



November 13, 2019

Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2019 (under IFRS)

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 Listing: Tokyo Stock Exchange
 Securities code: 4597
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Scheduled date to file quarterly securities report: November 13, 2019

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, 2019 (from January 1, 2019 to September 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	%
Nine months ended September 30, 2019	291	163.2	(1,585)	–	(1,621)	–	(1,672)	–
September 30, 2018	110	(72.9)	(1,538)	–	(1,549)	–	(1,533)	–

	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
Nine months ended September 30, 2019	(1,672)	–	(1,675)	–	(15.93)	(15.93)
September 30, 2018	(1,533)	–	(1,534)	–	(17.16)	(17.16)

(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, 2019	6,073	5,422	5,422	89.3	51.58
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	To	to	To	to	to	to	to	to	to	to
	1,700	433.4	(2,000)	–	(2,000)	–	(2,000)	–	(2,000)	–	(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 September 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 September 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 Nine months ended September 30, 2019	105,012,839 shares
For the Nine months ended September 30, 2018	89,379,777 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.

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1. Qualitative information regarding results for the nine months

(1) Explanation of operating results

1) Overview of results

Operating results

	(Millions of yen)		
	Nine months ended September 30, 2018	Nine months ended September 30, 2019	Year-on-year
Revenue	110	291	180
Gross profit	38	243	204
Operating profit (loss)	(1,538)	(1,585)	(47)
Profit (loss)	(1,533)	(1,672)	(138)

In the nine months ended September 30, 2019, Solasia Pharma K.K. (the “Company”) and its group company (collectively, the “Group”) focused 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 Sancuso®(SP-01), the February 2019 approval in China and the July 2019 launch in China of pipeline product episil®(SP-03). The other pipeline products have reached the final stages of clinical development; the registration of subjects reached the target number of cases in phase II clinical trials (final clinical trial) for SP-02, and a phase III clinical trial is underway for SP-04. Although business involving pipeline products is proceeding favorably, we continue making up-front investments, as product sales have just entered the initial stages. Given these circumstances, our financial performance during the nine months ended September 30, 2019, was as follows.

[Revenue]

During the nine months ended September 30, 2019, revenue totaled 291 million yen, up 180 million yen from the nine months of the preceding fiscal year. Revenue mainly came from the sales of pipeline products Sancuso®(SP-01) and episil®(SP-03), as well as milestone revenue upon obtaining approval of pipeline product episil®(SP-03) in China.

[Gross profit]

Pipeline products mainly Sancuso®(SP-01) and episil®(SP-03) produced gross profit of 243 million yen, stemming from milestone and sales revenue, up 204 million yen from the first nine months of the preceding fiscal year.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Nine months ended September 30, 2018	Nine months ended September 30, 2019	Year-on-year
R&D expenses	893	716	(177)
SG&A expenses	683	1,113	429
Total	1,577	1,829	252
(Breakdown) Personnel expenses	305	412	107

Outsourcing expenses	941	900	(41)
Depreciation and amortization of intangible assets	53	348	294
Other	277	168	(108)

[R&D expenses, SG&A expenses]

R&D expenses amounted to 716 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 1,113 million yen, up 429 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)]

The Company incurred an operating loss of 1,585 million yen, which is an increase of 47 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)]

The Company incurred an overall loss of 1,672million 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 677 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, 2019, pipeline investment amounted to 1,394 million yen. This figure includes the 677 million yen in intangible assets derived from capitalization of such outlays and 716 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 episil®(SP-03). Also, the amortization of intangible assets related to the Japanese business for pipeline product episil®(SP-03) and of intangible assets related to pipeline product Sancuso®(SP-01) started in the previous year. The amortization amounted 308 million yen during the nine months under review. As a result, the balance of intangible assets was 3,492 million yen as of September 30, 2019.

2) Cash flows

	(Millions of yen)		
	Nine months ended September 30, 2018	Nine months ended September 30, 2019	Year-on-year
Net cash provided by (used in) operating activities	(1,849)	(1,372)	477
Net cash provided by (used in) investing activities	(176)	(680)	(504)
Net cash provided by (used in) financing activities	3,301	(20)	(3,322)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 1,372 million yen (compared with 1,849 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 1,621 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 680 million yen (up from 176 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 679 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash used in financing activities amounted to 20 million yen (down from 3,301 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 31 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 716 million yen. In addition, the Company recorded a 677 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 1,394 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2019	Nine months ended September 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; Completion of subject- enrollment	Multinational phase II clinical study (final clinical study) in progress; Completion of subject- enrollment
SP-03 episil® Japan	Ongoing sale	Ongoing sale	Ongoing sale
SP-03 episil® China	Application for approval filed	Obtained approval (in February 2019), Launch (in July 2019)	Ongoing sale
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 September 30, 2019, total assets amounted to 6,073 million yen, down 1,655 million yen from the previous year-end. Current assets were 2,412 million yen, including 1,956 million yen in cash and cash equivalents. Non-current assets came to 3,660 million yen. This figure includes 3,492 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 650 million yen, up 9 million yen from the previous year-end. Current liabilities were

