Financial Results for the Third Quarter of Fiscal Year 2019(Consolidated)

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

Code: 4507 URL: <u>http://www.shionogi.co.jp</u>

Representative: Isao Teshirogi, President and CEO

Contact responsibility: Yoshimasa Kyokawa, Vice President , Corporate Communications Department Tel.:(06)6202-2161 Scheduled date of quarterly securities report submission: February 10, 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, 2019 to December 31, 2019

(1) Consolidated operating results

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

	Net sales		Operating income		Operating income		Operating income		Ordinary inc	come	Profit attributa owners of p	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%				
Nine months ended December 31, 2019	253,514	(4.4)	99,249	1.9	114,899	(0.6)	90,844	(3.7)				
Nine months ended December 31, 2018	265,242	0.7	97,423	8.1	115,649	9.7	94,344	18.3				

Note: Comprehensive income Nine months ended December 31, 2019: 81,044 million yen ((9.0)%) Nine months ended December 31, 2018: 89,061 million yen ((10.6)%)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Nine months ended December 31, 2019	292.78	292.42
Nine months ended December 31, 2018	300.95	297.78

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of December 31, 2019	765,439	689,477	90.0
As of March 31, 2019	778,741	672,429	85.7

Reference: Shareholders' equity As of December 31, 2019: 688,896 million yen As of March 31, 2019: 667,502 million yen

2. Dividends

	Dividends per share					
(Date of record)	End of first quarter	End of second quarter	End of third quarter	Year-end	Annual	
	Yen	Yen	Yen	Yen	Yen	
Year ended March 31, 2019	—	44.00	—	50.00	94.00	
Year ending March 31, 2020	—	50.00	—			
Year ending March 31, 2020				50.00	100.00	
(forecast)				50.00	100.00	

Note: Revisions of the most recent dividend forecast: None

3. Consolidated financial forecast for the year ending March 31, 2020

(% shows changes from the same period of the previous fiscal ye						revious fiscal year)		
	Net sales	Operating income Ordinary income		Profit attributa	ble to	Earnings per		
	iner sales			owners of parent		share		
	Millions of yen %	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Year ending March 31, 2020	355,000 (2.4)	141,500	2.1	167,000	0.3	133,000	0.2	433.65

Note: Revisions of the most recent consolidated financial forecast: Yes

February 3, 2020 Listed Exchanges: Section I of Tokyo

FASE

※ Notes

- (1) Significant changes in subsidiaries during the period (changes in specified subsidiaries involving changes in scope of consolidation): None
- (2) Adoption of accounting methods specific to the preparation of quarterly consolidated financial statements: None
- (3) Changes in accounting policies, changes/restatements of accounting estimates
 - a) Changes in accounting policies in connection with amendments to accounting standards, etc.: None
 - b) Changes in accounting policies other than a) above: None
 - c) Changes in accounting estimates: None
 - d) Restatements: None
- (4) Number of shares issued (common stock)

a) Number of shares issue	d (including treasury stock)				
	As of December 31, 2019:	316,786,165 shares			
	As of March 31, 2019:	316,786,165 shares			
b) Number of treasury stoc	k				
	As of December 31, 2019:	10,088,542 shares			
	As of March 31, 2019:	5,498,751 shares			
c) Average number of shares issued during the period					
	Nine months ended December 31, 2019: Nine months ended December 31, 2018:				

- ※ This report of financial results is unaudited.
- ※ Notes to consolidated financial forecasts and other items

(Cautionary note concerning forward-looking statements)

The forecasts and other forward-looking statements contained in this document are based on the information currently available and 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 (3) Outlook" on page 3 of the supplemental materials for the Financial Results for the Third Quarter of Fiscal Year 2019 (Consolidated).

(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, February 3, 2020. Plans are also in place to post audio explanatory details together with financial results explanatory materials distributed to analysts on February 3, 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

(1) Operating Results for the Third Quarter of the Fiscal Year Ending March 31, 2020

For the nine months ended December 31, 2019 (April 1, 2019 to December 31, 2019), net sales were ¥253,514 million, operating income was ¥99,249 million, ordinary income was ¥114,899 million, and profit attributable to owners of parent was ¥90,844 million.

