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May 15, 2019

**Consolidated Financial Results for the First Three Months of  
the Fiscal Year Ending December 31, 2019  
(under IFRS)**

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 Listing: Tokyo Stock Exchange  
 Securities code: 4597  
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Scheduled date to file quarterly securities report: May 15, 2019

Scheduled date to commence dividend payments: –

Preparation of supplementary material on quarterly financial results: None

Holding of quarterly financial results presentation meeting: None

(Millions of yen with fractional amounts discarded, unless otherwise noted)

**1. Consolidated financial results for the first three months of the fiscal year ending December 31, 2019  
(from January 1, 2019 to March 31, 2019)**

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Three months ended								
March 31, 2019	61	712.4	(494)	–	(499)	–	(560)	–
March 31, 2018	7	111.1	(325)	–	(325)	–	(320)	–

  

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Three months ended						
March 31, 2019	(560)	–	(560)	–	(5.35)	(5.35)
March 31, 2018	(320)	–	(320)	–	(3.65)	(3.65)

(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	Equity attributable to owners of parent per share
As of	Millions of yen	Millions of yen	Millions of yen	%	Yen
March 31, 2019	7,014	6,534	6,534	93.2	62.23
December 31, 2018	7,728	7,087	7,087	91.7	67.69

**2. Cash dividends**

	Annual cash dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2018	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2019	–				
Fiscal year ending December 31, 2019 (Forecast)		0.00	–	0.00	0.00

Note: Revisions to the forecast of cash dividends most recently announced: None

**3. Consolidated earnings forecasts for the fiscal year ending December 31, 2019  
(from January 1, 2019 to December 31, 2019)**

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Fiscal year ending December 31, 2019	500	56.9	(3,000)	–	(3,000)	–	(3,000)	–	(3,000)	–	(28.57)
	to 1,700	To 433.4	to (2,000)	to –	to (2,000)	to –	to (2,000)	to –	to (2,000)	to –	to (19.05)

Note: Revisions to the consolidated earnings forecasts most recently announced: None

\* Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in the change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates

1) Changes in accounting policies required by IFRS: Yes

2) Changes in accounting policies due to other reasons: None

3) Changes in accounting estimates: None

(3) Number of issued shares (ordinary shares)

1) Total number of issued shares at the end of the period (including treasury shares)

As of March 31, 2019	105,321,753 shares
As of December 31, 2018	105,022,169 shares

2) Number of treasury shares at the end of the period

As of March 31, 2019	320,000 shares
As of December 31, 2018	320,000 shares

3) Average number of shares during the period (cumulative from the beginning of the fiscal year)

For the three months ended March 31, 2019	104,814,577 shares
For the three months ended March 31, 2018	87,888,393 shares

\* Quarterly consolidated financial results reports are not subject to quarterly review procedures by the Company's independent auditor.

\* Proper use of earnings forecasts, and other special matters

The forward-looking statements, including earnings forecasts, contained in these materials are based on information currently available to the Company and on certain assumptions deemed to be reasonable. Actual business and other results may differ from the statements herein due to various factors.

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## 1. Qualitative information regarding results for the first three months

### (1) Explanation of operating results

#### 1) Overview of results

##### Operating results

	(Millions of yen)		
	Three months ended March 31, 2018	Three months ended March 31, 2019	Year-on-year
Revenue	7	61	53
Gross profit	1	61	60
Operating profit (loss)	(325)	(494)	(168)
Profit (loss)	(320)	(560)	(240)

In the three months ended March 31, 2019, Solasia Pharma K.K. (the “Company”) and its group company (collectively, the “Group”) have been focusing on strengthening the drug pipeline, through efforts centered on conducting clinical trials. We achieved a certain amount of progress with respect to the development pipeline such as through the March 2019 launch in China of pipeline product SP-01 and the February 2018 approval in China of pipeline product SP-03, as described below in section “3) R&D activities,” but continued making up-front investments, including those to promote clinical trials for pipeline products SP-02 and SP-04. Given these circumstances, our financial performance during the three months ended March 31, 2019, was as follows.

##### [Revenue]

During the three months ended March 31, 2019, pipeline products SP-03 etc. generated 61 million yen in milestone revenue owing to approval of SP-03 in China, up 53 million yen from the first three months of the preceding fiscal year.

##### [Gross profit]

Pipeline products mainly SP-03 produced gross profit of 61 million yen, stemming from milestone revenue, up 60 million yen from the first three months of the preceding fiscal year.

##### Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Three months ended March 31, 2018	Three months ended March 31, 2019	Year-on-year
R&D expenses	151	243	91
SG&A expenses	174	311	137
Total	326	555	228
(Breakdown)			
Personnel expenses	97	127	30
Outsourcing expenses	161	267	106
Other	67	159	92

[R&D expenses, SG&A expenses]

R&D expenses amounted to 243 million yen, up 91 million yen year on year. This amount is mainly attributable to expenses incurred for a multinational phase II clinical study (pivotal study) of SP-02 and a multinational phase III clinical study of SP-04 (Initiated in December 2018). SG&A expenses amounted to 555 million yen, up 228 million yen year on year, as a result of building of an independent sales structure in China by strengthening organization of personnel.