542 million yen, including 453 million yen in trade and other payables. Non-current liabilities amounted to 108million yen, mainly due to 62 million yen in deferred tax liabilities.

Total equity equaled 5,422 million yen, down 1,664 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 1,672 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 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 September 30, 2019
Assets		
Current assets		
Cash and cash equivalents	4,046	1,956
Trade and other receivables	193	158
Inventories	122	116
Other current assets	143	181
Total current assets	4,504	2,412
Non-current assets		
Property, plant and equipment	58	49
Light-of-use asset	—	77
Intangible assets	3,123	3,492
Other non-current assets	42	42
Total non-current assets	3,224	3,660
Total assets	7,728	6,073
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	580	453
Lease liabilities	—	43
Other current liabilities	39	44
Total current liabilities	619	542
Non-current liabilities		
Deferred tax liabilities	11	62
Lease liabilities	—	35
Other non-current liabilities	10	10
Total non-current liabilities	21	108
Total liabilities	641	650
Equity		
Share capital	7,632	105
Capital surplus	7,483	3,776
Retained earnings	(7,975)	1,596
Treasury stock	(48)	(48)
Other components of equity	(3)	(6)
Total equity	7,087	5,422
Total liabilities and equity	7,728	6,073

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2018	Nine months ended September 30, 2019
Revenue	110	291
Cost of sales	71	47
Gross profit	38	243
Research and development expenses	893	716
Selling, general and administrative expenses	683	1,113
Operating profit (loss)	(1,538)	(1,585)
Finance income	0	0
Finance costs	11	35
Other income	0	0
Profit (loss) before tax	(1,549)	(1,621)
Income taxes	(15)	51
Profit (loss)	(1,533)	(1,672)
Profit (loss) attributable to:		
Owners of parent	(1,533)	(1,672)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(17.16)	(15.93)
Diluted earnings (loss) per share [yen]	(17.16)	(15.93)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2018	Nine months ended September 30, 2019
Profit (loss)	(1,533)	(1,672)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(0)	(2)
Subtotal	(0)	(2)
Total other comprehensive income	(0)	(2)
Comprehensive income	(1,534)	(1,675)
Comprehensive income attributable to:		
Owners of parent	(1,534)	(1,675)

(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)	—	—	(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
Balance at January 1, 2019	7,632	7,483	(7,975)	(48)	(3)	7,087
Comprehensive income						
Profit (loss)	—	—	(1,672)	—	—	(1,672)
Other comprehensive income	—	—	—	—	(2)	(2)
Total comprehensive income	—	—	(1,672)	—	(2)	(1,675)
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 September 30, 2019	105	3,776	1,596	(48)	(6)	5,422

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2018	Nine months ended September 30, 2019
Cash flows from operating activities		
Profit (loss) before tax	(1,549)	(1,621)
Depreciation and amortization	53	348
Finance income	(0)	(0)
Finance costs	11	35
Decrease (increase) in trade and other receivables	(40)	34
Decrease (increase) in inventories	(93)	5
Increase (decrease) in trade and other payables	(230)	(127)
Other	(1)	(47)
Subtotal	(1,849)	(1,371)
Interest received	0	0
Interest paid	(0)	(0)
Net cash provided by (used in) operating activities	(1,849)	(1,372)
Cash flows from investing activities		
Purchase of property, plant and equipment	(41)	(2)
Purchase of intangible assets	(136)	(679)
Other	1	0
Net cash provided by (used in) investing activities	(176)	(680)
Cash flows from financing activities		
Proceeds from issuance of new shares	3,301	10
Repayment of lease liabilities	—	(31)
Net cash provided by (used in) financing activities	3,301	(20)
Net increase (decrease) in cash and cash equivalents	1,275	(2,073)
Cash and cash equivalents at beginning of period	3,370	4,046
Effect of exchange rate changes on cash and cash equivalents	1	(16)
Cash and cash equivalents at end of period	4,647	1,956

(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, 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%.