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November 13, 2024

## Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2024 (under IFRS)

Company name: Solasia Pharma K.K.  
 Listing: Tokyo Stock Exchange  
 Securities code: 4597  
 URL: <https://solasia.co.jp/en/>  
 Representative: Yoshihiro Arai, President and Chief Executive Officer  
 Contact: Toshio Miyashita, Chief Financial Officer  
 TEL: +81-3-5843-8046

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 first nine months of the fiscal year ending December 31, 2024 (from January 1, 2024 to September 30, 2024)

#### (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, 2024	81	(86.5)	(892)	–	(892)	–	(871)	–
September 30, 2023	602	24.3	(787)	–	(784)	–	(768)	–

	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, 2024	(871)	–	(873)	–	(4.53)	(4.53)
September 30, 2023	(768)	–	(756)	–	(4.57)	(4.57)

#### (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
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of					
September 30, 2024	2,375	2,209	2,209	93.0	10.15
December 31, 2023	2,229	1,875	1,875	84.1	10.78

### 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, 2023	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2024	–	0.00	–		
Fiscal year ending December 31, 2024 (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, 2024  
(from January 1, 2024 to December 31, 2024)**

(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, 2024	1,250	102.5	(800)	—	(800)	—	(800)	—	(800)	—	(3.67)
	~ 1,500	~ 143.0	~ (550)	~ —	~ (550)	~ —	~ (550)	~ —	~ (550)	~ —	~ (2.53)

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 September 30, 2024	218,168,910 shares
As of December 31, 2023	174,373,910 shares

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

As of September 30, 2024	409,110 shares
As of December 31, 2023	430,910 shares

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

For the Nine months ended September 30, 2024	192,263,724 shares
For the Nine months ended September 30, 2023	168,058,069 shares

\* Review of the attached condensed quarterly consolidated financial statements by certified public accountants or an audit firm: None

\* 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 first nine months

### (1) Explanation of operating results

#### 1) Overview of results

##### Operating results

	(Millions of yen)		
	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year
Revenue	602	81	(521)
Gross profit	331	5	(325)
Operating profit (loss)	(787)	(892)	(105)
Profit (loss)	(768)	(871)	(102)

The Group intends to focus business operations on expanding its oncology development pipeline, which consists of three products that have already been launched. Under this goal, the Group primarily engaged in the following business activities in the nine months ended September 30, 2024.

#### [Launched products (development completed)]

##### **SP-01 (Chemotherapy-induced nausea and vomiting)**

##### **SP-03 (Oral mucositis/stomatitis caused by chemotherapy and radiotherapy)**

Sales of Sancuso® (SP-01) and episil® (SP-03), which are mainly sold in China, were substantially lower than in the corresponding period of the previous fiscal year, due to the restricted shipment of Sancuso®(SP-01) and episil®(SP-03) resulting from the addition and relocation of the manufacturing facility in a bid to lower costs. The regulatory procedures for the addition of the Sancuso® manufacturing facility in China have been completed. The Company obtained regulatory approval for the transfer of manufacturing site in Japan for episil® in August 2024.

##### **SP-02 (Indication: Relapsed or Refractory Peripheral T-cell Lymphoma)**

The Company obtained marketing approval and began sales for SP-02 in Japan in 2022.

Currently, the Company is investigating new targeting hematologic cancers other than Relapsed or Refractory peripheral T-cell lymphoma with an eye to expanding the drug's indications.

The Company is continuing out-licensing activities for marketing and other rights in China and other regions.

#### [Pipeline products in the non-clinical study phase]

##### **SP-04 (Target Indication: Chemotherapy-induced peripheral neuropathy)**

Based on the results of the international Phase III clinical trials (POLAR-A study and POLAR-M study) including Japan in patients with colorectal cancer of SP-04 targeting oxaliplatin-induced peripheral neuropathy, the Company has decided to park the development of the pipeline product for this indication; instead, we have determined to conduct additional animal studies to investigate the product's potential in treating taxane-induced peripheral neuropathy. Based on information obtained from the results of animal studies conducted so far, we have started new animal studies in Japan in collaboration with licensor Egetis Therapeutics.

#### **Pipeline product (development stopped temporarily)]**

##### **SP-05 (Target Indication: Increase in antitumor efficacy of fluorouracil)**

In 2022, it was found out that neither the primary endpoint nor the key secondary endpoint showed

statistically significant differences as the final results of the international Phase III AGENT Study including Japan in colorectal cancer. We have decided to stop to the development of this pipeline product.

The developed product's licensor, Isofol, has been conducting a detailed analysis of the AGENT study results with external professionals and new non-clinical studies since 2023 with a view to resuming clinical development of SP-05, and has concluded that these overall evaluations show that SP-05 (arfolitixorin) is different from that used in the AGENT study in the study concluded that these overall evaluations indicate that SP-05 (arfolitixorin) is clinically effective at new doses and dosages different from those used in the AGENT study.

