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November 14, 2018

Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2018 (under IFRS)

Company name:	Solasia Pharma K.K.
Listing:	Tokyo Stock Exchange
Securities code:	4597
URL:	https://www.solasia.co.jp/en/
Representative:	Yoshihiro Arai, President and Chief Executive Officer
Contact:	Toshio Miyashita, Chief Financial Officer, Director TEL: +81-3-5843-8049

Scheduled date to file quarterly securities report:	November 14, 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 nine months of the fiscal year ending December 31, 2018 (from January 1, 2018 to September 30, 2018)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
Nine months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
September 30, 2018	110	(72.9)	(1,538)	–	(1,549)	–	(1,533)	–
September 30, 2017	409	103.4	(424)	–	(430)	–	(411)	–

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
Nine months ended	Millions of yen	%	Millions of yen	%	Yen	Yen
September 30, 2018	(1,533)	–	(1,534)	–	(17.16)	(17.16)
September 30, 2017	(411)	–	(411)	–	(5.11)	(5.11)

(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
September 30, 2018	8,233	7,975	7,975	96.9	76.19
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	–	0.00	–		
Fiscal year ending December 31, 2018 (Forecast)				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.)

	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, 2018	100 to 600	(75.7) to 46.0	(3,200) to (3,000)	– to –	(3,200) to (3,000)	– to –	(3,200) to (3,000)	– to –	(3,200) to (3,000)	– to –	(35.80) to (33.56)

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 September 30, 2018	104,681,669 shares
As of December 31, 2017	87,753,903 shares

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

As of September 30, 2018	– shares
As of December 31, 2017	– shares

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

For the nine months ended September 30, 2018	89,379,777 shares
For the nine months ended September 30, 2017	80,426,425 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 nine months ended September 30, 2018

(1) Explanation of operating results

1) Overview of results

Operating results

(Millions of yen)

	Nine months ended September 30, 2017	Nine months ended September 30, 2018	Year-on-year
Revenue	409	110	(298)
Gross profit	409	38	(370)
Operating profit (loss)	(424)	(1,538)	(1,114)
Profit (loss)	(411)	(1,533)	(1,122)

In the nine months ended September 30, 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, such as through the May 2018 launch in Japan of pipeline product SP-03 (brand name in Japan: episil® (oral liquid)) and the July 2018 approval in China of pipeline product SP-01, as described below in section "3) Research and development activities," but continue making upfront investments. Given these circumstances, our financial performance during the nine months ended September 30, 2018, was as follows.

[Revenue]

During the nine months ended September 30, 2018, pipeline products SP-03 and SP-01 generated 110 million yen in sales and milestone revenue. Revenue in the nine months ended September 30, 2017 was mainly attributable to pipeline product SP-03 generated 400 million yen in milestone revenue owing to manufacturing/marketing approval in Japan. Revenue decreased by 298 million yen year on year.

[Gross profit]

Pipeline products mainly SP-03 and SP-01 produced gross profit of 38 million yen, stemming from sales and milestone revenue in Japan and other. This figure was 370 million yen lower than in the corresponding period of the previous fiscal year, due mainly to lower revenue.

[Operating profit (loss)]

We incurred an operating loss of 1,538 million yen, which is an increase of 1,114 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 893 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 683 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 1,533 million yen, mainly as a consequence of having posted the aforementioned operating loss.

Breakdown of R&D and SG&A expenses

(Millions of yen)

	Nine months ended September 30, 2017	Nine months ended September 30, 2018	Year-on-year
R&D expenses	391	893	502
SG&A expenses	442	683	240
Total	833	1,577	743
(Breakdown) Personnel expenses	201	305	103
Outsourcing expenses	487	941	453
Other	144	330	186

[R&D expenses, SG&A expenses]

R&D expenses amounted to 893 million yen, up 502 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 preparation of multinational phase III clinical study (pivotal study) of SP-04. SG&A expenses amounted to 683 million yen, up 240 million yen year on year, as a result of strengthening our corporate structure and amortization of intangible assets.

[Capitalized costs included in intangible assets]

The Group posted a 173 million yen increase in intangible assets attributable to development costs and in-licensing expenses recognized as assets among pipeline investment outlays. In the nine months ended September 30, 2018, pipeline investment amounted to 1,067 million yen. This figure includes the 173 million yen in intangible assets derived from capitalization of such outlays and 893 million yen in R&D expenses. However, sales triggered amortization of intangible assets related to the Japanese business for pipeline product SP-03, and regulatory approval and the start of purchase order of pipeline product SP-01 triggered amortization of intangible assets, leading to amortization of 50 million yen during the nine months under review. As a result, the balance of intangible assets was 3,208 million yen as of September 30, 2018.

2) Cash flows

(Millions of yen)

	Nine months ended September 30, 2017	Nine months ended September 30, 2018	Year-on-year
Net cash provided by (used in) operating activities	(522)	(1,849)	(1,326)
Net cash provided by (used in) investing activities	(397)	(176)	221
Net cash provided by (used in) financing activities	3,781	3,301	(480)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 1,849 million yen (compared with 522 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 1,549 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 176 million yen (down from 397 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 136 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 3,301 million yen (down from 3,781 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 3,301 million yen in proceeds from issuance of new shares by public offering, etc.

