

Note: This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the Japanese original shall prevail.



August 14, 2019

**Consolidated Financial Results for the Six Months of
the Fiscal Year Ending December 31, 2019
(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: August 14, 2019
 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, 2019 (from January 1, 2019 to June 30, 2019)

(1) Consolidated operating results (cumulative) (Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Six months ended June 30, 2019	130	54.9	(1,010)	–	(1,036)	–	(1,093)	–
June 30, 2018	84	–	(923)	–	(926)	–	(916)	–

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Six months ended June 30, 2019	(1,093)	–	(1,094)	–	(10.42)	(10.42)
June 30, 2018	(916)	–	(916)	–	(10.41)	(10.41)

(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, 2019	6,688	6,003	6,003	89.8	57.11
December 31, 2018	7,728	7,087	7,087	91.7	67.69

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, 2018	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2019	–	0.00			
Fiscal year ending December 31, 2019 (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, 2019 (from January 1, 2019 to December 31, 2019)

(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, 2019	500	56.9	(3,000)	–	(3,000)	–	(3,000)	–	(3,000)	–	(28.54)
	to 1,700	To 433.4	to (2,000)	to –	to (2,000)	to –	to (2,000)	to –	to (2,000)	to –	to (19.02)

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, 2019	105,450,795 shares
As of December 31, 2018	105,022,169 shares

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

As of June 30, 2019	320,000 shares
As of December 31, 2018	320,000 shares

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

For the six months ended June 30, 2019	104,952,884 shares
For the six months ended June 30, 2018	88,019,949 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 Monday, August 19, 2019 for institutional investors and analysts.

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

Index

1.	Qualitative information regarding results for the first three months	2
(1)	Explanation of operating results	2
(2)	Explanation of financial position.....	4
(3)	Explanation of consolidated earnings forecasts and other forward-looking statements	5
2.	Condensed quarterly consolidated financial statements and significant notes thereto	6
(1)	Condensed consolidated statement of financial position.....	6
(2)	Condensed consolidated statement of profit or loss	7
(3)	Condensed consolidated statement of comprehensive income	8
(4)	Condensed consolidated statement of changes in equity.....	9
(5)	Condensed consolidated statement of cash flows.....	10
(6)	Notes to condensed quarterly consolidated financial statements.....	11

1. Qualitative information regarding results for the six months

(1) Explanation of operating results

1) Overview of results

Operating results

	(Millions of yen)		
	Six months ended June 30, 2018	Six months ended June 30, 2019	Year-on-year
Revenue	84	130	46
Gross profit	12	111	98
Operating profit (loss)	(923)	(1,010)	(86)
Profit (loss)	(916)	(1,093)	(176)

In the six months ended June 30, 2019, 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 March 2019 launch in China of pipeline product SP-01, the February 2019 approval in China and the June 2019 products shipment for Chinese market of pipeline product SP-03, however, we continued making up-front investments, including to promote clinical trials for pipeline products SP-02 and SP-04. Given these circumstances, our financial performance during the six months ended June 30, 2019, was as follows.

[Revenue]

During the six months ended June 30, 2019, revenue totaled 130 million yen, up 46 million yen from the first six months of the preceding fiscal year. Revenue mainly came from the sales of pipeline products SP-01 and SP-03, as well as milestone revenue upon obtaining approval of pipeline product SP-03 in China.

[Gross profit]

Pipeline products mainly SP-03 produced gross profit of 111 million yen, stemming from milestone and sales revenue, up 98 million yen from the first six months of the preceding fiscal year.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Six months ended June 30, 2018	Six months ended June 30, 2019	Year-on-year
R&D expenses	483	455	(27)
SG&A expenses	452	666	213
Total	935	1,121	185
(Breakdown)			
Personnel expenses	195	265	70
Outsourcing expenses	514	514	(0)
Depreciation and amortization of intangible assets	13	225	211
Other	211	116	(95)

[R&D expenses, SG&A expenses]

R&D expenses amounted to 455 million yen. 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 (pivotal study) of SP-04 (initiated in December 2018). SG&A expenses amounted to 666 million yen, up 213 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.

[Operating profit (loss)]

We incurred an operating loss of 1,010 million yen, which is an increase of 86 million yen year on year. In addition to gross profit having remained at the aforementioned levels, the operating loss is attributable to both research and development (R&D) expenses and selling, general and administrative (SG&A) expenses.