In February 2024, Isofol's Board of Directors decided to prepare a new clinical development program for SP-05 and to initiate a new clinical trial as soon as possible. In conjunction with this decision, Isofol also announced that it plans to conduct small clinical trials in a time- and cost-efficient manner to demonstrate the clinical efficacy of SP-05 using the new dosage and administration compared to standard therapy as the first approach.

The Company has been in regular communication with Isofol since the suspension of the development of SP-05. In light of Isofol's recent decision to resume development of SP-05 and its plans to conduct a small clinical trial, we will continue to exchange information with Isofol and evaluate the results of the new non-clinical study and the content of the clinical trial plan in order to decide on the resumption of development in Japan and Isofol's plan to participate in a new development program.

In July 2024, Isofol has announced results from a post hoc per-Protocol analysis of the AGENT Study and two preclinical studies that support the dose-response relationship for SP-05(arfolitixorin). The results show even the likely suboptimal dosing regimen used in the Phase III AGENT study results in a numerical advantage for SP-05(arfolitixorin). Additionally, previous studies suggest that an optimized dosing regimen could generate even better efficacy. These preclinical studies confirm previous findings and thereby provide further support for Isofol's strategy to conduct a clinical study with an expected new optimized dosing regimen of arfolitixorin, where higher doses than the one used in the Phase III AGENT study are tested. This is considered to further increase the likelihood of generating positive data in the Phase Ib/II study, which is anticipated to start before the end of 2024,

The Company has made progress in the development of its pipeline products as outlined above, and intends to enhance corporate value in the medium to long term through structural reforms implemented the year before last aimed at improving earnings began to produce results. However, in the short term, upfront expenditures for pipeline product development continue to exceed earnings from product sales due to the impact of competing products and the impact of the anti-corruption campaign in China, product sales are struggling to grow.. As a result, our financial performance during the nine months ended September 30, 2024, was as follows.

[Revenue, Gross profit]

During the nine months ended September 30, 2024, revenue totaled 81 million yen. Currently, procedures are underway to change the manufacturing site of the drug in a bid to lower manufacturing costs, and we expect prescription volume of the drug to fall temporarily until the procedures are complete. Revenue mainly came from the sales of pipeline products of DARVIAS® (SP-02). In addition, gross profit amounted to 5 million yen.

## Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year
R&D expenses	308	317	9
SG&A expenses	810	580	(229)
Total	1,118	898	(220)
(Breakdown)			
Personnel expenses	349	314	(34)
Outsourcing expenses	322	344	21
Depreciation and amortization of intangible assets	378	161	(216)
Other	68	77	9

[R&D expenses, SG&A expenses, Operating profit (loss), Profit (loss)]

R&D expenses amounted to 317 million yen. This amount mainly reflected costs for changing the manufacturing site to lower manufacturing costs, R&D aimed at preparing the clinical studies and expanding the indications for DARVIAS® (SP-02), animal studies for SP-04, and investments in new development candidates. SG&A expenses amounted to 580 million yen, down 229 million yen year on year.

The Company incurred an operating loss of 892 million yen.

The Company incurred an overall loss of 871 million yen.

[Capitalized costs included in intangible assets and amortization of intangible assets]

The Group posted no 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, 2024, pipeline investment amounted to 317 million yen. This figure is 317 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01) and ,DARVIAS® (SP-02), leading to amortization of 133 million yen during the nine months under review. As a result, the balance of intangible assets was 983 million yen as of September 30, 2024.

## 2) Cash flows

	(Millions of yen)		
	Nine months ended September 30, 2023	Nine months ended September 30, 2024	Year-on-year
Net cash provided by (used in) operating activities	(262)	(865)	(602)
Net cash provided by (used in) investing activities	(0)	(0)	(0)
Net cash provided by (used in) financing activities	(27)	1,182	1,210

### [Cash flows from operating activities]

Net cash used in operating activities amounted to 865 million yen (compared with 262 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 892 million yen.

### [Cash flows from investing activities]

Net cash used in investing activities amounted to 0 million yen (compared with 0 million yen used in these activities in the corresponding period of the previous fiscal year).

### [Cash flows from financing activities]

Net cash provided by financing activities amounted to 1,182 million yen (compared with 27 million yen used in these activities in the same period of the previous year). This figure was mainly attributable to 1,209 million yen in proceeds from issuance of new shares by the exercise of warrants.

## 3) R&D activities

R&D expenses amounted to 317 million yen. This amount mainly reflected costs for changing the manufacturing site to lower manufacturing costs, R&D aimed at preparing the clinical studies and expanding the indications for DARVIAS<sup>®</sup> (SP-02), animal studies for SP-04, and investments in new development candidates.

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, 2024, total assets amounted to 2,375 million yen, up 145 million yen from the previous year-end. Current assets were 1,284 million yen, including 1,043 million yen in cash and cash equivalents 40 million in trade and other receivables. Non-current assets came to 1,090 million yen. This figure includes 983 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 165 million yen, down 188 million yen from the previous year-end. Current liabilities were 150 million yen, including 71 million yen in trade and other payables. Non-current liabilities amounted to 15 million yen, including 3 million yen in lease liabilities.

