## Financial Results for the Third Quarter of Fiscal Year 2018(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 8, 2019

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, 2018 to December 31, 2018

(1) Consolidated operating results

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

	Net sales		Operating income		Ordinary income		Profit attributable to owners of parent	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Nine months ended December 31, 2018	265,242	0.7	97,423	8.1	115,649	9.7	94,344	18.3
Nine months ended December 31, 2017	263,362	2.7	90,124	2.7	105,471	15.9	79,727	18.0

Note: Comprehensive income Nine months ended December 31, 2018: 89,061 million yen ( (10.6)%) Nine months ended December 31, 2017: 99,603 million yen ( 66.5%)

	Earnings per share	Earnings per share (diluted)
	Yen	Yen
Nine months ended December 31, 2018	300.95	297.78
Nine months ended December 31, 2017	250.20	246.30

#### (2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity ratio
	Millions of yen	Millions of yen	%
As of December 31, 2018	718,607	633,438	87.5
As of March 31, 2018	711,463	604,840	84.5

Reference: Shareholders' equity As of December 31, 2018: 628,504 million yen As of March 31, 2018: 600,847 million yen

## 2. Dividends

Year ending March 31, 2019

	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, 2018	—	38.00	—	44.00	82.00			
Year ending March 31, 2019		44.00	—					
Year ending March 31, 2019				44.00	88.00			
(forecast)				44.00	00.00			

Note: Revisions of the most recent dividend forecast: None

## 3. Consolidated financial forecast for the year ending March 31, 2019

2.7

(% shows changes from the same period of the previous fiscal year) Profit attributable to Earnings per Net sales Ordinary income Operating income owners of parent share Millions of yen % Millions of yen % Millions of yen % Millions of yen % Yen

148,500

7.1

118.500

8.8

8.1

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

354.000

Pursuant to a resolution at a meeting of the Board of Directors held on July 30, 2018, the Company acquired its own shares.

"Earnings per share" in the consolidated financial forecast takes into account the impact of this share acquisition.

124.500



381.10

January 31, 2019 Listed Exchanges: Section I of Tokyo

## **※ 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, 2018:	324,136,165 shares
	As of March 31, 2018:	324,136,165 shares
b) Number of treasury stoc	k	
	As of December 31, 2018:	13,194,652 shares
	As of March 31, 2018:	9,780,027 shares
c) Average number of shar	es issued during the period	
	Nine months ended December 31, 2018: Nine months ended December 31, 2017:	

※ 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 2 of the supplemental materials for the Financial Results for the Third Quarter of Fiscal Year 2018 (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 Thrusday, January 31, 2019. Plans are also in place to post audio explanatory details together with financial results explanatory materials distributed to analysts on January 31, 2019 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, 2019

For the nine months ended December 31, 2018 (April 1, 2018 to December 31, 2018), net sales were ¥265,242 million, operating income was ¥97,423 million, ordinary income was ¥115,649 million, and profit attributable to owners of parent was ¥94,344 million.

Domestic sales of prescription drugs decreased 18.5 percent compared with the same period of the previous fiscal year. In the domestic prescription drug market, sales of strategic products Cymbalta, Intuniv and Symproic expanded steadily from the previous fiscal year. In addition, sales of anti-flu drug Xofluza increased sharply in the third quarter. At the same time, the significant impact of generic competition on sales of Crestor and Irbetan through the second quarter moderated in the third quarter. Despite a decrease in royalty income associated with the drop in sales of authorized generics in the United States, overseas subsidiary sales and exports increased 26.6 percent because Shionogi received a one-time payment in connection with the termination of the alliance with Purdue Pharma L.P. for the U.S. co-commercialization of Symproic. Royalty income increased 16.4 percent compared with the same period of the previous fiscal year as royalty income from ViiV Healthcare Ltd. (ViiV) grew with the steady expansion of global sales of anti-HIV drugs Tivicay and Triumeq by ViiV, and Shionogi received milestone payments from Roche in connection with the global development and U.S. approval of anti-flu drug Xofluza.

