



August 10, 2018

Consolidated Financial Results for the Six 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: August 10, 2018
 Scheduled date to commence dividend payments: –
 Preparation of supplementary material on quarterly financial results: Yes
 Holding of quarterly financial results presentation meeting: Yes (for institutional investors and analysts)

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

1. Consolidated financial results for the six months of the fiscal year ending December 31, 2018 (from January 1, 2018 to June 30, 2018)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
June 30, 2018	84	–	(923)	–	(926)	–	(916)	–
June 30, 2017	5	(97.2)	(553)	–	(558)	–	(545)	–

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
Six months ended	Millions of yen	%	Millions of yen	%	Yen	Yen
June 30, 2018	(916)	–	(916)	–	(10.41)	(10.41)
June 30, 2017	(545)	–	(545)	–	(7.11)	(7.11)

(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
June 30, 2018	5,676	5,303	5,303	93.4	60.01
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	(75.7)	(3,200)	–	(3,200)	–	(3,200)	–	(3,200)	–	(36.47)
	to	to	to	to	to	to	to	to	to	to	to
	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 June 30, 2018	88,376,650 shares
As of December 31, 2017	87,753,903 shares

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

As of June 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 six months ended June 30, 2018	88,019,949 shares
For the six months ended June 30, 2017	76,720,414 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.

A financial results presentation meeting will be held on Thursday, August 16, 2018 for institutional investors and analysts.

The presentation materials used at the meeting will be available on our website immediately after the meeting.

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1. Qualitative information regarding results for the six months

(1) Explanation of operating results

1) Overview of results

Operating results

	Six months ended June 30, 2017	Six months ended June 30, 2018	(Millions of yen) Year-on-year
Revenue	5	84	78
Gross profit	5	12	6
Operating profit (loss)	(553)	(923)	(370)
Profit (loss)	(545)	(916)	(370)

In the six months ended June 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, as described below in section “3) R&D activities,” but continue making upfront investment. Given these circumstances, our financial performance during the six months ended June 30, 2018, was as follows.

[Revenue, gross profit]

During the six months ended June 30, 2018, pipeline products SP-03(brand name in Japan: episil® (oral liquid)) and SP-01 generated 84 million yen in sales, up 78 million yen from the first six months of the preceding fiscal year.

[Gross profit]

Pipeline products SP-03 and SP-01 produced gross profit of 12 million yen, stemming from sales in Japan and other. This figure was 6 million yen higher than in the corresponding period of the previous fiscal year.

[Operating profit (loss)]

We incurred an operating loss of 923 million yen, which is an increase of 370 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 483 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 452 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 916 million yen, mainly as a consequence of having posted the aforementioned operating loss.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Six months ended June 30, 2017	Six months ended June 30, 2018	Year-on-year
R&D expenses	285	483	197
SG&A expenses	272	452	179
Total	558	935	377
(Breakdown)			
Personnel expenses	127	195	67
Outsourcing expenses	329	514	185
Other	102	225	123

[R&D expenses, SG&A expenses]

R&D expenses amounted to 483 million yen, up 197 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 452 million yen, up 179 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 157 million yen increase in intangible assets attributable to development costs and in-licensing expenses recognized as assets among pipeline investment outlays. In the six months ended June 30, 2018, pipeline investment amounted to 640 million yen. This figure includes the 157 million yen in intangible assets derived from capitalization of such outlays and 483 million yen in R&D expenses. However, sales triggered amortization of intangible assets related to the Japanese business for pipeline product SP-03, amortizing 12 million yen during the six months under review. As a result, the balance of intangible assets was 3,231 million yen as of June 30, 2018.

2) Cash flows

	(Millions of yen)		
	Six months ended June 30, 2017	Six months ended June 30, 2018	Year-on-year
Net cash provided by (used in) operating activities	(628)	(1,157)	(528)
Net cash provided by (used in) investing activities	(125)	(150)	(25)
Net cash provided by (used in) financing activities	3,780	11	(3,768)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 1,157 million yen (compared with 628 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 926 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 150 million yen (up from 125 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 118 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 11 million yen (down from 3,780 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 11 million yen in proceeds from issuance of new shares by exercising stock acquisition rights.

3) R&D activities

R&D expenses amounted to 483 million yen. In addition, the Company recorded a 157 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 640 million yen, and the balance of intangible assets was 3,231 million yen (after deducting amortization of 12 million yen) as of June 30, 2018, due to the application of the 12 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 China National Drug Administration (CNDA) approved (As of today)

■ 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 Launch (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)
- Japan, 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 June 30, 2018, total assets amounted to 5,676 million yen, down 978 million yen from the previous year-end. Current assets were 2,360 million yen, including 2,070 million yen in cash and cash equivalents. Non-current assets came to 3,316 million yen. This figure includes 3,231 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 373 million yen, down 72 million yen from the previous year-end. Current liabilities were 338 million yen, including 299 million yen in trade and other payables. Non-current liabilities amounted to 35 million yen, mainly due to 24 million yen in deferred tax liabilities.

