanatory details (Transcript) together with financial results explanatory materials distributed to analysts on July 31, 2020 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

The Shionogi Group has voluntarily applied International Financial Reporting Standards (IFRS) starting from the consolidated financial statements for the previous fiscal year (fiscal year ended March 31, 2020). The consolidated financial statements for the first quarter of the previous fiscal year are also restated in accordance with IFRS.

(1) Operating Results for the First Quarter of the Fiscal Year Ending March 31, 2021

For the three months ended June 30, 2020 (April 1, 2020 to June 30, 2020), operating results were as follows.

	<i>Millions of yen</i>			
	Three months ended June 30, 2020	Three months ended June 30, 2019	Change	Percentage change (%)
Revenue	71,402	80,778	(9,376)	(11.6)
Operating profit	25,617	31,671	(6,054)	(19.1)
Core operating profit *	25,854	31,858	(6,003)	(18.8)
Profit before tax	30,063	35,343	(5,279)	(14.9)
Profit attributable to owners of parent	21,536	27,128	(5,591)	(20.6)

* In conjunction with the change in accounting standard, 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 decreased 11.6 percent year on year. In domestic sales of prescription drugs, revenue for Cymbalta and Intuniv expanded steadily, but the contraction of the pharmaceutical market due to the COVID-19 pandemic and the impact of drug price revisions, mainly for long-term listed items, resulted in a 15.1 percent decrease in revenue. Overseas subsidiary sales and exports were also impacted by the COVID-19 pandemic, resulting in a decrease in revenue from Rabeprazole and other products sold in China. In addition, in the United States, revenue declined significantly mainly due to the absence of a one-time payment that was received in the first quarter of the previous fiscal year in connection with a co-commercialization agreement for Symproic with BioDelivery Sciences International. As a result, revenue from overseas subsidiary sales and exports decreased 49.1 percent. In contract manufacturing, orders for Dolutegravir active pharmaceutical ingredient increased, mainly from ViiV, resulting in a 17.6 percent increase in revenue. With regard to royalty income, despite ViiV’s continued strong global sales of anti-HIV drugs Tivicay, Triumeq, Juluca and Dovato, the company was forced to make shipment adjustments in response to the COVID-19 pandemic, resulting in a 2.4 percent decrease in royalty income from ViiV. Total royalty income decreased 2.4 percent.

Although selling, general and administrative expenses decreased as we refrained from visiting medical institutions in order to prevent the spread of COVID-19, an increase in research and development investments for priority issues such as potential treatments and vaccines for COVID-19 and key projects, combined with the decrease in revenue, resulted in a decrease in operating profit of 19.1 percent year on year. Core operating profit decreased 18.8 percent, basically in line with the decrease in operating profit. Profit before tax decreased 14.9 percent, mainly due to a decrease in foreign exchange losses. Furthermore, profit attributable to owners of parent decreased 20.6 percent.

(2) Financial Position for the First Quarter of the Fiscal Year Ending March 31, 2021

As of June 30, 2020, total assets were ¥864,573 million, a decrease of ¥6,953 million from the end of the previous fiscal year.

Non-current assets increased ¥12,550 million from the end of the previous fiscal year, mainly reflecting an increase in goodwill due to the conversion of shares of Tetra Therapeutics into a consolidated subsidiary. Current assets decreased ¥19,503 million, mainly reflecting a decrease in trade receivables and cash and cash equivalents, despite increases in inventories and fixed term deposits of more than three months (included in “Other financial assets” in current assets).

Equity was ¥768,490 million, an increase of ¥3,878 million from the end of the previous fiscal year, mainly due to recording of profit and cash dividends paid.

Liabilities totaled ¥96,083 million, a decrease of ¥10,832 million from the end of the previous fiscal year.

Non-current liabilities decreased ¥690 million. Current liabilities decreased ¥10,141 million, mainly because income taxes payable decreased due to payment of income taxes.

A provisional accounting treatment has been used for UMN Pharma, which became a consolidated subsidiary during the year ended March 31, 2020, and Tetra Therapeutics, which became a consolidated subsidiary during the year ending March 31, 2021, as the purchase price allocations have not yet been completed.