Gross profit increased 8.8 percent compared with the same period of the previous fiscal year, mainly due to the aforementioned increase in royalty income. Selling, general and administrative expenses increased 9.4 percent due to an increase in research and development expenses in connection with strategic business investments. However, operating income increased 8.1 percent because of the increase in gross profit. Ordinary income increased 9.7 percent due to the increase in dividends received from ViiV. Profit attributable to owners of parent increased 18.3 percent. During the nine months ended December 31, 2018, Shionogi recorded an extraordinary gain on the sale of the Nanjing Plant of C&O Pharmaceutical Technology (Holdings) Limited, and on the sale of investment securities. In addition, Shionogi recorded an extraordinary loss related to an earthquake centered in northern Osaka Prefecture that occurred in June 2018.

## (2) Financial Position for the Third Quarter of the Fiscal Year Ending March 31, 2019

As of December 31, 2018, total assets were ¥718,607 million, an increase of ¥7,143 million from the end of the previous fiscal year. Current assets increased ¥12,651 million to ¥392,155 million mainly because of an increase in cash and deposits and a decrease in short-term investment securities for surplus fund management. Non-current assets decreased ¥5,507 million to ¥326,451 million, largely because of the amortization of Intangible assets.

Total liabilities decreased ¥21,453 million from the end of the previous fiscal year to ¥85,169 million. Current liabilities increased ¥42 million to ¥72,608 million. Non-current liabilities decreased ¥21,496 million to ¥12,560 million, mainly due to the conversion of bonds (convertible bonds with warrants) and the reclassification of non-current liabilities to current portion of bonds.

Net assets increased ¥28,597 million from the end of the previous fiscal year to ¥633,438 million. Shareholders' equity increased ¥33,272 million to ¥612,529 million as a result of factors including an increase from profit attributable to owners of parent, a decrease due to cash dividends paid, and the purchase of treasury stock. Accumulated other comprehensive income decreased ¥5,614 million to ¥15,975 million, mainly due to foreign currency translation adjustment. Subscription rights to shares stood at ¥527 million, and non-controlling interests increased ¥939 million to ¥4,406 million.

## (3) Outlook

There are no revisions to the consolidated financial forecast announced on October 29, 2018.

# 2. Consolidated Financial Statements and Notes

(1) Consolidated balance sheets

	As of March 31, 2018	As of December 31, 2018
Assets		
Current assets		
Cash and deposits	140,106	173,27
Notes and accounts receivable-trade	53,240	59,60
Short-term investment securities	124,300	94,03
Merchandise and finished goods	14,716	16,43
Work in process	6,993	7,49
Raw materials and supplies	12,926	15,62
Other	27,257	25,73
Allowance for doubtful accounts	(36)	(3
Total current assets	379,504	392,15
Non-current assets		
Property, plant and equipment	75,956	73,53
Intangible assets		
Goodwill	32,852	31,69
Other	42,207	37,78
Total intangible assets	75,060	69,47
Investments and other assets		
Investment securities	155,675	156,02
Other	25,309	27,46
Allowance for doubtful accounts	(42)	(4
Total investments and other assets	180,942	183,44
Total non-current assets	331,959	326,45
Total assets	711,463	718,60
Liabilities		
Current liabilities		
Notes and accounts payable-trade	8,016	10,17
Current portion of bonds	—	2,35
Current portion of long-term loans payable	10,000	5,00
Income taxes payable	19,513	23,10
Provision for bonuses	8,741	5,06
Provision for sales returns	1,360	1,42
Other provision	105	
Other	24,829	25,48
Total current liabilities	72,565	72,60
Non-current liabilities		
Bonds payable	18,491	
Net defined benefit liability	8,096	8,07
Other	7,468	4,48
Total non-current liabilities	34,056	12,56
Total liabilities	106,622	85,16

		Millions of yen
	As of March 31, 2018	As of December 31, 2018
Net assets		
Shareholders' equity		
Capital stock	21,279	21,279
Capital surplus	20,227	20,512
Retained earnings	574,392	640,040
Treasury stock	(36,641)	(69,302)
Total shareholders' equity	579,257	612,529
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	35,856	34,570
Deferred gains or losses on hedges	1,174	2,195
Foreign currency translation adjustment	(15,330)	(21,896)
Remeasurements of defined benefit plans	(111)	1,104
Total accumulated other comprehensive income	21,589	15,975
Subscription rights to shares	527	527
Non-controlling interests	3,466	4,406
Total net assets	604,840	633,438
Total liabilities and net assets	711,463	718,607

