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May 14, 2020

# Consolidated Financial Results for the First Three Months of the Fiscal Year Ending December 31, 2020 (under IFRS)

Company name: Solasia Pharma K.K. Listing: Tokyo Stock Exchange

Securities code: 4597

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Scheduled date to file quarterly securities report: May 14, 2020

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, 2020 (from January 1, 2020 to March 31, 2020)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
Three months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
March 31, 2020	156	154.5	(534)	_	(537)	_	(531)	_
March 31, 2019	61	712.4	(494)	_	(499)	_	(560)	_

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
Three months ended	Millions of yen	%	Millions of yen	%	Yen	Yen
March 31, 2020	(531)	_	(532)	_	(4.57)	(4.57)
March 31, 2019	(560)	_	(560)	_	(5.35)	(5.35)

(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, 2020	7,136	6,385	6,385	89.5	54.84
December 31, 2019	7,946	6,917	6,917	87.0	59.43

#### 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, 2019	_	0.00	-	0.00	0.00				
Fiscal year ending December 31, 2020	_								
Fiscal year ending December 31, 2020 (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, 2020 (from January 1, 2020 to December 31, 2020)

(Percentages indicate year-on-year changes.)

	Reve	nue	Operating profit		Profit before tax Profit		fit	Profit attributable to owners of parent		Basic earnings per share	
	Millions	%	Millions	%	Millions	%	Millions	%	Millions	%	Yen
	of yen		of yen		of yen		of yen		of yen		
Fiscal year ending	500	(61.8)	(2,900)	_	(2,900)	_	(2,900)	_	(2,900)	_	(24.91)
December 31,2020	~	~	~	~	~	~	~	~	~	~	~
December 51,2020	2,000	52.6	(2,000)	_	(2,000)	_	(2,000)	_	(2,000)	_	(17.18)

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: None
  - 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, 2020		116,865,795 shares
As of December 31, 2019		116,835,795 shares

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

As of March 31, 2020	440,000 shares
As of December 31, 2019	440,000 shares

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

For the three months ended March 31, 2020	116,406,015 shares
For the three months ended March 31, 2019	104,814,577 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.

### [Attached Material]

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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, 2019	Three months ended March 31, 2020	Year-on-year
Revenue	61	156	94
Gross profit	61	112	51
Operating profit (loss)	(494)	(534)	(40)
Profit (loss)	(560)	(531)	29

In the three months ended March 31, 2020, Solasia Pharma K.K. (the "Company") and its group company (collectively, the "Group") focused on enhancing the pharmaceutical business, as well as strengthening and commercializing the drug development pipeline, while weathering impact from the spread of the novel coronavirus disease.

The spread of the novel coronavirus disease greatly hindered access to medical sites and various activities performed by Group medical representatives (MRs) responsible for promoting sales of Sancuso® (SP-01) and episil® (SP-03), which were launched in China during the previous fiscal year. However, as of the submission date of this document, MRs are gradually regaining permission to visit hospitals and contact medical personnel in the Company's sales areas in China.

Aside from products that have been successfully commercialized, two pipeline products reached the final stages of clinical development. Patient registration reached the target number of cases for the Phase II clinical trial (pivotal study) of our pipeline product SP-02 in 2019, and during the three months ended March 31, 2020, we conducted development that primarily involved the study drug administration and case data collection. Development of SP-04 has reached the Phase III clinical trial stage. As of the submission date of this document, 590 patients had been enrolled for the trial (out of a target of 700). However, we have decided to suspend both new patient enrollment and study drug administration in March and April 2020 and to bring this trial to its conclusion after making an early cut-off of case data collection (data cut-off) in the third quarter of 2020. Starting in the fourth quarter of the fiscal year ending December 31, 2020, we will conduct detailed and robust evaluations of the safety and effectiveness of SP-04 focusing on information acquired through the completion of trial. The decision was taken after a recommendation from the independent Drug Safety Monitoring Board (DSMB) to stop the studies due to a number of severe allergic reactions, which have been observed after repeated dosing. Afterward, we will formulate further plans for SP-04.

As indicated above, we have focused on achieving progress in terms of both our products and pipeline products. On the financial front, however, we continue making up-front investments, as product sales have just entered the initial stages. Given these circumstances, our financial performance during the three months ended March 31, 2020, was as follows.