Net sales decreased 4.4 percent compared with the same period of the previous fiscal year. Domestic sales of prescription drugs decreased 7.2 percent compared with the same period of the previous fiscal year as sales of strategic products Cymbalta and Intuniv expanded, but sales of Xofluza decreased substantially from the same period of the previous fiscal year, its first year of full-scale sales. Overseas subsidiary sales and exports increased 8.4 percent. In the United States, Shionogi received a one-time payment during the period in connection with a licensing agreement with BioDelivery Sciences International, Inc. for the co-commercialization of Symproic, but sales decreased 9.8 percent, reflecting the substantial impact of the absence of the one-time payment received from Purdue Pharma L.P. in the same period of the previous fiscal year due to the termination of the alliance for Symproic. In China, sales increased 24.7 percent as a result of steady expansion in sales of Rabeprazole. Sales from contract manufacturing increased 30.5 percent compared with the same period of the previous fiscal year, at healthcare Ltd. ("ViiV") increased 5.2 percent, reflecting ViiV's expansion in global sales of Tivicay, Triumeq and Juluca, although certain royalty income was impacted by exchange rate fluctuations. However, royalty income overall decreased 8.1 percent compared with the same period of the previous fiscal year because Shionogi received milestone payments from Roche during the third quarter in connection with the global development of Xofluza, but also received these milestone payments from Roche in the same period of the previous fiscal year.

Gross profit decreased 5.5 percent compared with the same period of the previous fiscal year because of the decrease in sales mentioned above, in addition to an increase in cost of sales due to an increase in contract manufacturing. Operating income increased 1.9 percent as a result of a decrease in research and development expenses, reflecting the absence of the strategic business investments made in the previous fiscal year. Ordinary income decreased 0.6 percent due to a decrease in dividend income received from ViiV and fluctuations in foreign exchange rates. Profit attributable to owners of parent decreased 3.7 percent.

(2) Financial Position for the Third Quarter of the Fiscal Year Ending March 31, 2020

As of December 31, 2019, total assets were ¥765,439 million, a decrease of ¥13,301 million from the end of the previous fiscal year. Cash and deposits increased, but current assets decreased ¥641 million to ¥461,102 million, mainly because of a decrease in notes and accounts receivable-trade due to factors including progress in collection of accounts receivable related to seasonal products including Xofluza, and a decrease in short-term investment securities for surplus fund management. Non-current assets decreased ¥12,660 million to ¥304,336 million, largely because of a decrease in investment securities reflecting lower stock prices and sales of securities.

Total liabilities decreased ¥30,349 million from the end of the previous fiscal year to ¥75,962 million. Current liabilities decreased ¥29,747 million to ¥59,359 million, mainly because income taxes payable decreased. Non-current liabilities decreased ¥601 million to ¥16,602 million.

Net assets increased ¥17,047 million from the end of the previous fiscal year to ¥689,477 million. Shareholders' equity increased ¥30,950 million to ¥683,321 million as a result of profit attributable to owners of parent, cash dividends paid and the repurchase of shares. Accumulated other comprehensive income decreased ¥9,555 million to ¥5,575 million, due to a decrease in valuation difference on available-for-sale securities, mainly because of lower stock prices. Subscription rights to shares decreased ¥88 million to ¥438 million and non-controlling interests decreased ¥4,258 million to ¥141 million.

During the nine-month period, Shionogi acquired additional shares of UMN Pharma Inc. and made it a consolidated subsidiary, but has used a provisional accounting treatment because the purchase price allocation was not yet completed at the end of the third quarter.

(3) Outlook

Based on recent performance trends, the Shionogi Group has revised its financial forecast for the fiscal year ending March 31, 2020, released on October 30, 2019, as follows.