(3) Cash Flows for the First Quarter of the Fiscal Year Ending March 31, 2021

Net cash provided by operating activities during the first quarter of the fiscal year ending March 31, 2021 was ¥14,285 million, a decrease of ¥17,683 million year on year. Factors included a decrease in profit before tax and an increase in cash due to a decrease in trade and other receivables.

Net cash used in investing activities was ¥34,034 million, a decrease of ¥8,530 million year on year. Factors included increases and decrease of time deposits, acquisition and sale of securities for investment of surplus, and payments for acquisition of subsidiaries.

Net cash used in financing activities was ¥18,582 million, an increase of ¥2,189 million year on year, mainly due to dividends paid.

As a result, cash and cash equivalents at the end of the first quarter totaled ¥170,038 million, a decrease of ¥38,822 million from the end of the previous fiscal year.

(4) Outlook

There are no revisions to the consolidated financial forecast announced on May 11, 2020. The Company will promptly announce any revision to the consolidated financial forecast resulting from any revision of business activities due to the COVID-19 pandemic.

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, 2019	Three months ended June 30, 2020
Revenue	80,778	71,402
Cost of sales	(12,662)	(11,488)
Gross profit	68,116	59,913
Selling, general and administrative expenses	(23,063)	(20,866)
Research and development expenses	(11,678)	(12,166)
Amortization of intangible assets associated with products	(809)	(808)
Other income	143	81
Other expenses	(1,036)	(536)
Operating profit	31,671	25,617
Finance income	5,723	4,894
Finance costs	(2,051)	(447)
Profit before tax	35,343	30,063
Income tax expense	(8,186)	(8,524)
Profit	27,157	21,539
Profit attributable to		
Owners of parent	27,128	21,536
Non-controlling interests	28	2
Profit	27,157	21,539
Earnings per share		
Basic earnings per share	87.14	70.88
Diluted earnings per share	87.02	70.85

Consolidated statement of comprehensive income

Millions of yen

	Three months ended June 30, 2019	Three months ended June 30, 2020
Profit	27,157	21,539
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	(2,636)	1,969
Remeasurements of defined benefit plans	(566)	54
Total of items that will not be reclassified to profit or loss	(3,202)	2,024
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(18,327)	(2,211)
Effective portion of cash flow hedges	1,906	(1,370)
Total of items that may be reclassified to profit or loss	(16,421)	(3,581)
Total other comprehensive income, net of tax	(19,623)	(1,557)
Comprehensive income	7,533	19,981
Comprehensive income attributable to		
Owners of parent	7,432	19,979
Non-controlling interests	100	2
Comprehensive income	7,533	19,981

(2) Consolidated statement of financial position

Millions of yen

	As of March 31, 2020	As of June 30, 2020
Assets		
Non-current assets		
Property, plant and equipment	71,350	69,973
Goodwill	10,854	27,433
Intangible assets	46,536	47,922
Right-of-use assets	4,657	4,524
Other financial assets	202,161	203,634
Deferred tax assets	3,048	5,227
Other non-current assets	16,890	9,335
Total non-current assets	355,500	368,050
Current assets		
Inventories	33,818	39,786
Trade receivables	79,804	74,852
Other financial assets	171,157	189,641
Income taxes receivable	192	171
Other current assets	22,191	22,032
Cash and cash equivalents	208,861	170,038
Total current assets	516,026	496,522
Total assets	871,526	864,573

Millions of yen

	As of March 31, 2020	As of June 30, 2020
Equity and liabilities		
Equity		
Share capital	21,279	21,279
Capital surplus	20,432	20,734
Treasury shares	(77,292)	(45,875)
Retained earnings	708,291	682,550
Other components of equity	91,848	89,747
Equity attributable to owners of parent	764,560	768,436
Non-controlling interests	51	53
Total equity	764,611	768,490
Liabilities		
Non-current liabilities		
Lease liabilities	4,791	4,591
Other financial liabilities	4,179	3,621
Retirement benefit liability	16,089	16,179
Deferred tax liabilities	373	364
Other non-current liabilities	362	348
Total non-current liabilities	25,795	25,104
Current liabilities		
Lease liabilities	3,361	3,435
Trade payables	10,763	11,129
Other financial liabilities	17,557	14,677
Income taxes payable	21,886	15,193
Other current liabilities	27,551	26,542
Total current liabilities	81,119	70,978
Total liabilities	106,915	96,083
Total equity and liabilities	871,526	864,573

