August 10, 2017

Consolidated Financial Results for the Six Months of the Fiscal Year Ending December 31, 2017 (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
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Scheduled date to file quarterly securities report: August 10, 2017
Scheduled date to commence dividend payments: –
Preparation of supplementary material on quarterly financial results: None
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, 2017 (from January 1, 2017 to June 30, 2017)

(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, 2017	5	(97.2)	(553)	–	(558)	–	(545)	–
June 30, 2016	201	–	(254)	–	(266)	–	(261)	–

	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, 2017	(545)	–	(545)	–	(7.11)	(7.11)
June 30, 2016	(261)	–	(263)	–	(10.61)	(10.61)

(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, 2017	6,904	6,668	6,668	96.6	76.08
December 31, 2016	3,704	3,433	3,433	92.7	53.14

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, 2016	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2017	–	0.00			
Fiscal year ending December 31, 2017 (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, 2017 (from January 1, 2017 to December 31, 2017)

(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, 2017	423	(15.6)	(1,787)	–	(1,793)	–	(1,798)	–	(1,798)	–	(23.44)

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 June 30, 2017	87,648,903 shares
As of December 31, 2016	64,608,303 shares

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

As of June 30, 2017	– shares
As of December 31, 2016	– shares

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

For the six months ended June 30, 2017	76,720,414 shares
For the six months ended June 30, 2016	38,963,233 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.

A financial results presentation meeting will be held on Tuesday, August 22, 2017 for institutional investors and analysts.

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

[Attached Material]

Index

1. Qualitative information regarding results for the six months

(1) Explanation of operating results

1) Overview of results

Operating results

(Thousands of yen)

	Six months ended June 30, 2016	Six months ended June 30, 2017	Year-on-year
Revenue	201,319	5,632	(195,686)
Gross profit	201,319	5,632	(195,686)
Operating profit (loss)	(254,350)	(553,091)	(298,740)
Profit (loss)	(261,809)	(545,737)	(283,928)

In the six months ended June 30, 2017, Solasia Pharma K.K. (the “Company”) and its group company (collectively, the “Group”) have been focusing on strengthening the drug development pipeline and commercializing products, 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 continue making upfront investment amid a situation where we still have an absence of products on the market. Amid these circumstances, our financial performance during the six months ended June 30, 2017, was as follows.

[Revenue, gross profit]

During the six months ended June 30, 2017, pipeline product SP-01 generated net proceeds on product sales of 5,632 thousand yen. Consequently, there was revenue and gross profit of that same amount. Revenue and gross profit both decreased by 195,686 thousand yen year on year because of 200,000 thousand yen in milestone payments generated by pipeline product SP-02 in the six months ended June 30, 2016.

[Operating profit (loss)]

In the six months ended June 30, 2017, we incurred an operating loss of 553,091 thousand yen, which is an increase of 298,740 thousand yen in comparison with the operating loss incurred during the six months ended June 30, 2016. In addition to gross profit having remained at aforementioned levels, the operating loss is attributable both to having posted 285,761 thousand yen in research and development expenses which are a component of development investment undertaken to enhance pipeline development, and to having posted 272,963 thousand yen in selling, general and administrative expenses mainly incurred for establishing a framework geared to promoting such development. The breakdown of selling, general and administrative expenses are as presented in the table titled, “Breakdown of research and development expenses and selling, general and administrative expenses.”

[Profit (loss)]

In the six months ended June 30, 2017, we incurred an overall loss of 545,737 thousand yen mainly as a consequence of having posted the aforementioned operating loss.

Breakdown of research and development expenses and selling, general and administrative expenses

(Thousands of yen)

	Six months ended June 30, 2016	Six months ended June 30, 2017	Year-on-year
Research and development expenses	252,145	285,761	33,616
Selling, general and administrative expenses	203,525	272,963	69,437
Total	455,670	558,724	103,053
(Breakdown) Personnel expenses	110,576	127,362	16,785
Outsourcing expenses	267,183	329,349	62,166
Other	77,910	102,012	24,101

[Research and development expenses, selling, general and administrative expenses]

In the six months ended June 30, 2017, research and development expenses amounted to 285,761 thousand yen, which is an increase of 33,616 thousand yen in comparison with the six months ended June 30, 2016. This amount is mainly attributable to expenses incurred for multinational phase II clinical study (pivotal study) of SP-02. Selling, general and administrative expenses amounted to 272,963 thousand yen, which is an increase of 69,437 thousand yen in comparison with the six months ended June 30, 2016, as a result of strengthening corporate structure.

[Capitalized costs included in intangible assets]

In the six months ended June 30, 2017, there was a 125,513 thousand yen increase recorded 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, 2017, pipeline investment amounted to 411,274 thousand yen in total, which consists of the 125,513 thousand yen in intangible assets derived from capitalization of such outlays and 285,761 thousand yen in research and development expenses. The balance of intangible assets amounted to 2,700,969 thousand yen as of June 30, 2017.