1) Revisions of Financial Forecast

Revised forecasts for the year ending March 31, 2020

	Net sales	Operating income	Ordinary income	Profit attributable to owners of parent	Earnings per share
	Millions of yen	Millions of yen	Millions of yen	Millions of yen	Yen
Previous forecast (A)	367,000	150,000	171,500	135,000	440.17
New forecast (B)	355,000	141,500	167,000	133,000	433.65
Change (B-A)	(12,000)	(8,500)	(4,500)	(2,000)	—
Percentage change (%)	(3.3)	(5.7)	(2.6)	(1.5)	—
(reference) For the year ended March 31, 2019	363,721	138,537	166,575	132,759	424.31

Note: Shionogi is repurchasing shares of its own stock based on a resolution approved at the Board of Directors meeting held on September 30, 2019. The effect of this repurchase of shares was considered in the calculation of earnings per share in the previously announced forecast.

2) Reasons for Revision of Financial Forecast

Although Shionogi projects that contract manufacturing and royalty income from ViiV will increase from the previous forecast, net sales overall are expected to be lower than the previous forecast because of an expected decrease in sales of prescription drug in Japan. As for profits, Shionogi strives constantly to optimize total costs by clear priorities and focused resourcing for the growth, but operating income is projected to be lower than the previous forecast due to the aforementioned decrease in net sales. Ordinary income and profit attributable to owners of parent are each projected to be less than the previous forecast for the fiscal year, reflecting the decrease in operating income.

2. Consolidated Financial Statements and Notes

(1) Consolidated balance sheets

	As of March 31, 2019	As of December 31, 2019
Assets		
Current assets		
Cash and deposits	193,549	231,61
Notes and accounts receivable-trade	65,918	47,38
Short-term investment securities	133,264	105,87
Merchandise and finished goods	18,741	18,01
Work in process	7,272	11,85
Raw materials and supplies	14,097	11,83
Other	28,942	34,56
Allowance for doubtful accounts	(43)	(42
Total current assets	461,743	461,10
Non-current assets		
Property, plant and equipment	74,653	75,60
Intangible assets		
Goodwill	19,258	25,00
Other	35,511	31,58
Total intangible assets	54,769	56,64
Investments and other assets		
Investment securities	151,851	131,9
Other	35,765	40,1
Allowance for doubtful accounts	(42)	(4
Total investments and other assets	187,574	172,0
Total non-current assets	316,997	304,33
Total assets	778,741	765,43
iabilities		
Current liabilities		
Notes and accounts payable-trade	9,442	9,74
Current portion of bonds	920	
Income taxes payable	35,870	15,03
Provision for bonuses	9,058	4,9
Provision for sales returns	1,428	99
Other provision	166	
Other	32,219	28,63
Total current liabilities	89,107	59,3
Non-current liabilities		
Net defined benefit liability	11,930	10,98
Other	5,272	5,62
Total non-current liabilities	17,203	16,60
Total liabilities	106,311	75,96

		Millions of yen
	As of March 31, 2019	As of December 31, 2019
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,512	21,298
Retained earnings	639,461	698,751
Treasury stock	(28,882)	(58,008)
Total shareholders' equity	652,371	683,321
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	28,927	22,122
Deferred gains or losses on hedges	747	1,353
Foreign currency translation adjustment	(18,370)	(21,213)
Remeasurements of defined benefit plans	3,826	3,313
Total accumulated other comprehensive income	15,130	5,575
Subscription rights to shares	527	438
Non-controlling interests	4,400	141
Total net assets	672,429	689,477
Total liabilities and net assets	778,741	765,439

(2) Consolidated statements of income and Consolidated statements of comprehensive income Consolidated statements of income