(3) Consolidated statement of changes in equity

Three months ended June 30, 2019

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, 2019	21,279	21,277	(28,882)	613,483	181,616	808,774	4,313	813,087
Profit				27,128		27,128	28	27,157
Total other comprehensive income, net of tax					(19,696)	(19,696)	72	(19,623)
Comprehensive income	—	—	—	27,128	(19,696)	7,432	100	7,533
Purchase of treasury shares			(2)			(2)		(2)
Disposal of treasury shares		(221)	241			20		20
Cancellation of treasury shares						—		—
Dividends				(15,564)		(15,564)		(15,564)
Transfer from other components of equity to retained earnings				(566)	566	—		—
Other		132		(132)		—		—
Balance as of June 30, 2019	21,279	21,188	(28,643)	624,349	162,486	800,660	4,414	805,074

Three months ended June 30, 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	20,432	(77,292)	708,291	91,848	764,560	51	764,611
Profit				21,536		21,536	2	21,539
Total other comprehensive income, net of tax					(1,557)	(1,557)		(1,557)
Comprehensive income	—	—	—	21,536	(1,557)	19,979	2	19,981
Purchase of treasury shares			(2)			(2)		(2)
Disposal of treasury shares		(506)	507			0		0
Cancellation of treasury shares		(30,912)	30,912			—		—
Dividends				(16,100)		(16,100)		(16,100)
Transfer from other components of equity to retained earnings				54	(54)	—		—
Other		31,720		(31,231)	(488)	(0)		(0)
Balance as of June 30, 2020	21,279	20,734	(45,875)	682,550	89,747	768,436	53	768,490

(4) Consolidated statement of cash flows

Millions of yen

	Three months ended June 30, 2019	Three months ended June 30, 2020
Cash flows from operating activities		
Profit before tax	35,343	30,063
Depreciation and amortization	3,437	3,630
Finance income and finance costs	(4,456)	(4,703)
Decrease (increase) in trade and other receivables	21,651	4,952
Decrease (increase) in inventories	(1,276)	(5,976)
Increase (decrease) in trade and other payables	(4,796)	(4,100)
Other	(929)	(4,321)
Subtotal	48,974	19,546
Interest and dividends received	11,923	11,930
Interest paid	(36)	(25)
Income taxes paid	(28,891)	(17,165)
Net cash provided by (used in) operating activities	31,969	14,285
Cash flows from investing activities		
Payments into time deposits	(79,399)	(69,077)
Proceeds from withdrawal of time deposits	40,346	48,328
Purchase of property, plant and equipment	(2,335)	(2,602)
Purchase of intangible assets	(1,166)	(685)
Payments for acquisition of subsidiaries	—	(3,221)
Purchase of investments	(25,200)	(29,066)
Proceeds from sale of investments	25,879	22,168
Other	(689)	122
Net cash provided by (used in) investing activities	(42,565)	(34,034)

Millions of yen

	Three months ended June 30, 2019	Three months ended June 30, 2020
Cash flows from financing activities		
Repayments of lease liabilities	(830)	(905)
Purchase of treasury shares	(2)	(2)
Dividends paid	(15,560)	(16,097)
Payments for acquisition of interests in subsidiaries from non-controlling interests	—	(1,575)
Other	—	(1)
Net cash provided by (used in) financing activities	(16,393)	(18,582)
Effect of exchange rate changes on cash and cash equivalents	(1,002)	(490)
Net increase (decrease) in cash and cash equivalents	(27,992)	(38,822)
Cash and cash equivalents at beginning of period	195,800	208,861
Cash and cash equivalents at end of period	167,808	170,038

(5) Notes

Going concern assumption

None

Change in accounting policies

Shionogi group has applied the following standard from the first quarter of the fiscal year ending March 31, 2021. The adoption does not have a significant impact on the consolidated financial statements.

IFRS		Overview of new standards and revisions
IFRS 3	Business Combinations	Amendments to the definition of a business in Business Combinations

Notes to 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.

Important Subsequent Events

(Disposal of treasury shares by third-party allotment)

At a meeting on March 30, 2020, the Company's Board of Directors passed resolutions to form a basic agreement for a capital and business alliance with Ping An Insurance (Group) Company of China Ltd. The plan for this alliance includes the disposal of treasury shares by way of third-party allotment to Ping An Life Insurance of China, Ltd., which is a subsidiary of Ping An Insurance, as a planned allottee.