[Operating profit (loss)]

We incurred an operating loss of 494 million yen, which is an increase of 168 million yen year on year. In addition to gross profit having remained at the aforementioned levels, the operating loss is attributable to both research and development (R&D) expenses and selling, general and administrative (SG&A) expenses.

[Profit (loss)]

We incurred an overall loss of 560 million yen, mainly as a consequence of having posted the aforementioned operating loss.

[Capitalized costs included in intangible assets and amortization of intangible assets]

The Group posted a 669 million yen increase in intangible assets attributable to development costs and in-licensing expenses recognized as assets among pipeline investment outlays. In the three months ended March 31, 2019, pipeline investment amounted to 913 million yen. This figure includes the 669 million yen in intangible assets derived from capitalization of such outlays and 243 million yen in R&D expenses. However, amortization of intangible assets related to the Japanese business for pipeline product SP-03 and of intangible assets related to pipeline product SP-01 started in the previous year, leading to amortization of 97 million yen during the three months under review. As a result, the balance of intangible assets was 3,695 million yen as of March 31, 2019.

## 2) Cash flows

	(Millions of yen)		
	Three months ended March 31, 2018	Three months ended March 31, 2019	Year-on-year
Net cash provided by (used in) operating activities	(541)	(599)	(58)
Net cash provided by (used in) investing activities	(58)	(671)	(612)
Net cash provided by (used in) financing activities	4	(2)	(6)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 599 million yen (compared with 541 million yen in net cash used in these activities in the corresponding period of the previous fiscal year), which was mainly attributable to loss before tax of 499 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 671 million yen (compared with 58 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 669 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash used in financing activities amounted to 2 million yen (compared with 4 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 9 million yen in outflows related to repayments of lease liabilities and 7 million yen in proceeds from issuance of new shares by exercising stock acquisition rights.

3) R&D activities

R&D expenses amounted to 243 million yen. In addition, the Company recorded a 669 million yen increase in intangible assets attributable to development costs, which have been recognized as assets from among pipeline investment outlays. Meanwhile, total pipeline investment amounted to 913 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2019	Three months ended March 31, 2019	As of today
SP-01 Sancuso® China	Preparing for launch	Launch (in March 2019)	Ongoing sale
SP-02 darinaparsin Japan etc.	Multinational phase II clinical study (final clinical study) in progress	Multinational phase II clinical study (final clinical study) in progress	Multinational phase II clinical study (final clinical study) in progress
SP-03 episil® Japan	Ongoing sale	Ongoing sale	Ongoing sale
SP-03 episil® China	Application for approval filed	Obtained approval (in February 2019)	Preparing for launch
SP-04 PledOx® Japan etc.	Multinational phase III clinical study (final clinical study) in progress	Multinational phase III clinical study (final clinical study) in progress	Multinational phase III clinical study (final clinical study) in progress

Details regarding progress achieved with pipeline products are please refer to today's news release, entitled "Business Overview of Pipeline Products".

(2) Explanation of financial position

As of March 31, 2019, total assets amounted to 7,014 million yen, down 714 million yen from the previous year-end. Current assets were 3,127 million yen, including 2,774 million yen in cash and cash equivalents. Non-current assets came to 3,887 million yen. This figure includes 3,695 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 479 million yen, down 161 million yen from the previous year-end. Current liabilities were 345 million yen, including 259 million yen in trade and other payables. Non-current liabilities amounted to 133 million yen, mainly due to 72 million yen in deferred tax liabilities.

Total equity equaled 6,534 million yen, down 552 million yen from the previous year-end. The increase was mainly attributable to 7 million yen in proceeds from issuance of new shares by exercising stock acquisition rights. The decrease was mainly attributable to the overall loss of 560 million yen.

As of today, the overdraft and committed credit line with domestic banks total 3.5 billion yen. The entire amount is unused.

(3) Explanation of consolidated earnings forecasts and other forward-looking statements

The consolidated earnings forecasts are unchanged from the forecasts announced on February 13, 2019.

## 2. Condensed quarterly consolidated financial statements and significant notes thereto

### (1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2018	As of March 31, 2019
<b>Assets</b>		
Current assets		
Cash and cash equivalents	4,046	2,774
Trade and other receivables	193	69
Inventories	122	124
Other current assets	143	159
Total current assets	4,504	3,127
Non-current assets		
Property, plant and equipment	58	56
Light-of-use asset	—	92
Intangible assets	3,123	3,695
Other non-current assets	42	42
Total non-current assets	3,224	3,887
Total assets	7,728	7,014
<b>Liabilities and equity</b>		
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	580	259
Lease liabilities	—	41
Other current liabilities	39	43
Total current liabilities	619	344
Non-current liabilities		
Deferred tax liabilities	11	72
Lease liabilities	—	52
Other non-current liabilities	10	10
Total non-current liabilities	21	135
Total liabilities	641	479
<b>Equity</b>		
Share capital	7,632	7,636
Capital surplus	7,483	7,486
Retained earnings	(7,975)	(8,536)
Treasury stock	(48)	(48)
Other components of equity	(3)	(2)
Total equity	7,087	6,534
Total liabilities and equity	7,728	7,014