#### [Revenue, Gross profit]

During the three months ended March 31, 2020, revenue totaled 156 million yen, up 94 million yen from the first three months of the preceding fiscal year. Revenue mainly came from the sales of pipeline products of Sancuso® (SP-01) and episil® (SP-03). In addition, gross profit amounted to 112 million yen, up 51 million yen from the first three months of the preceding fiscal year. The increase was attributable to

the aforementioned growth in revenue.

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

(Millions of yen)

	Three months ended March 31, 2019	Three months ended March 31, 2020	Year-on-year
R&D expenses	243	255	12
SG&A expenses	311	391	79
Total	555	647	91
(Breakdown) Personnel expenses	127	158	30
Outsourcing expenses	267	302	34
Depreciation and amortization of intangible assets	110	124	13
Other	49	62	13

#### [R&D expenses, SG&A expenses, Operating profit (loss), Profit (loss)]

R&D expenses amounted to 255 million yen, up 12 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. SG&A expenses amounted to 391 million yen, up 79 million yen year on year, as a result of building of an independent sales structure in China by strengthening organization of personnel and amortization of intangible assets.

The Company incurred an operating loss of 534 million yen, which is a increase of 40 million yen year on year.

The Company incurred an overall loss of 531million 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 2 million yen increase in intangible assets attributable to development costs and inlicensing expenses recognized as assets among pipeline investment outlays. In the three months ended March 31, 2020, pipeline investment amounted to 258 million yen. This figure includes the 2 million yen in intangible assets derived from capitalization of such outlays and 255 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01) and episil® (SP-03), leading to amortization of 109 million yen during the three months under review. As a result, the balance of intangible assets was 3,378 million yen as of March 31, 2020.

#### 2) Cash flows

(Millions of ven)

	Three months ended March 31, 2019	Three months ended March 31, 2020	Year-on-year
Net cash provided by (used in) operating activities	(599)	(751)	(151)
Net cash provided by (used in) investing activities	(671)	(4)	666
Net cash provided by (used in) financing activities	(2)	(11)	(8)

#### [Cash flows from operating activities]

Net cash used in operating activities amounted to 751 million yen (compared with 599 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 537 million yen.

#### [Cash flows from investing activities]

Net cash used in investing activities amounted to 4 million yen (compared with 671 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 2 million yen in outflows related to capitalized development investment.

#### [Cash flows from financing activities]

Net cash used in financing activities amounted to 11 million yen (compared with 2 million yen used in these activities in the same period of the previous year). This figure was mainly attributable to 11 million yen in outflows related to repayments of lease liabilities.

#### 3) R&D activities

R&D expenses amounted to 255 million yen. In addition, the Company recorded a 2 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 258 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2020	Three months ended March 31, 2020	As of today
SP-01 Sancuso® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-02 darinaparsin Japan etc. SP-03 episil®	Multinational phase II clinical study (final clinical study) in progress; Completion of subject- enrollment Ongoing sale	Multinational phase II clinical study (final clinical study) in progress; Completion of subject- enrollment Ongoing sale	Multinational phase II clinical study (final clinical study) in progress Completion of subject- enrollment Ongoing sale
Japan SP-03 episil® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-04 PledOx <sup>®</sup> Japan etc.	Multinational phase III clinical study (completion of subject-enrollment for POLAR-A study) in progress	Suspended patient recruitment and the study drug administration in the multinational phase III clinical study	Decision reached to suspend patient recruitment and the study drug administration in the multinational phase III clinical study, and to make an early cut-off of case data collection in the third quarter of 2020

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, 2020, total assets amounted to 7,136 million yen, down 810 million yen from the previous year-end. Current assets were 3,612 million yen, including 3,344 million yen in cash and cash equivalents. Non-current assets came to 3,523 million yen. This figure includes 3,378 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 751 million yen, down 278 million yen from the previous year-end. Current liabilities were 661 million yen, including 578 million yen in trade and other payables. Non-current liabilities amounted to 89 million yen, mainly due to 60 million yen in deferred tax liabilities.

Total equity equaled 6,385 million yen, down 532 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 531 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 for the fiscal year ending December 31, 2020 (announced on February 13, 2020) reflect the impact of the novel coronavirus disease to some extent, and the Company has made no change to its forecasts as of the date this document was published. However, if the spread of the virus continues longer than anticipated, we cannot deny the possibility that it could have a stronger impact on product sales, development (primarily clinical development), and other elements of our business than initially estimated. We will promptly disclose any potential impact on our earnings forecasts as soon as the Company becomes clear.