The prerequisites for execution of the third-party allotment included the following: 1) The joint venture agreement for the establishment of the joint venture has been executed between Shionogi and Ping An Insurance or its Group company; and 2) The allottee has obtained the various licenses required to undertake the third-party allotment. As these prerequisites were satisfied, the disposal of treasury shares was conducted in July 29, 2020.

1. Outline of Disposal

- a) Date of Share Disposal: July 29, 2020
- b) Shares for Disposal: 6,356,000 Shionogi common shares
- c) Disposal Price: ¥5,276 per share
- d) Capital Raised: ¥33,534,256,000
- e) Disposal Method: Disposal by third-party allotment
- f) Allottee: Ping An Life
- g) Other: The Company has filed a Securities Registration Statement concerning the disposal of treasury shares in accordance with the Financial Instruments and Exchange Act.

2. Purposes and Reasons for the Disposal

The third-party allotment of shares to Ping An Life will be implemented as part of the capital and business alliance with Ping An Insurance, which is the parent company of Ping An Life, and is intended to support a strong long-term strategic partnership with Ping An Insurance to help the Company execute its global strategy.

(Significant Facility investment)

At a meeting on July 13, 2020, the Company's Board of Directors has resolved a facility investment as below.

1. Reason for facility investment

Provide total care for COVID-19 infection and expand our business model by full-scale entry into vaccine business

2. Outline of facility investment

- a) Location: Gifu Prefecture, Japan
- b) Purpose: Vaccine production facilities
- c) Investment amount: ¥41.7 billion
- d) Financing: Fund on hand

3. Installation time of equipment

FY2020

4. Significant impact on marketing and productivity

No significant impact on the current consolidated fiscal year.

Supplemental material for financial results for the 1st quarter of fiscal year 2020

July 31, 2020
Shionogi & Co., Ltd.

1. Revenue by segment

(Billions of yen)

	FY2020 1H forecast	FY2020 forecast	FY2020 1Q actual	FY2019 1Q actual	change	Progress% vs. 2020 1H forecast
Prescription drugs	53.1	123.9	22.4	26.3	(4.0)	42.1
<i>change %</i>	-	16.6	(15.1)	-		
CYMBALTA	13.9	28.6	6.9	6.7	0.2	49.8
INTUNIV	6.8	16.7	2.6	1.8	0.8	38.4
VYVANSE	0.2	0.8	0.0	-	0.0	11.3
Infectious Disease Drugs	7.1	26.5	2.1	3.6	(1.5)	30.1
OXYCONTIN Franchise	2.9	5.6	1.4	1.7	(0.3)	47.3
SYMPROIC	1.3	2.9	0.5	0.5	(0.0)	36.6
ACTAIR	0.2	0.3	0.1	0.1	0.0	36.9
MULPLETA	0.1	0.1	0.0	0.0	(0.0)	42.5
PIRESPA	2.9	4.9	1.4	1.7	(0.3)	49.6
Others	17.7	37.5	7.3	10.2	(2.9)	41.1
CRESTOR	4.2	8.3	1.5	2.4	(0.8)	37.3
IRBETAN Franchise	1.8	3.7	0.8	1.2	(0.4)	47.0
Overseas subsidiaries/Export	11.3	24.0	5.5	10.7	(5.3)	48.5
<i>change %</i>	-	(21.9)	(49.1)	-		
Shionogi Inc.	2.6	5.1	1.7	5.3	(3.6)	64.1
C&O	5.7	11.9	2.4	3.8	(1.4)	41.4
Contract manufacturing	7.9	15.4	2.9	2.4	0.4	36.5
<i>change %</i>	-	(12.2)	17.6	-		
OTC and quasi-drugs	4.9	10.4	2.3	1.8	0.5	46.5
<i>change %</i>	-	7.6	26.1	-		
Royalty income	77.8	148.3	38.0	38.9	(0.9)	48.8
<i>change %</i>	-	(11.1)	(2.4)	-		
HIV Franchise	64.2	126.3	31.0	31.7	(0.8)	48.2
CRESTOR	11.1	16.9	5.6	5.7	(0.1)	50.0
Others	2.5	5.2	1.5	1.5	(0.1)	60.3
Others	0.7	1.3	0.4	0.5	(0.1)	65.8
<i>change %</i>	-	(39.0)	(17.2)	-		
Total	155.6	323.5	71.4	80.8	(9.4)	45.9
<i>change %</i>	-	(3.0)	(11.6)	-		

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.