		Millions of yen
	Nine months ended	Nine months ended
	December 31, 2018	December 31, 2019
Net sales	265,242	253,514
Cost of sales	40,380	40,994
Gross profit	224,861	212,519
Selling, general and administrative expenses	127,438	113,270
Operating income	97,423	99,249
Non-operating income		
Interest income	1,657	2,206
Dividends income	18,859	16,240
Other	584	402
Total non-operating income	21,101	18,848
Non-operating expenses		
Interest expenses	256	75
Contribution	495	886
Other	2,123	2,236
Total non-operating expenses	2,875	3,198
Ordinary income	115,649	114,899
Extraordinary income		
Gain on sales of non-current assets	2,870	1,251
Gain on sales of investment securities	1,497	2,672
Gain on step acquisitions	_	1,331
Total extraordinary income	4,368	5,255
Extraordinary loss		
Loss on valuation of investment securities	439	696
Loss on disaster	826	-
Special retirement expenses	346	-
Total extraordinary losses	1,611	696
Income before income taxes	118,406	119,459
Income taxes-current	28,165	29,529
Income taxes-deferred	(4,562)	(879)
Total income taxes	23,602	28,650
Profit	94,803	90,808
Profit (loss) attributable to non-controlling interests	458	(36)
Profit attributable to owners of parent	94,344	90,844

Consolidated statements of comprehensive income

		Millions of yen
	Nine months ended	Nine months ended
	December 31, 2018	December 31, 2019
Profit	94,803	90,808
Other comprehensive income		
Valuation difference on available-for-sale securities	(1,286)	(6,805)
Deferred gains or losses on hedges	1,020	606
Foreign currency translation adjustment	(6,692)	(3,052)
Remeasurements of defined benefit plans	1,216	(513)
Total other comprehensive income	(5,741)	(9,764)
Comprehensive income	89,061	81,044
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	88,730	81,289
Comprehensive income attributable to non-controlling interests	331	(245)

(3) Notes Going concern assumption None

Significant changes in shareholders' equity

Repurchase of Shares

By resolution of the Board of Directors on September 30, 2019, Shionogi is repurchasing up to 8,350,000 shares of common stock, at a cost up to ¥50,000 million in total, during the period from October 1, 2019 through February 28, 2020. Based on this resolution, Shionogi repurchased 4,879,600 shares during the third quarter at a cost of ¥30,719 million.

In addition, treasury stock increased by ¥29,126 million in the third quarter, partly due to the conversion of convertible bonds. The amount of treasury stock held as of December 31, 2019 was ¥58,008 million.

Supplemental material for financial results for the 3rd quarter of fiscal year 2019

1. Sales of segments

1. Sales of segments						(B	illions of yen
	FY2019 2H forecast	FY2019 forecast	FY2019 3Q actual	FY2018 3Q actual	FY2019 1Q-3Q actual	FY2018 1Q-3Q actual	Progress %vs.FY2019 forecast
Prescription drugs	76.6	129.1	29.5	38.3	82.0	88.3	63.5
change %	(2.6)	0.3	(23.0)	8.8	(7.2)	(18.5)	
CYMBALTA	14.4	27.3	7.3	6.7	20.2	18.6	73.9
INTUNIV	6.2	10.6	2.6	1.6	7.1	3.9	66.4
VYVANSE	0.1	0.1	0.0	-	0.0	-	10.1
XOFLUZA	18.0	18.0	0.4	9.5	0.4	9.9	2.1
RAPIACTA	2.6	2.6	1.0	0.8	1.0	0.8	38.2
BRIGHTPOC Flu	1.8	2.2	0.5	0.3	0.8	0.6	35.5
Total of strategic products	43.1	60.7	11.7	18.8	29.4	33.8	48.4
OXYCONTIN Franchise	3.2	6.4	1.7	2.0	4.9	5.8	76.2
SYMPROIC	1.2	2.3	0.5	0.5	1.6	1.2	70.5
ACTAIR	0.1	0.3	0.1	0.1	0.2	0.1	73.1
MULPLETA	0.2	0.2	0.0	0.0	0.1	0.1	45.5
PIRESPA	3.5	7.0	1.5	1.6	5.0	4.5	71.2
Total of new products	51.3	76.9	15.6	23.0	41.1	45.6	53.5
CRESTOR	4.9	9.5	2.2	2.7	6.8	7.8	71.7
IRBETAN Franchise	2.4	4.6	1.1	1.3	3.3	4.4	72.0
Other	18.0	38.1	10.6	11.4	30.7	30.5	80.6
Overseas subsidiaries/Export	13.8	31.3	6.4	6.7	24.0	22.1	76.4
change %	(1.6)	6.5	(4.2)	27.5	8.4	26.6	
Shionogi Inc.	3.4	10.2	1.7	2.0	8.5	9.4	83.2
Mulpleta	0.7	1.0	0.1	0.0	0.4	0.0	43.3
C&O	6.2	13.3	3.0	3.2	10.2	8.2	76.5
Contract manufacturing	6.8	16.9	1.9	3.4	12.0	9.2	70.9
change %	(24.6)	14.3	(44.8)	2.7	30.5	(22.1)	
OTC and quasi-drugs	5.0	9.7	2.8	2.5	7.5	6.3	77.6
change %	15.1	19.7	11.7	7.1	19.8	10.2	
Royalty income	90.8	165.7	51.4	45.3	126.4	137.5	76.2
change %	3.0	(8.1)	13.5	2.3	(8.1)	16.4	
HIV Franchise	66.0	127.1	33.4	32.8	94.5	89.9	74.4
CRESTOR	11.0	22.0	5.5	5.5	16.6	16.4	75.2
Others	13.8	16.6	12.4	6.9	15.3	31.2	91.7
Others	1.1	2.2	0.6	0.8	1.7	1.9	77.2
change %	(16.4)	(8.7)	(21.4)	(0.5)	(8.4)	(4.5)	
Total	194.1	355.0	92.6	97.0	253.5	265.2	71.4
change %	(0.7)	(2.4)	(4.5)	6.4	(4.4)	0.7	

