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May 15, 2018

# Consolidated Financial Results for the First Three Months of the Fiscal Year Ending December 31, 2018 (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 15, 2018

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, 2018 (from January 1, 2018 to March 31, 2018)

(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, 2018	7	111.1	(325)	_	(325)	_	(320)	_
March 31, 2017	3	(98.2)	(243)	_	(247)	_	(241)	_

	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, 2018	(320)	_	(320)	_	(3.65)	(3.65)
March 31, 2017	(241)	_	(241)	_	(3.62)	(3.62)

(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, 2018	6,131	5,892	5,892	96.1	66.98
December 31, 2017	6,655	6,208	6,208	93.3	70.75

#### 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, 2017	_	0.00	_	0.00	0.00				
Fiscal year ending December 31, 2018	_								
Fiscal year ending December 31, 2018 (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, 2018 (from January 1, 2018 to December 31, 2018)

(Percentages indicate year-on-year changes.)

	(1 eronitages mareate year on year enaugest)										
	Reve	nue	Operating	g profit	Profit bef	ore tax	Prof	fit	Prot attributa owners of	ble to	Basic earnings per share
	Millions	%	Millions	%	Millions	%	Millions	%	Millions	%	Yen
	of yen		of yen		of yen		of yen		of yen		
T2' 1 1'	100	(75.7)	(3,200)	_	(3,200)	_	(3,200)	_	(3,200)	_	(36.47)
Fiscal year ending December 31, 2018	to	to	to	to	to	to	to	to	to	to	to
Beccinioci 31, 2010	600	46.0	(3,000)	_	(3,000)	_	(3,000)	_	(3,000)	_	(34.19)

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, 2018	87,972,341 shares
As of December 31, 2017	87,753,903 shares

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

As of March 31, 2018	- shares
As of December 31, 2017	- shares

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

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For the thr	ee months ended March 31, 2018	87,888,393 shares
For the thr	ee months ended March 31, 2017	66,552,053 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.

In the past, the Company posted amounts for the line items in its condensed quarterly consolidated financial statements and other matters in thousands of yen. From the first three months under review, we have changed this notation to millions of yen.

### [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, 2017	Three months ended March 31, 2018	Year-on-year
Revenue	3	7	3
Gross profit	3	1	(2)
Operating profit (loss)	(243)	(325)	(82)
Profit (loss)	(241)	(320)	(79)

In the three months ended March 31, 2018, 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 as described below in section "3) Research and development activities," but continued making upfront investments despite an absence of products on the market. Given these circumstances, our financial performance during the three months ended March 31, 2018, was as follows.

#### [Revenue, gross profit]

Pipeline product SP-03 generated 7 million yen in sample sales in preparation for launch in Japan and other sales, up 3 million yen from the first three months of the preceding fiscal year.

#### [Gross profit]

Pipeline product SP-03 produced gross profit of 1 million yen, stemming from sample sales in preparation for launch in Japan and other sales. This figure was 2 million yen lower than in the corresponding period of the previous fiscal year.

#### [Operating profit (loss)]

We incurred an operating loss of 325 million yen, which is an increase of 82 million yen year on year. In addition to gross profit having remained at the aforementioned levels, the operating loss is attributable both to having posted 151 million yen in research and development (R&D) expenses—which are a component of development investment undertaken to enhance pipeline development—and to having posted 174 million yen in selling, general and administrative (SG&A) expenses. We incurred SG&A expenses to establish a framework geared to promoting development and commercialization. A breakdown of SG&A expenses is presented in the table titled, "Breakdown of R&D and SG&A expenses."

#### [Profit (loss)]

We incurred an overall loss of 320 million yen, mainly as a consequence of having posted the aforementioned operating loss.

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

(Millions of yen)

	Three months ended March 31, 2017	Three months ended March 31, 2018	Year-on-year
R&D expenses	126	151	25
SG&A expenses	120	174	54
Total	246	326	79
(Breakdown) Personnel expenses	57	97	39
Outsourcing expenses	135	161	25
Other	53	67	13

#### [R&D expenses, SG&A expenses]

R&D expenses amounted to 151 million yen, up 25 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 phase I clinical study of SP-04. SG&A expenses amounted to 174 million yen, up 54 million yen year on year, as a result of strengthening our corporate structure.

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

The Group posted a 19 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, 2018, pipeline investment amounted to 171 million yen. This figure includes the 19 million yen in intangible assets derived from capitalization of such outlays and 151 million yen in R&D expenses. However, sample sales triggered amortization of intangible assets related to the Japanese business for pipeline product SP-03, amortizing 3 million yen during the three months under review. As a result, the balance of intangible assets was 3,101 million yen as of March 31, 2018.