2) Cash flows

(Thousands of yen)

	Six months ended June 30, 2016	Six months ended June 30, 2017	Year-on-year
Net cash provided by (used in) operating activities	(277,708)	(628,898)	(351,190)
Net cash provided by (used in) investing activities	(362,534)	(125,192)	237,341
Net cash provided by (used in) financing activities	(132)	3,780,171	3,780,303

[Cash flows from operating activities]

During the six months ended June 30, 2017, net cash used in operating activities amounted to 628,898 thousand yen (in comparison with net cash used in operating activities of 277,708 thousand yen during the six months ended June 30, 2016), which was mainly attributable to loss before tax of 558,419 thousand yen.

[Cash flows from investing activities]

During the six months ended June 30, 2017, net cash used in investing activities amounted to 125,192 thousand yen (in comparison with net cash used in investing activities of 362,534 thousand yen during the six months ended June 30, 2016), which was mainly attributable to 123,406 thousand yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

During the six months ended June 30, 2017, net cash provided by financing activities amounted to 3,780,171 thousand yen (in comparison with net cash used in financing activities of 132 thousand yen during the six months ended June 30, 2016), which was mainly attributable to 3,780,303 thousand yen in proceeds from issuance of new shares associated with initial public offering.

3) Research and development activities

In the six months ended June 30, 2017, research and development expenses amounted to 285,761 thousand yen. In addition, there was a 125,513 thousand yen increase recorded in intangible assets attributable to SP-01 and SP-03 development costs which have been recognized as assets from among pipeline investment outlays. Meanwhile, during the six months ended June 30, 2017, total pipeline investment amounted to 411,274 thousand yen, and the balance of intangible assets amounted to 2,700,969 thousand yen as of June 30, 2017.

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 and pending approval

■ 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

Indication: Mechanically acts for the protection and relief of oral pain associated with oral mucositis/stomatitis and other inflammatory conditions of the mouth caused by chemotherapy and radiotherapy

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, application for approval filed and pending approval (As of today: Approved)
- China — Development completed, application for approval filed and pending approval

We obtained manufacturing/marketing approval for a new medical device (SP-03: episil® oral liquid) in Japan by the Ministry of Health, Labour and Welfare on July 6, 2017 for the relief of oral pain associated with oral mucositis/stomatitis caused by chemotherapy and radiotherapy. We have received milestone payments of 400,000 thousand yen from Meiji Seika Pharma Co., Ltd. which we have granted exclusive marketing rights in Japan.

(2) Explanation of financial position

As of June 30, 2017, total assets amounted to 6,904,999 thousand yen, for an increase of 3,200,003 thousand yen in comparison with assets held on June 30, 2016. Current assets amounted to 4,196,093 thousand yen, which includes 4,062,271 thousand yen in cash and cash equivalents. Non-current assets amounted to 2,708,906 thousand yen, which includes 2,700,969 thousand yen in intangible assets constituting the capitalized amount of development investment.

As of June 30, 2017, total liabilities amounted to 236,916 thousand yen, for a decrease of 34,610 thousand yen in comparison with liabilities held on June 30, 2016. Current liabilities amounted to 205,244 thousand yen, which includes 174,872 thousand yen in trade and other payables. Non-current liabilities amounted to 31,672 thousand yen, which mainly consists of 30,338 thousand yen in deferred tax liabilities.

As of June 30, 2017, total equity amounted to 6,668,082 thousand yen, for an increase of 3,234,613 thousand yen in comparison with equity held on June 30, 2016. The increase was mainly attributable to issuance of new shares amounting to 3,780,303 thousand yen.

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

The consolidated earnings forecasts are unchanged from the forecasts announced on March 24, 2017.

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Thousands of yen)

	As of December 31, 2016	As of June 30, 2017
Assets		
Current assets		
Cash and cash equivalents	1,038,996	4,062,271
Trade and other receivables	1,628	27,303
Inventories	67,685	93,291
Other current assets	14,755	13,225
Total current assets	1,123,066	4,196,093
Non-current assets		
Property, plant and equipment	1,236	1,127
Intangible assets	2,575,456	2,700,969
Other non-current assets	5,236	6,808
Total non-current assets	2,581,928	2,708,906
Total assets	3,704,995	6,904,999
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	199,596	174,872
Other current liabilities	27,447	30,371
Total current liabilities	227,044	205,244
Non-current liabilities		
Deferred tax liabilities	43,020	30,338
Other non-current liabilities	1,461	1,333
Total non-current liabilities	44,482	31,672
Total liabilities	271,526	236,916
Equity		
Share capital	4,053,384	5,961,887
Capital surplus	3,929,039	5,800,839
Retained earnings	(4,546,179)	(5,091,917)
Other components of equity	(2,775)	(2,727)
Total equity	3,433,468	6,668,082
Total liabilities and equity	3,704,995	6,904,999

(2) Condensed consolidated statement of profit or loss

(Thousands of yen)