Total equity equaled 2,209 million yen, up 333 million yen from the previous year-end. The increase was mainly attributable to 1,209 million yen in proceeds from issuance of new shares by the exercise of warrants. The decrease was mainly attributable to the overall loss of 871 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 14, 2024

## 2. Condensed quarterly consolidated financial statements and significant notes thereto

### (1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December31,2023	As of September 30, 2024
<b>Assets</b>		
Current assets		
Cash and cash equivalents	728	1,043
Trade and other receivables	67	40
Inventories	122	175
Other current assets	58	25
Total current assets	976	1,284
Non-current assets		
Property, plant and equipment	21	19
Light-of-use asset	60	37
Intangible assets	1,117	983
Investments accounted for using equity method	6	2
Other non-current assets	46	46
Total non-current assets	1,252	1,090
Total assets	2,229	2,375
<b>Liabilities and equity</b>		
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	213	71
Lease liabilities	33	33
Other current liabilities	45	44
Total current liabilities	293	150
Non-current liabilities		
Deferred tax liabilities	22	0
Lease liabilities	27	3
Other non-current liabilities	10	10
Total non-current liabilities	61	15
Total liabilities	354	165
<b>Equity</b>		
Share capital	1,596	2,208
Capital surplus	1,657	2,251
Retained earnings	(1,336)	(2,207)
Treasury stock	(69)	(65)
Other components of equity	26	22
Total equity	1,875	2,209
Total liabilities and equity	2,229	2,375



(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Revenue	602	81
Cost of sales	271	76
Gross profit	331	5
Research and development expenses	308	317
Selling, general and administrative expenses	810	580
Operating profit (loss)	(787)	(892)
Finance income	8	5
Finance costs	0	0
Other income	—	0
Share of profit (loss) of investments accounted for using equity method	(4)	(3)
Profit (loss) before tax	(784)	(892)
Income taxes	(15)	(21)
Profit (loss)	(768)	(871)
Profit (loss) attributable to:		
Owners of parent	(768)	(871)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(4.57)	(4.53)
Diluted earnings (loss) per share [yen]	(4.57)	(4.53)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Profit (loss)	(768)	(871)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	12	(2)
Subtotal	12	(2)
Total other comprehensive income	12	(2)
Comprehensive income	(756)	(873)
Comprehensive income attributable to:		
Owners of parent	(756)	(873)

(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
					Exchange differences on translation of foreign operations	Share acquisition rights	Total Other components of equity	
Balance at January 1, 2023	1,436	1,500	(223)	(70)	15	3	19	2,662
Comprehensive income								
Profit (loss)	—	—	(768)	—	—	—	—	(768)
Other comprehensive income	—	—	—	—	12	—	12	12
Total comprehensive income	—	—	(768)	—	12	—	12	(756)
Transactions with owners								
Exercise of share acquisition rights	3	3	—	—	—	—	—	7
Total transactions with owners	3	3	—	—	—	—	—	7
Balance at September 30, 2023	1,439	1,504	(992)	(70)	28	3	32	1,913
Balance at January 1, 2024	1,596	1,657	(1,336)	(69)	25	1	26	1,875
Comprehensive income								
Profit (loss)	—	—	(871)	—	—	—	—	(871)
Other comprehensive income	—	—	—	—	(2)	—	(2)	(2)
Total comprehensive income	—	—	(871)	—	(2)	—	(2)	(873)
Transactions with owners								
Exercise of share acquisition rights	611	597	—	—	—	—	—	1,209
Disposal of share acquisition rights	—	—	—	—	—	(1)	(1)	(1)
Disposal of treasury shares	—	—	—	3	—	—	—	3
Share-based payment transactions	—	(3)	—	—	—	—	—	(3)
Total transactions with owners	611	594	—	3	—	(1)	(1)	1,207
Balance at September 30, 2024	2,208	2,251	(2,207)	(65)	22	—	22	2,209

## (5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2023	Nine months ended September 30, 2024
Cash flows from operating activities		
Profit (loss) before tax	(784)	(892)
Depreciation and amortization	378	161
Finance income	(8)	(1)
Finance costs	0	0
Share of loss (profit) of investments accounted for using equity method	4	3
Decrease (increase) in trade and other receivables	402	26
Decrease (increase) in inventories	(106)	(52)
Increase (decrease) in trade and other payables	(123)	(142)
Other	(0)	31
Subtotal	(237)	(864)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	(25)	(0)
Net cash provided by (used in) operating activities	(262)	(865)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Net cash provided by (used in) investing activities	(0)	(0)
Cash flows from financing activities		
Proceeds from issuance of bonds	—	500-
Redemption of bonds	—	(500)
Proceeds from issuance of new shares	7	1,209
Acquisition of share acquisition rights	—	(1)
Repayment of lease liabilities	(34)	(24)
Net cash provided by (used in) financing activities	(27)	1,182
Net increase (decrease) in cash and cash equivalents	(290)	316
Cash and cash equivalents at beginning of period	803	728
Effect of exchange rate changes on cash and cash equivalents	7	(0)
Cash and cash equivalents at end of period	520	1,043

(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.

(Segment information)

Disclosure is omitted as the Group has a single reportable segment.