(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, 2017	December 31, 2018
Net sales	263,362	265,242
Cost of sales	56,723	40,380
Gross profit	206,638	224,861
Selling, general and administrative expenses	116,514	127,438
Operating income	90,124	97,423
Non-operating income		
Interest income	805	1,657
Dividends income	16,934	18,859
Other	401	584
Total non-operating income	18,141	21,101
Non-operating expenses		
Interest expenses	292	256
Loss on retirement of non-current assets	275	681
Other	2,226	1,937
Total non-operating expenses	2,794	2,875
Ordinary income	105,471	115,649
Extraordinary income		
Gain on sales of non-current assets	_	2,870
Gain on sales of investment securities	_	1,497
Total extraordinary income	_	4,368
Extraordinary loss		
Loss on disaster	_	826
Loss on valuation of investment securities	733	439
Special retirement expenses	-	346
Impairment loss	333	-
Total extraordinary losses	1,067	1,611
Income before income taxes	104,404	118,406
Income taxes-current	25,613	28,165
Income taxes-deferred	(907)	(4,562)
Total income taxes	24,706	23,602
Profit	79,698	94,803
Profit (loss) attributable to non-controlling interests	(28)	458
Profit attributable to owners of parent	79,727	94,344

## Consolidated statements of comprehensive income

		Millions of yen
	Nine months ended	Nine months ended
	December 31, 2017	December 31, 2018
Profit	79,698	94,803
Other comprehensive income		
Valuation difference on available-for-sale securities	10,925	(1,286)
Deferred gains or losses on hedges	(1,701)	1,020
Foreign currency translation adjustment	8,403	(6,692)
Remeasurements of defined benefit plans	2,277	1,216
Total other comprehensive income	19,904	(5,741)
Comprehensive income	99,603	89,061
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	99,613	88,730
Comprehensive income attributable to non-controlling interests	(10)	331

(3) Notes

## Going concern assumption

None

## Significant changes in shareholders' equity

## Repurchase of Shares

Shionogi executed a repurchase of its own shares (7,350,400 shares) pursuant to the resolution of its Board of Directors meeting on July 30, 2018. As a result, treasury stock increased ¥49,999 million during the nine months ended December 31, 2018.

In addition, treasury stock increased by  $\pm$ 32,661 million in the third quarter, partly due to the conversion of convertible bonds. The amount of treasury stock held as of December 31, 2018 was  $\pm$ 69,302 million.

## Additional information

Application of Partial Amendments to Accounting Standard for Tax-Effect Accounting, Etc.

Shionogi has adopted the "Partial Amendments to Accounting Standard for Tax-Effect Accounting" (Accounting Standards Board of Japan Statement No. 28, February 16, 2018), etc. as of the first quarter of the fiscal year ending March 31, 2019. Accordingly, deferred tax assets are classified under investments and other assets, and deferred tax liabilities are classified under non-current liabilities.