Note: Change % shows changes from the same period of the previous fiscal year. Sales of prescription drugs are shown on non-consolidated basis.

February 3, 2020 Shionogi & Co., Ltd.

2 - 1. Quarterly trend for FY2018 and FY2019 (Sales of segments)

Fiscal year ended March 31, 2019							(Billions of	of yen)
FY2018	FY2018 1Q	Y on Y	FY2018 2Q	Y on Y	FY2018 3Q	Y on Y	FY2018 4Q	Y on Y
1 12010	actual	change %	actual	change %	actual	change%	actual	change%
Prescription drugs	25.4	(31.9)	24.6	(31.5)	38.3	8.8	40.4	31.
CYMBALTA	6.1	6.1	5.8	(2.2)	6.7	2.1	5.5	4.2
INTUNIV	1.1	209.9	1.3	284.8	1.6	194.4	1.4	100.
XOFLUZA	0.0	-	0.4	-	9.5	-	16.4	578.
RAPIACTA	0.0	(76.4)	(0.0)	(131.8)	0.8	(33.9)	1.3	(39.9
BRIGHTPOC Flu	0.0	(90.5)	0.2	168.5	0.3	(11.6)	0.6	(0.9
OXYCONTIN Franchise	2.0	(15.2)	1.8	(16.8)	2.0	(18.7)	1.5	(11.6
SYMPROIC	0.3	526.3	0.4	257.6	0.5	123.0	0.4	72.
Total of strategic products	9.6	11.0	10.0	14.8	21.2	88.9	27.0	107.
ACTAIR	0.0	47.4	0.0	63.3	0.1	61.0	0.0	51.
MULPLETA	0.0	0.6	0.0	3.0	0.0	(2.2)	0.0	(21.6
PIRESPA	1.4	(5.1)	1.5	(10.5)	1.6	(10.8)	1.2	(22.2
Total of new products	11.0	8.8	11.6	10.8	23.0	74.7	28.2	93.
CRESTOR	2.6	(78.1)	2.5	(74.6)	2.7	(38.1)	2.0	(31.9
IRBETAN Franchise	1.9	(48.5)	1.1	(71.5)	1.3	(67.7)	1.0	(63.8
Other	9.8	(13.8)	9.3	(18.6)	11.4	(16.7)	9.1	(13.4
Overseas subsidiaries/Export	9.9	49.3	5.5	(1.1)	6.7	27.5	7.3	18.
Shionogi Inc.	6.1	75.7	1.3	(49.7)	2.0	(14.6)	2.4	8.
Osphena	0.8	(32.7)	0.7	(21.4)	1.0	(0.1)	0.6	(17.6
C&O	2.3	31.0	2.7	69.2	3.2	125.0	3.3	57.
Contract manufacturing	2.8	(20.5)	2.9	(40.1)	3.4	2.7	5.6	8.
OTC and quasi-drugs	1.6	1.3	2.2	21.9	2.5	7.1	1.8	18.
Royalty income	48.3	89.7	43.9	(9.2)	45.3	2.3	42.8	15.
HIV Franchise	24.5	31.4	32.6	18.2	32.8	18.1	34.5	17.
CRESTOR	5.5	(4.3)	5.4	(3.9)	5.5	(1.4)	5.5	(1.9
Others	18.3	-	5.9	(61.1)	6.9	(36.0)	2.7	43.
Others	0.6	1.8	0.6	(14.5)	0.8	(0.5)	0.6	(9.
Total	88.5	18.0	79.7	(18.0)	97.0	6.4	98.5	21