	Six months ended June 30, 2016	Six months ended June 30, 2017
Revenue	201,319	5,632
Cost of sales	–	–
Gross profit	201,319	5,632
Research and development expenses	252,145	285,761
Selling, general and administrative expenses	203,525	272,963
Operating profit (loss)	(254,350)	(553,091)
Finance income	244	55
Finance costs	12,519	5,383
Other income	3	0
Profit (loss) before tax	(266,622)	(558,419)
Income taxes	(4,813)	(12,682)
Profit (loss)	(261,809)	(545,737)
Profit (loss) attributable to:		
Owners of parent	(261,809)	(545,737)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(10.61)	(7.11)
Diluted earnings (loss) per share [yen]	(10.61)	(7.11)

(3) Condensed consolidated statement of comprehensive income

(Thousands of yen)

	Six months ended June 30, 2016	Six months ended June 30, 2017
Profit (loss)	(261,809)	(545,737)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(1,784)	47
Subtotal	(1,784)	47
Total other comprehensive income	(1,784)	47
Comprehensive income	(263,593)	(545,689)
Comprehensive income attributable to:		
Owners of parent	(263,593)	(545,689)

(4) Condensed consolidated statement of changes in equity

(Thousands of yen)

	Share capital	Capital surplus	Retained earnings	Other components of equity	Total equity
Balance at January 1, 2016	2,571,868	2,499,595	(4,071,743)	(878)	998,842
Comprehensive income					
Profit (loss)	–	–	(261,809)	–	(261,809)
Other comprehensive income	–	–	–	(1,784)	(1,784)
Total comprehensive income	–	–	(261,809)	(1,784)	(263,593)
Balance at June 30, 2016	2,571,868	2,499,595	(4,333,542)	(2,663)	735,248
Balance at January 1, 2017	4,053,384	3,929,039	(4,546,179)	(2,775)	3,433,468
Comprehensive income					
Profit (loss)	–	–	(545,737)	–	(545,737)
Other comprehensive income	–	–	–	47	47
Total comprehensive income	–	–	(545,737)	47	(545,689)
Transactions with owners					
Issuance of new shares	1,902,248	1,865,605	–	–	3,767,854
Exercise of share acquisition rights	6,254	6,194	–	–	12,449
Total transactions with owners	1,908,503	1,871,800	–	–	3,780,303
Balance at June 30, 2017	5,961,887	5,800,839	(5,091,917)	(2,727)	6,668,082

(5) Condensed consolidated statement of cash flows

(Thousands of yen)

	Six months ended June 30, 2016	Six months ended June 30, 2017
Cash flows from operating activities		
Profit (loss) before tax	(266,622)	(558,419)
Depreciation	503	321
Finance income	(244)	(55)
Finance costs	12,519	5,383
Decrease (increase) in trade and other receivables	7,394	(25,885)
Decrease (increase) in inventories	–	(25,606)
Increase (decrease) in trade and other payables	(29,922)	(26,625)
Other	(1,580)	1,933
Subtotal	(277,952)	(628,953)
Interest received	244	55
Net cash provided by (used in) operating activities	(277,708)	(628,898)
Cash flows from investing activities		
Purchase of property, plant and equipment	–	(212)
Purchase of intangible assets	(362,545)	(123,406)
Other	11	(1,572)
Net cash provided by (used in) investing activities	(362,534)	(125,192)
Cash flows from financing activities		
Proceeds from issuance of new shares	–	3,780,303
Other	(132)	(132)
Net cash provided by (used in) financing activities	(132)	3,780,171
Net increase (decrease) in cash and cash equivalents	(640,374)	3,026,080
Cash and cash equivalents at beginning of period	2,099,547	1,038,996
Effect of exchange rate changes on cash and cash equivalents	(11,343)	(2,805)
Cash and cash equivalents at end of period	1,447,828	4,062,271

(6) Notes to condensed quarterly consolidated financial statements

(Notes on premise of going concern)

No items to report.

3. Significant events regarding premise of going concern

The Group is in the business of engaging in research, development and ultimately sales of pharmaceuticals and other such products. Our research and development with respect to pharmaceuticals and other such products requires substantial upfront investment along with a medium- to long-term time horizon. Consequently, securing profits and recovering invested funds also entails considerable periods of time. As it now stands, we have yet to commercially launch a pipeline product, and consequently our overall business remains at the upfront investment stage. Therefore, our operations continue to incur negative earnings, net operating cash outflows, and a retained earnings deficit.

Upfront investment made thus far has enabled us to maintain a portfolio of pipeline products in the late stages of the commercialization process therefor, including a pipeline product that has obtained approval from the regulatory authorities (as of today), pipeline products whose application have been submitted to the authorities for approval, and pipeline products for which proof of concept (POC) has been confirmed. Moreover, we have been raising funds on the basis of positive assessments of progress that has been achieved with respect to developing such products. We issued new shares at the initial public offering in March 2017, and as such have secured operating funds sufficient for the time being. Going forward, we plan to further improve our financial status by getting products approved and placing them on the market. However, given uncertainties with respect to product launches, the Group’s financial status and business performance could be substantially affected where product development and commercialization fails to make progress as planned.

Having analyzed and reviewed the operating environment as presented above, the Company finds no significant uncertainty regarding the premise of going concern.