# Supplemental material for financial results for the 3rd quarter of fiscal year 2018

# 1. Sales of segments

1. Sales of segments						(Bi	illions of yen)
	FY2018 2H forecast	FY2018 forecast	FY2018 3Q actual	FY2017 3Q actual	FY2018 1Q-3Q actual	FY2017 1Q-3Q actual	Progress %vs.FY2018 forecast
Prescription drugs	69.3	119.3	38.3	35.2	88.3	108.4	74.0
change %	4.9	(14.3)	8.8	(16.3)	(18.5)	(10.6)	/ 1.0
CYMBALTA	14.0	26.0	6.7	6.5	18.6	18.2	71.6
INTUNIV	3.8	6.1	1.6	0.5	3.9	1.2	64.1
XOFLUZA	12.5	13.0	9.5	_	9.9	_	76.4
RAPIACTA	1.1	1.1	0.8	1.2	0.8	1.2	68.4
BRIGHTPOC Flu	1.0	1.3	0.3	0.4	0.6	0.5	46.2
OXYCONTIN Franchise	4.8	8.7	2.0	2.4	5.8	7.0	67.1
SYMPROIC	0.8	1.6	0.5	0.2	1.2	0.4	76.0
Total of strategic products	38.2	57.7	21.2	11.2	40.8	28.6	70.7
ACTAIR	0.1	0.2	0.1	0.0	0.1	0.1	78.7
MULPLETA	0.1	0.2	0.0	0.0	0.1	0.1	65.3
PIRESPA	3.0	5.9	1.6	1.8	4.5	4.9	76.4
Total of new products	41.4	64.0	23.0	13.1	45.6	33.7	71.2
CRESTOR	4.5	9.7	2.7	4.3	7.8	26.3	81.0
<b>IRBETAN</b> Franchise	2.9	6.0	1.3	4.1	4.4	11.9	73.2
Other	20.5	39.6	11.4	13.6	30.5	36.5	76.9
Overseas subsidiaries/Export	15.9	31.3	6.7	5.3	22.1	17.5	70.6
change %	39.3	32.5	27.5	(30.9)	26.6	(23.8)	
Shionogi Inc.	5.0	12.4	2.0	2.3	9.4	8.4	75.6
Osphena	2.7	4.1	1.0	1.0	2.4	3.0	58.4
C&O	7.3	12.4	3.2	1.4	8.2	4.8	66.1
Contract manufacturing	7.2	12.9	3.4	3.4	9.2	11.8	71.0
change %	(15.8)	(23.8)	2.7	(1.4)	(22.1)	33.8	
OTC and quasi-drugs	3.6	7.4	2.5	2.3	6.3	5.7	85.5
change %	(7.5)	1.7	7.1	12.1	10.2	3.7	
Royalty income	88.4	180.6	45.3	44.3	137.5	118.1	76.1
change %	8.9	16.5	2.3	42.6	16.4	44.6	
HIV Franchise	67.8	124.9	32.8	27.8	89.9	74.0	72.0
CRESTOR	10.2	21.1	5.5	5.6	16.4	17.0	77.9
Others	10.4	34.6	6.9	10.9	31.2	27.1	90.0
Others	1.4	2.5	0.8	0.8	1.9	2.0	76.1
change %	(2.4)	(4.5)	(0.5)	(95.0)	(4.5)	(87.9)	
Total	185.8	354.0	97.0	91.2	265.2	263.4	74.9
change % Note: Change % shows changes from t	7.7	2.7	6.4	(10.1)	0.7	2.7	

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

January 31, 2019 Shionogi & Co., Ltd.

# 2 - 1. Quarterly trend for FY2017 and FY2018 (Sales of segments)

Fiscal year ended March 31, 2018	1							illions of yer
FY2017	FY2017 1Q	Y on Y	FY2017 2Q	Y on Y	FY2017 3Q	Y on Y	FY2017 4Q	Y on Y
112017	actual	change %						
Prescription drugs	37.3	(6.6)	35.9	(8.6)	35.2	(16.3)	30.8	(16.2
CYMBALTA	5.8	30.6	6.0	32.9	6.5	23.8	5.3	8.
INTUNIV	0.4	-	0.3	-	0.5	-	0.7	
SYMPROIC	0.0	-	0.1	-	0.2	-	0.2	
XOFLUZA	-	-	-	-	-	-	2.4	
Total of strategic products	6.2	39.9	6.4	42.8	7.3	37.9	8.6	77.
ACTAIR	0.0	131.4	0.0	50.9	0.0	48.7	0.0	45.
MULPLETA	0.0	41.4	0.0	33.8	0.0	38.8	0.0	(3.2
PIRESPA	1.4	(11.6)	1.7	20.8	1.8	18.6	1.5	17.
OXYCONTIN Franchise	2.4	(8.2)	2.2	(10.5)	2.4	(8.9)	1.7	(14.5
RAPIACTA	0.1	(57.5)	0.0	(417.7)	1.2	2.3	2.1	30.
BRIGHTPOC Flu	0.0	3.9	0.1	86.5	0.4	(14.8)	0.6	38.
GLASHVISTA	0.1	(40.3)	0.1	(78.3)	0.0	(53.8)	0.1	198.
Total of new products	10.2	14.0	10.5	21.1	13.2	17.5	14.7	43.
CRESTOR	12.1	5.6	9.9	(5.7)	4.3	(61.3)	3.0	(70.1
IRBETAN Franchise	3.7	(11.8)	4.0	12.6	4.1	3.2	2.7	(22.2
Other	11.3	(26.3)	11.4	(30.7)	13.6	(13.4)	10.5	(19.7
Overseas subsidiaries/Export	6.6	1.2	5.6	(36.1)	5.3	(30.9)	6.2	(2.3
Shionogi Inc.	3.5	(3.9)	2.6	(53.1)	2.3	(51.0)	2.2	(44.6
Osphena	1.1	(5.6)	0.9	6.4	1.0	(24.9)	0.7	(49.9
C&O	1.8	20.3	1.6	(1.7)	1.4	12.4	2.1	42.
Contract manufacturing	3.5	35.4	4.9	75.2	3.4	(1.4)	5.2	55.
OTC and quasi-drugs	1.6	(7.8)	1.8	4.8	2.3	12.1	1.5	19.
Royalty income	25.5	16.9	48.3	67.5	44.3	42.6	37.0	8.
HIV Franchise	18.6	82.3	27.6	49.7	27.8	34.9	29.4	22.
CRESTOR	5.7	(45.6)	5.6	(17.1)	5.6	(27.8)	5.6	(29.0
Others	0.6	(8.4)	0.7	11.3	0.8	(95.0)	0.6	(5.8
Total	75.0	2.5	97.1	18.6	91.2	(10.1)	81.3	(1.3