Fiscal year ending March 31, 2020

FY2019	FY2019 1Q actual	Y on Y change%	FY2019 2Q actual	Y on Y change %	FY2019 3Q actual	Y on Y change%
Prescription drugs	26.7	5.0	25.8	4.9	29.5	(23.0)
CYMBALTA	6.7	10.3	6.1	5.3	7.3	9.6
INTUNIV	1.8	65.6	2.6	105.0	2.6	68.6
VYVANSE	-	-	-	-	0.0	-
XOFLUZA	0.0	(100.0)	0.0	(99.7)	0.4	(96.0)
RAPIACTA	0.0	(89.4)	0.0	(263.2)	1.0	29.3
BRIGHTPOC Flu	0.0	97.7	0.3	31.0	0.5	31.3
Total of strategic products	8.6	18.1	9.1	16.8	11.7	(37.5)
OXYCONTIN Franchise	1.7	(15.5)	1.5	(17.8)	1.7	(14.8)
SYMPROIC	0.5	70.6	0.6	37.2	0.5	6.9
ACTAIR	0.1	42.1	0.1	37.8	0.1	21.3
MULPLETA	0.0	(31.2)	0.0	(2.5)	0.0	(10.8)
PIRESPA	1.7	26.2	1.7	14.8	1.5	(5.8)
Total of new products	12.6	14.4	12.9	11.9	15.6	(32.2)
CRESTOR	2.4	(7.8)	2.1	(15.4)	2.2	(16.4)
IRBETAN Franchise	1.2	(35.5)	1.0	(11.9)	1.1	(17.4)
Other	10.4	5.8	9.7	3.7	10.6	(6.5)
Overseas subsidiaries/Export	10.6	7.4	6.9	25.6	6.4	(4.2)
Shionogi Inc.	5.2	(14.0)	1.6	20.2	1.7	(16.7)
Mulpleta	0.2	-	0.2	-	0.1	392.6
C&O	3.8	61.1	3.4	26.6	3.0	(3.9)
Contract manufacturing	2.4	(12.1)	7.6	158.8	1.9	(44.8)
OTC and quasi-drugs	2.1	29.4	2.7	22.0	2.8	11.7
Royalty income	36.9	(23.6)	38.1	(13.3)	51.4	13.5
HIV Franchise	29.7	21.4	31.4	(3.7)	33.4	1.9
CRESTOR	5.6	1.1	5.5	1.8	5.5	(0.5)
Others	1.6	(91.0)	1.2	(80.1)	12.4	79.2
Others	0.5	(5.9)	0.6	6.7	0.6	(21.4)
Total	79.2	(10.5)	81.7	2.5	92.6	(4.5)

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

2 - 2. Quarterly trend for FY2018 and FY2019 (Consolidated statements of income)