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

2 - 1. Quarterly trend for FY2019 and FY2020 (Revenue by segment)

Fiscal year ended March 31, 2020 *(Billions of yen)*

FY2019	FY2019 1Q actual	Y on Y change%
Prescription drugs	26.3	-
CYMBALTA	6.7	-
INTUNIV	1.8	-
VYVANSE	-	-
Infectious Disease Drugs	3.6	-
OXYCONTIN Franchise	1.7	-
SYMPROIC	0.5	-
ACTAIR	0.1	-
MULPLETA	0.0	-
PIRESPA	1.7	-
Others	10.2	-
CRESTOR	2.4	-
IRBETAN Franchise	1.2	-
Overseas subsidiaries/Export	10.7	-
Shionogi Inc.	5.3	-
C&O	3.8	-
Contract manufacturing	2.4	-
OTC and quasi-drugs	1.8	-
Royalty income	38.9	-
HIV Franchise	31.7	-
CRESTOR	5.7	-
Others	1.5	-
Others	0.5	-
Total	80.8	-

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

Fiscal year ending March 31, 2021

FY2020	FY2020 1Q actual	Y on Y change%
Prescription drugs	22.4	(15.1)
CYMBALTA	6.9	2.9
INTUNIV	2.6	42.2
VYVANSE	0.0	-
Infectious Disease Drugs	2.1	(40.7)
OXYCONTIN Franchise	1.4	(17.3)
SYMPROIC	0.5	(7.9)
ACTAIR	0.1	3.4
MULPLETA	0.0	(26.3)
PIRESPA	1.4	(17.1)
Others	7.3	(28.4)
CRESTOR	1.5	(35.3)
IRBETAN Franchise	0.8	(30.5)
Overseas subsidiaries/Export	5.5	(49.1)
Shionogi Inc.	1.7	(68.6)
C&O	2.4	(37.5)
Contract manufacturing	2.9	17.6
OTC and quasi-drugs	2.3	26.1
Royalty income	38.0	(2.4)
HIV Franchise	31.0	(2.4)
CRESTOR	5.6	(1.6)
Others	1.5	(3.6)
Others	0.4	(17.2)
Total	71.4	(11.6)

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

2 - 2. Quarterly trend for FY2019 and FY2020 (Consolidated statements of profit or loss)

Fiscal year ended March 31, 2020 *(Billions of yen)*

FY2019	FY2019 1Q actual	Y on Y change %
Revenue	80.8	-
Cost of sales	15.7 (12.7)	-
Gross profit	68.1	-
SG & A expenses	28.6 (23.1)	-
R & D expenses	14.5 (11.7)	-
Amortization of intangible assets associated with products	1.0 (0.8)	-
Other income & expenses	(0.9)	-
Operating profit	39.2 31.7	-
Finance income & costs	3.7	-
Profit before tax	43.8 35.3	-
Income tax expense etc.	(8.2)	-
Profit attributable to owners of parent	33.6 27.1	-

Fiscal year ending March 31, 2021

FY2020	FY2020 1Q actual	Y on Y change %
Revenue	71.4	(11.6)
Cost of sales	16.1 (11.5)	(9.3)
Gross profit	59.9	(12.0)
SG & A expenses	29.2 (20.9)	(9.5)
R & D expenses	17.0 (12.2)	4.2
Amortization of intangible assets associated with products	1.1 (0.8)	(0.1)
Other income & expenses	(0.5)	(49.0)
Operating profit	35.9 25.6	(19.1)
Finance income & costs	4.4	21.1
Profit before tax	42.1 30.1	(14.9)
Income tax expense etc.	(8.5)	3.8
Profit attributable to owners of parent	30.2 21.5	(20.6)