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Three months ended March 31, 2018	Three months ended March 31, 2019
Revenue	7	61
Cost of sales	6	—
Gross profit	1	61
Research and development expenses	151	243
Selling, general and administrative expenses	174	311
Operating profit (loss)	(325)	(494)
Finance income	0	0
Finance costs	0	6
Other income	0	0
Profit (loss) before tax	(325)	(499)
Income taxes	(5)	61
Profit (loss)	(320)	(560)
Profit (loss) attributable to:		
Owners of parent	(320)	(560)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(3.65)	(5.35)
Diluted earnings (loss) per share [yen]	(3.65)	(5.35)



(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Three months ended March 31, 2018	Three months ended March 31, 2019
Profit (loss)	(320)	(560)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	0	0
Subtotal	0	0
Total other comprehensive income	0	0
Comprehensive income	(320)	(560)
Comprehensive income attributable to:		
Owners of parent	(320)	(560)

## (4) Condensed consolidated statement of changes in equity

(Millions of yen)

	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity	Total equity
Balance at January 1, 2018	5,962	5,801	(5,553)	—	(2)	6,208
Comprehensive income						
Profit (loss)	—	—	(320)	—	—	(320)
Other comprehensive income	—	—	—	—	0	0
Total comprehensive income	—	—	(320)	—	0	(320)
Transactions with owners						
Issuance of new shares	—	—	—	—	—	—
Exercise of share acquisition rights	2	2	—	—	—	4
Total transactions with owners	2	2	—	—	—	4
Balance at March 31, 2018	5,965	5,803	(5,874)	—	(2)	5,892
Balance at January 1, 2019	7,632	7,483	(7,975)	(48)	(3)	7,087
Comprehensive income						
Profit (loss)	—	—	(560)	—	—	(560)
Other comprehensive income	—	—	—	—	0	0
Total comprehensive income	—	—	(560)	—	0	(560)
Transactions with owners						
Issuance of new shares	—	—	—	—	—	—
Exercise of share acquisition rights	4	3	—	—	—	7
Total transactions with owners	4	3	—	—	—	7
Balance at March 31, 2019	7,636	7,486	(8,536)	(48)	(2)	6,534

## (5) Condensed consolidated statement of cash flows

(Millions of yen)

	Three months ended March 31, 2018	Three months ended March 31, 2019
Cash flows from operating activities		
Profit (loss) before tax	(325)	(499)
Depreciation and amortization	3	110
Finance income	(0)	(0)
Finance costs	0	6
Decrease (increase) in trade and other receivables	(5)	124
Decrease (increase) in inventories	(34)	(2)
Increase (decrease) in trade and other payables	(202)	(320)
Other	21	(17)
Subtotal	(541)	(599)
Interest received	0	0
Interest paid	(0)	(0)
Net cash provided by (used in) operating activities	(541)	(599)
Cash flows from investing activities		
Purchase of property, plant and equipment	(22)	(1)
Purchase of intangible assets	(36)	(669)
Other	0	(0)
Net cash provided by (used in) investing activities	(58)	(671)
Cash flows from financing activities		
Proceeds from issuance of new shares	4	7
Repayment of lease liabilities	(0)	(9)
Net cash provided by (used in) financing activities	4	(2)
Net increase (decrease) in cash and cash equivalents	(595)	(1,273)
Cash and cash equivalents at beginning of period	3,370	4,046
Effect of exchange rate changes on cash and cash equivalents	(2)	1
Cash and cash equivalents at end of period	2,772	2,774

(6) Notes to condensed quarterly consolidated financial statements

(Notes on premise of going concern)

No items to report.

(Change in Accounting Policies)

The significant accounting policies adopted for the Group's condensed quarterly consolidated financial statements are the same as those for the consolidated financial statements for the previous year except for the items described below.

In the three months ended March 31, 2019, the Group adopted IFRS 16 "Leases" (announced in January 2016), in compliance with each transitional provision.

The Group has retroactively applied IFRS 16 in compliance with the transitional provisions. To determine whether arrangements included leases, when transitioning to IFRS 16 the Group selected the practical expedients in Paragraph C3 of IFRS 16, and maintained its judgments based on IAS 17 "Leases" (hereinafter, "IAS 17"), and IFRIC 4 "Determining Whether an Arrangement Contains a Lease." For leases categorized as operating leases, to which the Group previously applied IAS 17, lease obligations were recognized on the date the application of IFRS 16 began. For lease obligations, the remaining lease fees were measured at present value, discounted by the borrower's additional borrowing rate as of the date when application began. The weighted average of the borrower's additional borrowing rate applied to lease obligations recognized in the consolidated statement of financial position as of the date when application began is 1.4%.