## Fiscal year ending March 31, 2019

riscal year ending March 31, 2019						
EV2019	FY2018 1Q	Y on Y	FY2018 2Q	Y on Y	FY2018 3Q	Y on Y
FY2018	actual	change %	actual	change %	actual	change%
Prescription drugs	25.4	(31.9)	24.6	(31.5)	38.3	8.8
CYMBALTA	6.1	6.1	5.8	(2.2)	6.7	2.1
INTUNIV	1.1	209.9	1.3	284.8	1.6	194.4
XOFLUZA	0.0	-	0.4	-	9.5	-
RAPIACTA	0.0	(76.4)	(0.0)	(131.8)	0.8	(33.9)
BRIGHTPOC Flu	0.0	(90.5)	0.2	168.5	0.3	(11.6)
OXYCONTIN Franchise	2.0	(15.2)	1.8	(16.8)	2.0	(18.7)
SYMPROIC	0.3	526.3	0.4	257.6	0.5	123.0
Total of strategic products	9.6	11.0	10.0	14.8	21.2	88.9
ACTAIR	0.0	47.4	0.0	63.3	0.1	61.0
MULPLETA	0.0	0.6	0.0	3.0	0.0	(2.2)
PIRESPA	1.4	(5.1)	1.5	(10.5)	1.6	(10.8)
Total of new products	11.0	8.8	11.6	10.8	23.0	74.7
CRESTOR	2.6	(78.1)	2.5	(74.6)	2.7	(38.1)
IRBETAN Franchise	1.9	(48.5)	1.1	(71.5)	1.3	(67.7)
Other	9.8	(13.8)	9.3	(18.6)	11.4	(16.7)
Overseas subsidiaries/Export	9.9	49.3	5.5	(1.1)	6.7	27.5
Shionogi Inc.	6.1	75.7	1.3	(49.7)	2.0	(14.6)
Osphena	0.8	(32.7)	0.7	(21.4)	1.0	(0.1)
C&O	2.3	31.0	2.7	69.2	3.2	125.0
Contract manufacturing	2.8	(20.5)	2.9	(40.1)	3.4	2.7
OTC and quasi-drugs	1.6	1.3	2.2	21.9	2.5	7.1
Royalty income	48.3	89.7	43.9	(9.2)	45.3	2.3
HIV Franchise	24.5	31.4	32.6	18.2	32.8	18.1
CRESTOR	5.5	(4.3)	5.4	(3.9)	5.5	(1.4)
Others	18.3	-	5.9	(61.1)	6.9	(36.0)
Others	0.6	1.8	0.6	(14.5)	0.8	(0.5)
Total	88.5	18.0	79.7	(18.0)	97.0	6.4