Fiscal year ended March 31, 20	19						(Bi	illions of yen)
FY2018	FY2018 1Q	Y on Y	FY2018 2Q	Y on Y	FY2018 3Q	Y on Y	FY2018 4Q	Y on Y
112010	actual	change %	actual	change %	actual	change %	actual	change %
Net sales	88.5	18.0	79.7	(18.0)	97.0	6.4	98.5	21.1
	13.5		16.1		16.1		14.7	
Cost of sales	11.9	(40.2)	12.8	(35.1)	15.7	(8.2)	14.5	(15.6)
Gross profit	76.6	39.0	66.9	(13.6)	81.4	9.8	84.0	31.0
	55.3		46.7		42.5		43.5	
SG & A expenses	49.0	25.2	37.2	(1.1)	41.3	3.8	42.9	9.8
Selling & administrative expenses	24.3	9.7	23.3	(5.2)	26.9	10.9	27.5	11.6
R & D expenses	24.7	45.3	13.9	6.5	14.3	(7.4)	15.3	6.8
	31.2		37.2		41.3		41.7	
Operating income	27.6	72.9	29.7	(25.4)	40.1	16.7	41.1	63.8
Non-operating income & expenses	10.3		2.5		5.5		9.8	
Ordinary income	42.9 37.9	80.1	40.3 32.1	(27.8)	47.0 45.6	14.3	^{51.7} 50.9	53.3
Extraordinary income & losses	2.1		(0.0)		0.7		1.0	
Income before income taxes	40.1		32.1		46.2		51.9	
Income taxes and etc.	8.2		6.1		9.8		13.5	
Profit attributable to owners of parent	^{36.0} 31.9	99.2	^{32.6} 26.0	(24.2)	^{37.6} 36.4	24.0	^{39.0} 38.4	31.8

Fiscal vear ending March 31, 2020

Fiscal year ending March 31, 2						
FY2019	FY2019 1Q	Y on Y	FY2019 2Q	Y on Y	FY2019 3Q	Y on Y
112017	actual	change %	actual	change %	actual	change %
Net sales	79.2	(10.5)	81.7	2.5	92.6	(4.5)
	16.1		18.6		14.1	
Cost of sales	12.7	6.9	15.2	18.4	13.1	(16.3)
Gross profit	66.5	(13.2)	66.5	(0.6)	79.5	(2.3)
	47.4		45.7		41.5	
SG & A expenses	37.5	(23.3)	37.3	0.2	38.5	(6.8)
Selling & administrative expenses	25.7	5.8	26.2	12.5	26.9	(0.2)
R & D expenses	11.9	(51.9)	11.1	(20.4)	11.6	(19.2)
	36.6		35.8		44.4	
Operating income	29.0	4.7	29.2	(1.5)	41.1	2.4
Non-operating income & expenses	3.4		3.7		8.5	
	40.9		40.3		53.5	
Ordinary income	32.4	(14.6)	32.9	2.4	49.6	8.8
Extraordinary income & losses	(0.5)		2.6		2.5	
Income before income taxes	31.9		35.5		52.1	
Income taxes and etc.	7.5		8.3		12.8	
Profit attributable to owners of parent	^{30.8} 24.4	(23.4)	^{33.3} 27.2	4.6	^{42.3} 39.2	7.6

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3. Pipeline (as of February 3, 2020)