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

# (1) Condensed consolidated statement of financial position

		(Millions of yen)
	As of December 31, 2019	As of March 31, 2020
Assets		
Current assets		
Cash and cash equivalents	4,116	3,344
Trade and other receivables	10	100
Inventories	3	1
Other current assets	172	165
Total current assets	4,302	3,612
Non-current assets		
Property, plant and equipment	46	44
Light-of-use asset	66	55
Intangible assets	3,485	3,378
Other non-current assets	45	45
Total non-current assets	3,644	3,523
Total assets	7,946	7,136
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	800	578
Lease liabilities	41	38
Other current liabilities	84	45
Total current liabilities	925	661
Non-current liabilities		
Deferred tax liabilities	65	60
Lease liabilities	27	19
Other non-current liabilities	10	10
Total non-current liabilities	103	89
Total liabilities	1,029	751
Equity		
Share capital	960	961
Capital surplus	4,630	4,630
Retained earnings	1,400	869
Treasury stock	(70)	(70)
Other components of equity	(4)	(5)
Total equity	6,917	6,385
Total liabilities and equity	7,946	7,136

## (2) Condensed consolidated statement of profit or loss

		(Millions of yen)
	Three months ended March 31, 2019	Three months ended March 31, 2020
Revenue	61	156
Cost of sales		43
Gross profit	61	112
Research and development expenses	243	255
Selling, general and administrative expenses	311	391
Operating profit (loss)	(494)	(534)
Finance income	0	3
Finance costs	6	6
Other income	0	_
Other costs		0
Profit (loss) before tax	(499)	(537)
Income taxes	61	(6)
Profit (loss)	(560)	(531)
Profit (loss) attributable to:		
Owners of parent	(560)	(531)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(5.35)	(4.57)
Diluted earnings (loss) per share [yen]	(5.35)	(4.57)

## (3) Condensed consolidated statement of comprehensive income

		(Millions of yen)
	Three months ended March 31, 2019	Three months ended March 31, 2020
Profit (loss)	(560)	(531)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	0	(1)
Subtotal	0	(1)
Total other comprehensive income	0	(1)
Comprehensive income	(560)	(532)
Comprehensive income attributable to:		
Owners of parent	(560)	(532)

# (4) Condensed consolidated statement of changes in equity

					(1	Millions of yen)
	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity	Total equity
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						
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
Balance at January 1, 2020 Comprehensive income	960	4,630	1,400	(70)	(4)	6,917
Profit (loss)	_	_	(531)	_	_	(531)
Other comprehensive income	_	_	_	_	(1)	(1)
Total comprehensive income		_	(531)	_	(1)	(532)
Transactions with owners						
Exercise of share acquisition rights	0	0	_	_	_	0
Total transactions with owners	0	0				0
Balance at March 31, 2020	961	4,630	869	(70)	(5)	6,385

#### (5) Condensed consolidated statement of cash flows

		(Millions of yen)
	Three months ended March 31, 2019	Three months ended March 31, 2020
Cash flows from operating activities		
Profit (loss) before tax	(499)	(537)
Depreciation and amortization	110	124
Finance income	(0)	(3)
Finance costs	6	6
Decrease (increase) in trade and other receivables	124	(90)
Decrease (increase) in inventories	(2)	1
Increase (decrease) in trade and other payables	(320)	(213)
Other _	(17)	(38)
Subtotal	(599)	(751)
Interest received	0	0
Interest paid	(0)	(0)
Net cash provided by (used in) operating activities	(599)	(751)
Cash flows from investing activities		
Purchase of property, plant and equipment	(1)	(1)
Purchase of intangible assets	(669)	(2)
Other	(0)	0
Net cash provided by (used in) investing activities	(671)	(4)
Cash flows from financing activities		
Proceeds from issuance of new shares	7	0
Repayment of lease liabilities	(9)	(11)
Net cash provided by (used in) financing activities	(2)	(11)
Net increase (decrease) in cash and cash equivalents	(1,273)	(766)
Cash and cash equivalents at beginning of period	4,046	4,116
Effect of exchange rate changes on cash and cash equivalents	1	(5)
Cash and cash equivalents at end of period	2,774	3,344

#### (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.