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

# 2 - 2. Quarterly trend for FY2017 and FY2018 (Consolidated statements of income)

Fiscal year ended March 31, 2018							(Bi	illions of yen)
FY2017	FY2017 1Q	Y on Y	FY2017 2Q	Y on Y	FY2017 3Q	Y on Y	FY2017 4Q	Y on Y
112017	actual	change %						
Net sales	75.0	2.5	97.1	18.6	91.2	(10.1)	81.3	(1.3)
	26.5		20.3		18.7		21.1	
Cost of sales	19.9	0.5	19.8	4.6	17.1	(18.6)	17.2	(5.1)
Gross profit	55.1	3.3	77.4	22.8	74.1	(7.9)	64.1	(0.2)
	52.1		38.7		43.6		48.0	
SG & A expenses	39.1	10.8	37.6	2.3	39.8	7.3	39.0	(10.9)
Selling & administrative expenses	22.1	(2.6)	24.5	7.8	24.3	3.8	24.7	2.0
R & D expenses	17.0	34.8	13.1	(6.8)	15.5	13.4	14.4	(26.7)
	21.3		40.9		37.7		30.9	
Operating income	16.0	(11.4)	39.8	51.5	34.4	(20.9)	25.1	22.7
Non-operating income & expenses	5.1		4.8		5.5		8.1	
	28.1		45.8		43.7		40.9	
Ordinary income	21.1	26.3	44.5	74.9	39.9	(18.3)	33.2	3.6
Extraordinary income & losses	(0.5)		(0.2)		(0.4)		(0.2)	
Income before income taxes	20.5		44.4		39.5		33.0	
Income taxes and etc.	4.5		10.0		10.1		3.8	
Profit attributable to	21.3		35.3		32.2		35.8	
owners of parent	16.0	27.7	34.3	83.9	29.4	(19.1)	29.1	78.4

## Fiscal year ending March 31, 2019

Fiscal year ending March 31, 2019						
FY2018	FY2018 1Q	Y on Y	FY2018 2Q	Y on Y	FY2018 3Q	Y on Y
	actual	change %	actual	change %	actual	change %
	00 <b>-</b>					
Net sales	88.5	18.0	79.7	(18.0)	97.0	6.4
	13.5		16.1		16.1	
Cost of sales	11.9	(40.2)	12.8	(35.1)	15.7	(8.2)
Gross profit	76.6	39.0	66.9	(13.6)	81.4	9.8
	55.3		46.7		42.5	
SG & A expenses	49.0	25.2	37.2	(1.1)	41.3	3.8
Selling & administrative expenses	24.3	9.7	23.3	(5.2)	26.9	10.9
R & D expenses	24.7	45.3	13.9	6.5	14.3	(7.4)
	31.2		37.2		41.3	
Operating income	27.6	72.9	29.7	(25.4)	40.1	16.7
Non-operating income & expenses	10.3		2.5		5.5	
	42.9		40.3		47.0	
Ordinary income	37.9	80.1	32.1	(27.8)	45.6	14.3
Extraordinary income & losses	2.1		(0.0)		0.7	
Income before income taxes	40.1		32.1		46.2	
Income taxes and etc.	8.2		6.1		9.8	
Profit attributable to	36.0		32.6		37.6	
owners of parent	31.9	99.2	26.0	(24.2)	36.4	24.0

# 3. Pipeline (as of January 31, 2019)

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
	S-649266 (Cefiderocol Tosilate Sulfate Hydrate)	Cephem antibiotic (injection)	Multidrug-resistant Gram -negative bacterial infections	Global: Phase III USA: NDA submission (in preparation)	In-house	In-house
	S-033188 (baloxavir marboxil) [Japan:Xofluza <sup>®</sup> ]	Anti-influenza virus infection (oral)	Influenza virus infection	Japan: Approval (Feb.2018) Taiwan: NDA submission (Jun.2018)	In-house	Shionogi/Roche (Switzerland)
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 (new dosage for children)	In-house	Shionogi/Roche (Switzerland)
	S-033188 (baloxavir marboxil) [Japan:Xofluza®]	Anti-influenza virus infection (oral)	Influenza virus infection (prophylaxis)	Japan: Phase III	In-house	Shionogi/Roche (Switzerland)
	S-297995 (naldemedine tosilate) [US/Japan:Symproic <sup>®</sup> ]	Peripheral opioid receptor antagonist (oral)	Opioid-induced constipation	USA, Japan: Approval (Mar.2017) Europe:MAA submission (Mar.2017)	In-house	In-house
	S-877489 (lisdexamfetamine mesilate)	DA and NE reuptake inhibitor/releaser of DA, NE (oral)	ADHD (pediatric)	Japan: NDA submission (Apr.2017)	Shire (Ireland)	Shionogi/Shire
	S-877503 (guanfacine hydrochloride) [Intuniv <sup>®</sup> ]	Alpha-2A-adrenergic receptor agonist (oral)	ADHD (adult)	Japan: NDA submission (Aug.2018)	Shire (Ireland)	Shionogi/Shire
	S-120083	Analgesic agent for inflammatory pain (oral)	Inflammatory pain	Japan: Phase I USA: Phase II	Shionogi/Purdue 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
Pain/CNS	S-117957	Agent for insomnia (oral)	Insomnia	USA: Phase I	Shionogi/Purdue Pharma L.P. (USA)	Shionogi/Purdue Pharma L.P.
	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	Japan: 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 <sup>®</sup> ]	SNRI (Serotonin– norepinephrine reuptake inhibitors) (oral)	Depression (pediatric)	Japan: Phase III	Eli Lilly (USA)	Shionogi/Eli Lilly Japan K.K.
	S-812217	GABAA receptor positive allosteric modulator (oral)	Depression	Japan: Phase I	Sage (USA)	Shionogi/Sage
Metabolic	S-237648	Neuropeptide Y Y5 receptor antagonist (oral)	Obesity	Japan: Phase II USA: Phase I	In-house	In-house
disorder	S-707106	Insulin sensitizer (oral)	Type 2 diabetes	USA: Phase IIa	In-house	In-house
Frontier	S-888711 (lusutrombopag) [US/Japan:Mulpleta <sup>®</sup> ]	Thrombopoetin (TPO) receptor agonist (oral)	Thrombocytopenia associated with chronic liver disease	Japan: Approval (Sep.2015) USA: Approval (Jul.2018) Europe:MAA submission (Jan.2018)	In-house	In-house
	S-588410	Cancer peptide vaccine (injection)	Esophageal cancer	Japan: Phase III	OncoTherapy Science, Inc. (Japan)	In-house