3) R&D activities

R&D expenses amounted to 893 million yen. In addition, the Company recorded a 173 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 1,067 million yen, and the balance of intangible assets was 3,208 million yen (after deducting amortization of 50 million yen) as of September 30, 2018, due to the application of the 50 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 Approved by China National Drug Administration (CNDA) (in July 2018)

■ 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.
- Latin America rights HB Human BioScience SAS

Status of development and commercialization:
- Japan, South 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, China (including Hong Kong and Macau) and South Korea

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 Launch (in May 2018)
- China Development completed, application for approval filed (in May 2016)
- South Korea In-licensing, preparing for application for approval

■ 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), South 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)
- Japan, South Korea, Taiwan and Hong Kong Multinational phase III clinical study (final clinical study) in preparation(scheduled to start in the second half of 2018)

(2) Explanation of financial position

As of September 30, 2018, total assets amounted to 8,233 million yen, up 1,578 million yen from the previous year-end. Current assets were 4,934 million yen, including 4,647 million yen in cash and cash equivalents. Non-current assets came to 3,299 million yen. This figure includes 3,208 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 258 million yen, down 188 million yen from the previous year-end. Current liabilities were 227 million yen, including 185 million yen in trade and other payables. Non-current liabilities amounted to 30 million yen, mainly due to 19 million yen in deferred tax liabilities.

Total equity equaled 7,975 million yen, up 1,767 million yen from the previous year-end. The increase was mainly attributable to 3,301 million yen in proceeds from issuance of new shares by public offering, etc. The decrease was mainly attributable to the overall loss (loss for the nine months ended September 30, 2018) of 1,533 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 indicated in our earnings announcement on February 9, 2018. However, one assumption behind these forecasts was that the multinational phase II clinical study (pivotal study) of SP-02 in Japan and other countries would be closed during 2018. Given that the registration of patients for this clinical study is currently at 80% over of the target number of cases, we have revised our expected closing date to "within 2019." For details, please refer to today's news release, entitled "Business Overview of Pipeline Products."

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 September 30, 2018
Assets		
Current assets		
Cash and cash equivalents	3,370	4,647
Trade and other receivables	18	58
Inventories	93	186
Other current assets	43	41
Total current assets	3,525	4,934
Non-current assets		
Property, plant and equipment	0	49
Intangible assets	3,085	3,208
Other non-current assets	43	41
Total non-current assets	3,129	3,299
Total assets	6,655	8,233
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	372	185
Other current liabilities	39	42
Total current liabilities	411	227
Non-current liabilities		
Deferred tax liabilities	34	19
Other non-current liabilities	0	10
Total non-current liabilities	34	30
Total liabilities	446	258
Equity		
Share capital	5,962	7,628
Capital surplus	5,801	7,438
Retained earnings	(5,553)	(7,087)
Other components of equity	(2)	(3)
Total equity	6,208	7,975
Total liabilities and equity	6,655	8,233

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2017	Nine months ended September 30, 2018
Revenue	409	110
Cost of sales	–	71
Gross profit	409	38
Research and development expenses	391	893
Selling, general and administrative expenses	442	683
Operating profit (loss)	(424)	(1,538)
Finance income	0	0
Finance costs	6	11
Other income	0	0
Profit (loss) before tax	(430)	(1,549)
Income taxes	(19)	(15)
Profit (loss)	(411)	(1,533)
Profit (loss) attributable to:		
Owners of parent	(411)	(1,533)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(5.11)	(17.16)
Diluted earnings (loss) per share [yen]	(5.11)	(17.16)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2017	Nine months ended September 30, 2018
Profit (loss)	(411)	(1,533)
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	(411)	(1,534)
Comprehensive income attributable to:		
Owners of parent	(411)	(1,534)

(4) Condensed consolidated statement of changes in equity

(Millions 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)	–	–	(411)	–	(411)
Other comprehensive income	–	–	–	0	0
Total comprehensive income	–	–	(411)	0	(411)
Transactions with owners					
Issuance of new shares	1,902	1,865	–	–	3,767
Exercise of share acquisition rights	7	6	–	–	14
Total transactions with owners	1,909	1,872	–	–	3,782
Balance at September 30, 2017	5,962	5,801	(4,957)	(2)	6,804
Balance at January 1, 2018	5,962	5,801	(5,553)	(2)	6,208
Comprehensive income					
Profit (loss)	–	–	(1,533)	–	(1,533)
Other comprehensive income	–	–	–	(0)	(0)
Total comprehensive income	–	–	(1,533)	(0)	(1,534)
Transactions with owners					
Issuance of new shares	1,643	1,614	–	–	3,257
Exercise of share acquisition rights	22	21	–	–	43
Total transactions with owners	1,665	1,636	–	–	3,301
Balance at September 30, 2018	7,628	7,438	(7,087)	(3)	7,975

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2017	Nine months ended September 30, 2018
Cash flows from operating activities		
Profit (loss) before tax	(430)	(1,549)
Depreciation and amortization	0	53
Finance income	(0)	(0)
Finance costs	6	11
Decrease (increase) in trade and other receivables	(15)	(40)
Decrease (increase) in inventories	(25)	(93)
Increase (decrease) in trade and other payables	(60)	(230)
Other	1	(1)
Subtotal	(523)	(1,849)
Interest received	0	0
Net cash provided by (used in) operating activities	(522)	(1,849)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(41)
Purchase of intangible assets	(377)	(136)
Other	(19)	1
Net cash provided by (used in) investing activities	(397)	(176)
Cash flows from financing activities		
Proceeds from issuance of new shares	3,782	3,301
Other	(0)	(0)
Net cash provided by (used in) financing activities	3,781	3,301
Net increase (decrease) in cash and cash equivalents	2,861	1,275
Cash and cash equivalents at beginning of period	1,038	3,370
Effect of exchange rate changes on cash and cash equivalents	(2)	1
Cash and cash equivalents at end of period	3,897	4,647

(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" (revised 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.