3. Pipeline (as of July 31, 2020)

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:PhaseIII (pediatric) USA:Approval (cUTI) (Nov.2019), NDA submission (Nosocomial pneumonia) (Mar.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) Japan:PhaseIII(high dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Cap-dependent endonuclease inhibition (oral)	Influenza virus infection (prophylaxis)	Japan:NDA submission (Oct.2019)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Not disclosed (oral)	HIV infection	USA,Japan:PhaseI	In-house	In-house
Pain/CNS	S-297995 (naldemedine tosilate) [US/Japan:Symproic®] [EU:Rizmoic®]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Europe:PhaseI/II	In-house	In-house
	S-297995 (naldemedine tosilate)	Peripheral opioid receptor antagonist (oral,)	Postoperative ileus	USA:PhaseII	In-house	In-house
	S-120083	Not disclosed (oral)	Inflammatory pain	Japan:PhaseI USA:PhaseII	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Not disclosed (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-117957	Not disclosed (oral)	Insomnia	USA:PhaseI	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-600918	P2X ₃ receptor antagonist (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	S-600918	P2X ₃ receptor antagonist (oral)	Refractory/unexplained chronic cough	Global:PhaseII	In-house	In-house
	S-600918	P2X ₃ receptor antagonist (oral)	Sleep Apnea Syndrome	Japan:PhaseII	In-house	In-house
	S-637880	Not disclosed (oral)	Neuropathic pain	Japan:PhaseI	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta®]	SNRI (Serotonin–norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan:PhaseIII	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217 (Zuranolone)	GABAA receptor positive allosteric modulator (oral)	Depression	Japan:PhaseII	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan:PhaseII	Akili (USA)	Shionogi/Akili
Metabolic disorder	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan:PhaseII USA:PhaseI	In-house	In-house
	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA:PhaseIIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan:PhaseI/II	Rohto	Shionogi/Rohto
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

Areas	Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Frontier	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:PhaseII	FunPep (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Stroke	Japan:PhaseII	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Mobilization of mesenchymal stem cells (MSCs) to peripheral blood (injection)	Epidermolysis bullosa	Japan:PhaseII (preparing NDA submission)	StemRIM (Japan)	In-house

<Out-Licensing Activity>

Code No. (Generic name) [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (dolutegravir)	Integrase inhibitor (oral)	For the treatment of HIV infection	(DTG ^{*1} /3TC ^{*2} 2-drug fixed dose combination tablet) USA:Approval(naïve patients) (Apr.2019) Europe:Approval(naïve and switch patients) (Jul.2019) Japan:Approval(naïve patients)(Jan. 2020) Global:NDA submission(switch patients)	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK)
S/GSK1265744 LAP ^{*3} (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	(CAB ^{*4} LAP+RPV ^{*5} LAP 2-drug regimen for treatment) Canada: Approval(Mar.2020) USA:NDA re-submission(Jul.2020) Europe:MAA submission(Jul.2019) (CAB LAP for prevention) Global:PhaseIII	Shionogi-ViiV Healthcare LLC	ViiV Healthcare Ltd. (UK) for treatment Collaboration among ViiV,HPTN,NIAID and Gilead Sciences, Inc.(USA)for prevention
S-0373	Non-peptide mimetic of TRH (oral)	Spinocerebellar ataxia	Japan:PhaseIII	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA:Xofluz 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:NDA submission (Granule)(Mar.2020) USA:NDA submission (Phophylaxis) (Mar.2020) Europe:MAA submission(treatment, prophylaxis)(Nov.2019) Global:PhaseIII(severe influenza virus infection) Global:PhaseIII(pediatric, < 1 year old) Global:PhaseIII(transmission)	In-house	Shionogi/Roche (Switzerland)

*1: Dolutegravir, *2: Lamivudine, *3: Long acting parenteral formulation, *4: Cabotegravir, *5: Rilpivirine

<Drugs to acquire new indication requested by the Ministry of Health, Labour and Welfare>

Generic name [Product name]	Mechanism of action (Administration)	Indication	Stage	Origin	Development
Oxycodone hydrochloride hydrate [OxyContin [®]]	Natural opium alkaloids (oral)	For the treatment of moderate to severe chronic pain	Japan;NDA re-submission(May.2019)	Napp Pharmaceuticals Limited (UK)	In-house

Since May 11, 2020

Change of phase	S-648414:USA PhaseI→USA,Japan:PhaseI
	S-005151(Epidermolysis bullosa):Japan PhaseII→NDA submission(in preparation)
	S/GSK1349572:USA PhaseIII→Additional submission