#### 2) Cash flows

(Millions of yen)

	Three months ended March 31, 2017	Three months ended March 31, 2018	Year-on-year
Net cash provided by (used in) operating activities	(283)	(541)	(257)
Net cash provided by (used in) investing activities	(40)	(58)	(18)
Net cash provided by (used in) financing activities	3,273	4	(3,269)

#### [Cash flows from operating activities]

Net cash used in operating activities amounted to 541 million yen (compared with 283 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 325 million yen.

#### [Cash flows from investing activities]

Net cash used in investing activities amounted to 58 million yen (up from 40 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 36 million yen in outflows related to capitalized development investment.

#### [Cash flows from financing activities]

Net cash provided by financing activities amounted to 4 million yen (down from 3,273 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 4 million yen in proceeds from issuance of new shares by exercising stock acquisition rights.

#### 3) R&D activities

R&D expenses amounted to 151 million yen. In addition, the Company recorded a 19 million yen increase in intangible assets attributable to SP-01 and SP-03 development costs, which have been recognized as assets from among pipeline investment outlays. Meanwhile, total pipeline investment amounted to 171 million yen, and the balance of intangible assets was 3,101 million yen (after deducting amortization of 3 million yen) as of March 31, 2018, due to the application of the 3 million yen in amortization described above.

Details regarding progress achieved with pipeline products are as follows.

#### ■ SP-01 Sancuso®

Granisetron transdermal delivery system

Indication: Chemotherapy-induced nausea and vomiting

Company's rights: China (including Hong Kong and Macau), Taiwan, Malaysia and Singapore

Licensee of commercial rights, etc.:

- · China rights (excluding Beijing, Shanghai, and Guangzhou) Lee's Pharmaceutical (HK) Limited
- · Rights for Hong Kong, Macau, Taiwan, Malaysia, and Singapore Kyowa Hakko Kirin Co., Ltd.

Status of development and commercialization:

· China Phase III clinical study completed, application for approval filed (filed in June 2014)

#### ■ SP-02 darinaparsin

Mitochondria-targeted apoptosis inducer

Indication: Peripheral T-cell lymphoma

Company's rights: Worldwide rights Licensee of commercial rights, etc.:

· Japan rights Meiji Seika Pharma Co., Ltd.

Status of development and commercialization:

· Japan, Korea, Taiwan, and Hong Kong Multinational phase II clinical study (final clinical study) in progress

· U.S. Phase II clinical study completed (conducted by licensor ZIOPHARM Oncology, Inc.)

#### ■ SP-03 episil®

Substance for covering oral lesions (brand name in Japan: episil® (oral liquid))

Indication: The protection and relief of oral pain associated with oral mucositis/stomatitis caused

by chemotherapy and radiotherapy for cancer

Company's rights: Japan and China (including Hong Kong and Macau)

Licensee of commercial rights, etc.:

· Japan rights Meiji Seika Pharma Co., Ltd.

· China rights (excluding Beijing, Shanghai and Guangzhou) Lee's Pharmaceutical (HK) Limited

Status of development and commercialization:

· Japan Development completed, NDA approved, Listing of Reimbursement (in April 2018)

and Launch (scheduled in May 2018)

· China Development completed, application for approval filed (in May 2016)

#### ■ SP-04 PledOx®

Intracellular superoxide removing agent (iron chelating agent)

Indication: Chemotherapy-induced peripheral neuropathy

Company's rights: Japan, China (including Hong Kong and Macau), Korea and Taiwan

Status of development and commercialization:

· Japan Phase I clinical study (subjects of the trial have consisted of Japanese nationals

residing in the U.S.) terminated (in February 2018)

#### (2) Explanation of financial position

As of March 31, 2018, total assets amounted to 6,131 million yen, down 524 million yen from the previous year-end. Current assets were 2,943 million yen, including 2,772 million yen in cash and cash equivalents. Non-current assets came to 3,187 million yen. This figure includes 3,101 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 239 million yen, down 207 million yen from the previous year-end. Current liabilities were 198 million yen, including 161 million yen in trade and other payables. Non-current liabilities amounted to 40 million yen, mainly due to 29 million yen in deferred tax liabilities.

Total equity equaled 5,892 million yen, down 316 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 320 million yen.