	Code No.	<u> </u>			1	
Areas	(Generic name)	Category (Administration)	Indication	Stage	Origin	Development
	[Product name]	. ,			× .	x 1
	S-649266 (Cefiderocol Tosilate Sulfate Hydrate) [US:Fetroja [®]]	Cephem antibiotic (injection)	USA: Complicated urinary tract infections, including pyelonephritis Europe: Infections due to aerobic gram-negative bacteria in adult patients with limited treatment options	Global: Phase III USA: Approval (Nov.2019) Europe: MAA submission (Mar.2019)	In-house	In-house
Infectious disease	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral, granule)	Influenza virus infection	Japan: Approval (body weight ≥20kg) (Sep.2018) Japan: NDA submission (body weight <20kg) (Aug.2018) Japan: Phase III (high dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: NDA submission (Oct. 2019)	In-house	Shionogi/Roche (Switzerland)
	S-648414	Anti-HIV infection (oral)	HIV infection	USA: Phase I	In-house	In-house
	S-297995 (naldemedine tosilate) [US/Japan:Symproic [®]] [EU: Rizmoic [®]]	Peripheral opioid receptor antagonist (oral, granule)	Opioid-induced constipation(pediatric)	Europe: Phase I/II	In-house	In-house
	S-297995 (naldemedine tosilate)	Peripheral opioid receptor antagonist (oral,)	Postoperative ileus	USA: Phase II	In-house	In-house
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purd ue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	S-010887	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purd ue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
Pain/CNS	S-600918	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	S-600918	Antitussive agent (oral)	Refractory/unexplained chronic cough	Global: Phase II	In-house	In-house
	S-637880	Analgesic agent for neuropathic pain (oral)	Neuropathic pain	Japan: Phase I	In-house	In-house
	LY248686 (duloxetine hydrochloride) [Cymbalta [®]]	SNRI (Serotonin– norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217 (Zuranolone)	GABAA receptor positive allosteric modulator (oral)	Depression	Japan: Phase I	Sage (USA)	Shionogi/Sage
	SDT-001	Treatment digital application based on cerebral mechanism	Inattention symptom in ADHD patients (pediatric)	Japan: Phase II	Akili (USA)	Shionogi/Akili

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II USA: Phase I	In-house	In-house
Metabolic disorder	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA: Phase IIa	In-house	In-house
	ADR-001	Human mesenchymal stem cells (injection)	Decompensated liver cirrhosis	Japan: Phase I/II	Rohto	Shionogi/Rohto
	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
Frontier	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house
	S-770108	Anti-fibrosis (inhalation)	Idiopathic pulmonary fibrosis	Japan: Phase I	In-house	In-house
	SR-0379	Cutaneous ulcer (topical)	Cutaneous ulcer (Pressure ulcer, Diabetic ulcer)	Japan: Phase II	FunPep (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Stroke (injection)	Stroke	Japan: Phase II	StemRIM (Japan)	In-house
	S-005151 (Redasemtide Trifluoroacetate)	Epidermolysis bullosa (injection)	Epidermolysis bullosa	Japan: Phase II	StemRIM (Japan)	In-house

<out-licensing activ<br="">Code No. (Generic name)</out-licensing>	Category	Indication	Stage	Origin	Development
[Product name]	(Administration)			-	_
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: Phase III (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) USA: NDA submission (Apr.2019) (CAB LAP for prevention) Global: Phase III	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: Phase III	In-house	Kissei Pharmaceutical Co., Ltd. (Japan)
S-033188 (baloxavir marboxil) [USA: Xofluza TM]	Anti-influenza virus infection (oral)	Influenza virus infection	USA: Approval (Oct.2018) USA: Approval (high risk patients) (Oct.2019) Europe: NDA submission (Nov.2019) Global: Phase III (severe influenza virus infection) Global: Phase III (pediatric) Global: Phase III (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]	Category (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 Oct 30, 2019

	S-649266 (Complicated urinary tract infections, including pyelonephritis): USA: NDA submission (Dec.2018) → Approval (Nov.2019)
~	S-297995(Opioid-induced constipation/pediatric) : Japan: Phase I \rightarrow Europe: Phase I/II
Change of phase	S/GSK1349572 (DTG+3TC 2-drug fixed dose combination tablet/naïve patients): Japan: NDA submission (Sep.2019)→Approval (Jan.2020)
	S-033188 (Influenza virus infection) : Europe : NDA submission (Nov.2019)
Compound added to	S-297995 (Postoperative ileus) : USA: Phase II
the list	SDT-001 (Inattention symptom in ADHD patients/pediatric) : Japan: Phase II
Compound erased	S-033188 (Influenza virus infection (oral)): Approved (Japan: Feb.2018, Taiwan (12 years of age and older): Aug.2019)
from the list	S-525606 (Allergic rhinitis caused by Japanese cedar allergen): Stop development