[Profit (loss)]

We incurred an overall loss of 1,093million 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 673 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, 2019, pipeline investment amounted to 1,129 million yen. This figure includes the 673 million yen in intangible assets derived from capitalization of such outlays and 455 million yen in R&D expenses. However, a June 2019 products shipment triggered the amortization of intangible assets related to the Chinese business for pipeline product SP-03. Also, the amortization of intangible assets related to the Japanese business for pipeline product SP-03 and of intangible assets related to pipeline product SP-01 started in the previous year. The amortization amounted 199 million yen during the six months under review. As a result, the balance of intangible assets was 3,598 million yen as of June 30, 2019.

2) Cash flows

	(Millions of yen)		
	Six months ended June 30, 2018	Six months ended June 30, 2019	Year-on-year
Net cash provided by (used in) operating activities	(1,157)	(803)	354
Net cash provided by (used in) investing activities	(150)	(676)	(525)
Net cash provided by (used in) financing activities	11	(10)	(21)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 803 million yen (compared with 1,157 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 1,036 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 676 million yen (up from 150 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 674 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash used in financing activities amounted to 10 million yen (down from 11 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 20 million yen in outflows related to repayments of lease liabilities and 10 million yen in proceeds from issuance of new shares by exercising stock acquisition rights.

3) R&D activities

R&D expenses amounted to 455 million yen. In addition, the Company recorded a 673 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 1,129 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2019	Six months ended June 30, 2019	As of today
SP-01 Sancuso® China	Preparing for launch	Launch (in March 2019)	Ongoing sale
SP-02 darinaparsin Japan etc.	Multinational phase II clinical study (final clinical study) in progress	Multinational phase II clinical study (final clinical study) in progress	Multinational phase II clinical study (final clinical study) in progress
SP-03 episil® Japan	Ongoing sale	Ongoing sale	Ongoing sale
SP-03 episil® China	Application for approval filed	Obtained approval (in February 2019), Started shipping (in June 2019)	Launch (in July 2019)
SP-04 PledOx® Japan etc.	Multinational phase III clinical study (final clinical study) in progress	Multinational phase III clinical study (final clinical study) in progress	Multinational phase III clinical study (final clinical study) in progress

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 June 30, 2019, total assets amounted to 6,688 million yen, down 1,040 million yen from the previous year-end. Current assets were 2,913million yen, including 2,541 million yen in cash and cash equivalents. Non-current assets came to 3,774 million yen. This figure includes 3,598 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 684 million yen, up 42 million yen from the previous year-end. Current liabilities were 565 million yen, including 479 million yen in trade and other payables. Non-current liabilities amounted to 119 million yen, mainly due to 67 million yen in deferred tax liabilities.

Total equity equaled 6,003 million yen, down 1,083 million yen from the previous year-end. The increase was mainly attributable to 10 million yen in proceeds from issuance of new shares by exercising stock acquisition rights. The decrease was mainly attributable to the overall loss of 1,093 million yen.

As of today, the overdraft and committed credit line with domestic banks total 3.5 billion yen. The entire

amount is unused.

We aim to compensate for deficits and prepare ourselves for a future in which we will be able to provide shareholder returns through the payment of dividends from surplus and the acquisition of treasury stock. To make our capital policies more flexible and expeditious as our financial condition moves closer to this scenario, at a meeting on February 27, 2019 the Board of Directors resolved to reduce the legal capital surplus (3,712 million yen) and appropriate the surplus (compensating for a shortfall in retained earnings brought forward of 11,244 million yen) (includes increases stemming from reductions in the legal capital surplus and share capital). At an ordinary general meeting of shareholders on March 29, 2019, a reduction in the share capital (7,532 million yen) was approved. Thereafter, following procedures for protection of creditors, the said share capital amount and reduction in the legal capital surplus became effective and the surplus was appropriated as of May 10, 2019. In this process, amounts were transferred between certain net asset line items, but the Company's net assets and number of issued shares were unaffected.

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

The consolidated earnings forecasts are unchanged from the forecasts announced on February 13, 2019.