Areas	Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
	S-588410	Cancer peptide vaccine (injection)	Bladder cancer	Japan, Europe: Phase II	OncoTherapy Science, Inc. (Japan)	In-house
	8-525606	Sublingual tablet of Japanese cedar allergen extracts for immunotherapy (sublingual)	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase II	Stallergenes (France)	In-house
	S-488210	Cancer peptide vaccine (injection)	Head and neck squamous cell carcinoma	Europe: Phase I/II	OncoTherapy Science, Inc. (Japan)	In-house
Frontier	S-588210	Cancer peptide vaccine (injection)	Solid tumor	UK: Phase I	OncoTherapy Science, Inc. (Japan)	In-house
	S-222611 (epertinib)	HER2/EGFR dual inhibitor (oral)	Malignant tumor	Europe: Phase I/II	In-house	In-house
	S-770108	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	Stroke (injection)	Stroke	Japan: Phase I	StemRIM (Japan)	In-house

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Code No. (Generic name) [Product name]	Category (Administration)	Indication	Stage	Origin	Development
S/GSK1349572 (dolutegravir)	Integrase inhibitor (oral)	For the treatment of HIV infection	(DTG/3TC 2-drug fixed dose combination tablet for naïve patients) Europe: MAA submission (Sep.2018) USA: NDA submission (Oct.2018) (DTG+3TC 2-drug fixed dose combination tablet for maintenance therapy) Global: Phase III	Shionogi-ViiV Healthcare LLC	Viiv Healthcare Ltd. (UK)
S/GSK1265744 LAP* (cabotegravir)	Integrase inhibitor (injection)	For the treatment and prevention for HIV infection	Global: Phase III (treatment) Global: Phase III (prevention)	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)
Ospemifene [USA: Osphena <sup>®</sup> ]	Selective estrogen receptor modulator (oral)	Vaginal dryness associated with postmenopausal VVA	USA: Approval (Jan.2019)	QuatRx (USA)	Duchesnay(Canada)
S-033188 (baloxavir marboxil) [USA: Xofluza <sup>TM</sup> ]	Anti-influenza virus infection (oral)	Influenza virus infection	USA: Approval (Oct.2018) Global: Phase III (severe influenza virus infection) Global: Phase III (pediatric)	In-house	Shionogi/Roche (Switzerland)

\*: Long acting parenteral formulation

<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	Natural opium alkaloids (oral)	For the treatment of moderate to severe chronic pain	Japan;NDA submission (Nov.2016) Japan: Phase III	Napp Pharmaceuticals Limited (UK)	In-house
[OxyContin <sup>®</sup> ]					

Since October 29, 2018

	Ospemifene: USA: NDA submission (Mar. 2018)→Approval (Jan. 2019)
Change of phase	S-033188: Global: Phase III (high risk) Completion of study
	S-033188: Japan: Phase III (new dosage for children), Global: Phase III (pediatric) Initiation of studies
Pipeline	S-812217: Japan: Phase I
added to the list	S-588210 (Solid tumor): UK: Phase I