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

The consolidated earnings forecasts are unchanged from the forecasts announced on February 9, 2018.

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

# (1) Condensed consolidated statement of financial position

		(Millions of yen)
	As of December 31, 2017	As of March 31, 2018
Assets		
Current assets		
Cash and cash equivalents	3,370	2,772
Trade and other receivables	18	24
Inventories	93	127
Other current assets	43	19
Total current assets	3,525	2,943
Non-current assets		
Property, plant and equipment	0	42
Intangible assets	3,085	3,101
Other non-current assets	43	43
Total non-current assets	3,129	3,187
Total assets	6,655	6,131
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	372	161
Other current liabilities	39	37
Total current liabilities	411	198
Non-current liabilities		
Deferred tax liabilities	34	29
Other non-current liabilities	0	11
Total non-current liabilities	34	40
Total liabilities	446	239
Equity		
Share capital	5,962	5,965
Capital surplus	5,801	5,803
Retained earnings	(5,553)	(5,874)
Other components of equity	(2)	(2)
Total equity	6,208	5,892
Total liabilities and equity	6,655	6,131

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

		(Millions of yen)	
	Three months ended March 31, 2017	Three months ended March 31, 2018	
Revenue	3	7	
Cost of sales		6	
Gross profit	3	1	
Research and development expenses	126	151	
Selling, general and administrative expenses	120	174	
Operating profit (loss)	(243)	(325)	
Finance income	0	0	
Finance costs	4	0	
Other income	0	0	
Profit (loss) before tax	(247)	(325)	
Income taxes	(6)	(5)	
Profit (loss)	(241)	(320)	
Profit (loss) attributable to:			
Owners of parent	(241)	(320)	
Earnings (loss) per share			
Basic earnings (loss) per share [yen]	(3.62)	(3.65)	
Diluted earnings (loss) per share [yen]	(3.62)	(3.65)	

## (3) Condensed consolidated statement of comprehensive income

		(Millions of yen)
	Three months ended March 31, 2017	Three months ended March 31, 2018
Profit (loss)	(241)	(320)
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	(241)	(320)
Comprehensive income attributable to:		
Owners of parent	(241)	(320)

# (4) Condensed consolidated statement of changes in equity

				(M	fillions of yen)
	Share capital	Capital surplus	Retained earnings	Other components of equity	Total equity
Balance at January 1, 2017	4,053	3,929	(4,546)	(2)	3,433
Comprehensive income					
Profit (loss)	_	_	(241)	_	(241)
Other comprehensive income		_	_	0	0
Total comprehensive income			(241)	0	(241)
Transactions with owners					
Issuance of new shares	1,654	1,619		_	3,273
Total transactions with owners	1,654	1,619	_	_	3,273
Balance at March 31, 2017	5,707	5,548	(4,787)	(2)	6,465
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	_	<u> </u>	4
Total transactions with owners	2	2	_	_	4
Balance at March 31, 2018	5,965	5,803	(5,874)	(2)	5,892

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

		(Millions of yen)
	Three months ended March 31, 2017	Three months ended March 31, 2018
Cash flows from operating activities		
Profit (loss) before tax	(247)	(325)
Depreciation and amortization	0	3
Finance income	(0)	(0)
Finance costs	4	0
Decrease (increase) in trade and other receivables	(10)	(5)
Decrease (increase) in inventories	(25)	(34)
Increase (decrease) in trade and other payables	(20)	(202)
Other	16	21
Subtotal	(283)	(541)
Interest received	0	0
Net cash provided by (used in) operating activities	(283)	(541)
Cash flows from investing activities		
Purchase of property, plant and equipment	_	(22)
Purchase of intangible assets	(40)	(36)
Other	0	0
Net cash provided by (used in) investing activities	(40)	(58)
Cash flows from financing activities		
Proceeds from issuance of new shares	3,273	4
Other	(0)	(0)
Net cash provided by (used in) financing activities	3,273	4
Net increase (decrease) in cash and cash equivalents	2,949	(595)
Cash and cash equivalents at beginning of period	1,038	3,370
Effect of exchange rate changes on cash and cash equivalents	(2)	(2)
Cash and cash equivalents at end of period	3,985	2,772

#### (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, 2018, the Group adopted IFRS 9 "Financial instruments" (issued in July 2014), IFRS 15 "Revenue from contracts with Customers" (issued in May 2014) and "Clarifications to IFRS 15" (issued in April 2016) in compliance with each transitional provision. The application of these standards did not have any impact on the Group's condensed quarterly consolidated financial statements.