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2018	As of June 30, 2019
Assets		
Current assets		
Cash and cash equivalents	4,046	2,541
Trade and other receivables	193	95
Inventories	122	124
Other current assets	143	152
Total current assets	4,504	2,913
Non-current assets		
Property, plant and equipment	58	52
Light-of-use asset	—	81
Intangible assets	3,123	3,598
Other non-current assets	42	42
Total non-current assets	3,224	3,774
Total assets	7,728	6,688
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	580	479
Lease liabilities	—	41
Other current liabilities	39	44
Total current liabilities	619	565
Non-current liabilities		
Deferred tax liabilities	11	67
Lease liabilities	—	41
Other non-current liabilities	10	10
Total non-current liabilities	21	119
Total liabilities	641	684
Equity		
Share capital	7,632	105
Capital surplus	7,483	3,776
Retained earnings	(7,975)	2,175
Treasury stock	(48)	(48)
Other components of equity	(3)	(4)
Total equity	7,087	6,003
Total liabilities and equity	7,728	6,688

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Six months ended June 30, 2018	Six months ended June 30, 2019
Revenue	84	130
Cost of sales	71	19
Gross profit	12	111
Research and development expenses	483	455
Selling, general and administrative expenses	452	666
Operating profit (loss)	(923)	(1,010)
Finance income	0	0
Finance costs	3	26
Other income	0	0
Profit (loss) before tax	(926)	(1,036)
Income taxes	(10)	56
Profit (loss)	(916)	(1,093)
Profit (loss) attributable to:		
Owners of parent	(916)	(1,093)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(10.41)	(10.42)
Diluted earnings (loss) per share [yen]	(10.41)	(10.42)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Six months ended June 30, 2018	Six months ended June 30, 2019
Profit (loss)	(916)	(1,093)
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	(916)	(1,094)
Comprehensive income attributable to:		
Owners of parent	(916)	(1,094)

(4) Condensed consolidated statement of changes in equity

(Millions of yen)

	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity	Total equity
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
Balance at January 1, 2019	7,632	7,483	(7,975)	(48)	(3)	7,087
Comprehensive income						
Profit (loss)	—	—	(1,093)	—	—	(1,093)
Other comprehensive income	—	—	—	—	(1)	(1)
Total comprehensive income	—	—	(1,093)	—	(1)	(1,094)
Transactions with owners						
Issuance of new shares	—	—	—	—	—	—
Exercise of share acquisition rights	5	5	—	—	—	10
Capital reduction	(7,532)	(3,712)	11,244	—	—	—
Total transactions with owners	(7,526)	(3,706)	11,244	—	—	10
Balance at June 30, 2019	105	3,776	2,175	(48)	(4)	6,003

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Six months ended June 30, 2018	Six months ended June 30, 2019
Cash flows from operating activities		
Profit (loss) before tax	(926)	(1,036)
Depreciation and amortization	13	225
Finance income	(0)	(0)
Finance costs	3	26
Decrease (increase) in trade and other receivables	(41)	97
Decrease (increase) in inventories	(96)	(2)
Increase (decrease) in trade and other payables	(112)	(99)
Other	1	(12)
Subtotal	(1,157)	(803)
Interest received	0	0
Interest paid	(0)	(0)
Net cash provided by (used in) operating activities	(1,157)	(803)
Cash flows from investing activities		
Purchase of property, plant and equipment	(32)	(1)
Purchase of intangible assets	(118)	(674)
Other	0	0
Net cash provided by (used in) investing activities	(150)	(676)
Cash flows from financing activities		
Proceeds from issuance of new shares	11	10
Repayment of lease liabilities	—	(20)
Net cash provided by (used in) financing activities	11	(10)
Net increase (decrease) in cash and cash equivalents	(1,296)	(1,489)
Cash and cash equivalents at beginning of period	3,370	4,046
Effect of exchange rate changes on cash and cash equivalents	(3)	(14)
Cash and cash equivalents at end of period	2,070	2,541

(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 six months ended June 30, 2019, the Group adopted IFRS 16 "Leases" (announced in January 2016), in compliance with each transitional provision.

The Group has retroactively applied IFRS 16 in compliance with the transitional provisions. To determine whether arrangements included leases, when transitioning to IFRS 16 the Group selected the practical expedients in Paragraph C3 of IFRS 16, and maintained its judgments based on IAS 17 "Leases" (hereinafter, "IAS 17"), and IFRIC 4 "Determining Whether an Arrangement Contains a Lease." For leases categorized as operating leases, to which the Group previously applied IAS 17, lease obligations were recognized on the date the application of IFRS 16 began. For lease obligations, the remaining lease fees were measured at present value, discounted by the borrower's additional borrowing rate as of the date when application began. The weighted average of the borrower's additional borrowing rate applied to lease obligations recognized in the consolidated statement of financial position as of the date when application began is 1.4%.