Total equity equaled 5,303 million yen, down 905 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 916 million yen.

In June 2018, the Company signed commitment line agreements with Mizuho Bank, Ltd., and Sumitomo Mitsui Banking Corp. totaling 2.5 billion yen. As of June 30, 2018, the unused portion of these commitment lines was 2.5 billion yen. As of the same date, total liquidity on hand, which is the sum of cash and cash equivalents, overdraft facilities, and commitment lines, was 7,170 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 June 30, 2018
Assets		
Current assets		
Cash and cash equivalents	3,370	2,070
Trade and other receivables	18	59
Inventories	93	189
Other current assets	43	40
Total current assets	3,525	2,360
Non-current assets		
Property, plant and equipment	0	41
Intangible assets	3,085	3,231
Other non-current assets	43	43
Total non-current assets	3,129	3,316
Total assets	6,655	5,676
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	372	299
Other current liabilities	39	39
Total current liabilities	411	338
Non-current liabilities		
Deferred tax liabilities	34	24
Other non-current liabilities	0	11
Total non-current liabilities	34	35
Total liabilities	446	373
Equity		
Share capital	5,962	5,969
Capital surplus	5,801	5,807
Retained earnings	(5,553)	(6,470)
Other components of equity	(2)	(2)
Total equity	6,208	5,303
Total liabilities and equity	6,655	5,676

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Six months ended June 30, 2017	Six months ended June 30, 2018
Revenue	5	84
Cost of sales	—	71
Gross profit	5	12
Research and development expenses	285	483
Selling, general and administrative expenses	272	452
Operating profit (loss)	(553)	(923)
Finance income	0	0
Finance costs	5	3
Other income	0	0
Profit (loss) before tax	(558)	(926)
Income taxes	(12)	(10)
Profit (loss)	(545)	(916)
Profit (loss) attributable to:		
Owners of parent	(545)	(916)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(7.11)	(10.41)
Diluted earnings (loss) per share [yen]	(7.11)	(10.41)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Six months ended June 30, 2017	Six months ended June 30, 2018
Profit (loss)	(545)	(916)
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	(545)	(916)
Comprehensive income attributable to:		
Owners of parent	(545)	(916)

(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)	—	—	(545)	—	(545)
Other comprehensive income	—	—	—	0	0
Total comprehensive income	—	—	(545)	0	(545)
Transactions with owners					
Issuance of new shares	1,902	1,865	—	—	3,767
Exercise of share acquisition rights	6	6	—	—	12
Total transactions with owners	1,908	1,871	—	—	3,780
Balance at June 30, 2017	5,961	5,800	(5,091)	(2)	6,668
Balance at January 1, 2018	5,962	5,801	(5,553)	(2)	6,208
Comprehensive income					
Profit (loss)	—	—	(916)	—	(916)
Other comprehensive income	—	—	—	(0)	(0)
Total comprehensive income	—	—	(916)	(0)	(916)
Transactions with owners					
Issuance of new shares	—	—	—	—	—
Exercise of share acquisition rights	6	5	—	—	11
Total transactions with owners	6	5	—	—	11
Balance at June 30, 2018	5,969	5,807	(6,470)	(2)	5,303

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Six months ended June 30, 2017	Six months ended June 30, 2018
Cash flows from operating activities		
Profit (loss) before tax	(558)	(926)
Depreciation and amortization	0	13
Finance income	(0)	(0)
Finance costs	5	3
Decrease (increase) in trade and other receivables	(25)	(41)
Decrease (increase) in inventories	(25)	(96)
Increase (decrease) in trade and other payables	(26)	(112)
Other	1	1
Subtotal	(628)	(1,157)
Interest received	0	0
Net cash provided by (used in) operating activities	(628)	(1,157)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(32)
Purchase of intangible assets	(123)	(118)
Other	(1)	0
Net cash provided by (used in) investing activities	(125)	(150)
Cash flows from financing activities		
Proceeds from issuance of new shares	3,780	11
Other	(0)	(0)
Net cash provided by (used in) financing activities	3,780	11
Net increase (decrease) in cash and cash equivalents	3,026	(1,296)
Cash and cash equivalents at beginning of period	1,038	3,370
Effect of exchange rate changes on cash and cash equivalents	(2)	(3)
Cash and cash equivalents at end of period	4,062	2,070

(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.