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November 14, 2025

Consolidated Financial Results for the Nine Months Ended September 30, 2025 (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
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 nine months ended September 30, 2025 (from January 1, 2025 to September 30, 2025)

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

	Sales		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Total comprehensive income	
Nine months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
September 30, 2025	91	12.6	(713)	–	(725)	–	(726)	–	(726)	–	(722)	–
September 30, 2024	81	(86.5)	(892)	–	(892)	–	(871)	–	(871)	–	(873)	–

	Basic earnings per share	Diluted earnings per share
Nine months ended	Yen	Yen
September 30, 2025	(3.16)	(3.16)
September 30, 2024	(4.53)	(4.53)

(2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of parent	Equity attributable to owners of parent to total assets ratio	Equity attributable to owners of parent per share
As of	Millions of yen	Millions of yen	Millions of yen	%	Yen
September 30, 2025	2,340	1,796	1,796	76.8	6.92
December 31, 2024	1,362	1,156	1,156	84.9	5.30

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, 2024	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2025	–	0.00	–		
Fiscal year ending December 31, 2025 (Forecast)				0.00	0.00

Note: Revisions to the forecast of cash dividends most recently announced: None

3. Consolidated financial forecast for the fiscal year ending December 31, 2025 (from January 1, 2025 to December 31, 2025)

(Percentages indicate year-on-year changes.)

	Sales		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Basic earnings per share
Fiscal year ending	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
December 31, 2025	1,300	310.2	(650)	–	(650)	–	(650)	–	(650)	–	(2.50)

Note: Revisions to the earnings forecasts most recently announced : None

* Notes

(1) Significant changes in the scope of consolidation during the period：None

(2) Changes in accounting policies and changes in accounting estimates

(i) Changes in accounting policies required by IFRS：None

(ii) Changes in accounting policies due to other reasons ：None

(iii) Changes in accounting estimates ：None

(3) Number of issued shares (ordinary shares)

① Number of issued and outstanding shares at the period end (including treasury stock)	As of September 30, 2025	260,209,010shares	As of December 31, 2024	218,458,910shares
② Number of treasury stock at the period end	As of September 30, 2025	409,143shares	As of December 31, 2024	409,110shares
③ Average number of shares (quarterly period-YTD)	Nine months ended September 30, 2025	229,892,508shares	Nine months ended September 30, 2024	192,263,724shares

* Review of the Japanese-language originals of the attached consolidated quarterly 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.

[Attached Material]

Index

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, 2024	Nine months ended September 30, 2025	Year-on-year
Revenue	81	91	10
Gross profit	5	60	55
Operating profit (loss)	(892)	(713)	179
Profit (loss)	(871)	(726)	145

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, 2025.

[Launched products (development completed)]

SP-01 (Indication: **Chemotherapy-induced nausea and vomiting)**

Sales of Sancuso® sharply declined due to shipment constraints following the transfer of manufacturing facility.

The regulatory procedures for the addition of the Sancuso® manufacturing facility in China have been completed.

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 cancers other than Relapsed or Refractory peripheral T-cell lymphoma with an eye to expanding the new indications.

In April 2025, we entered into a license agreement with FIREBIRD BIOLOGICS PTE LTD (headquartered in Singapore, hereinafter “FB”). Under this agreement, FB was granted exclusive rights for sales and related activities in 19 countries across Southeast Asia, Oceania, the Middle East, and Africa. FB has commenced preparations for regulatory submissions in the licensed territories.

In August 2025, we terminated our existing agreement with WEP Clinical Ltd. (UK) and entered into a new license agreement with INTEGRIS PHARMA S.A. (headquartered in Athens, Greece; established in 2008; engaged in pharmaceutical sales; CEO: Harry Therianos), granting exclusive rights for sales and related activities under the Managed Access Program (MAP) in 13 countries across Eastern Europe.

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

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

In December 2024. The Group resolved to cancel the sales partner agreement with Lee’s Pharmaceutical (HK) Limited and enter into a new sales partner agreement with Changchun GeneScience Pharmaceutical Co., Ltd. (headquarters: China; hereinafter “GenSci”. The contracting party is Gensci Singapore Pte. Ltd., a wholly owned subsidiary of GenSci.) and began shipping to the company during this year. The Company is continuing out-licensing activities.

In April 2025, we entered into a license agreement with FB, granting exclusive rights for sales and related activities in 19 countries across Southeast Asia, Oceania, the Middle East, and Africa. In July of the same year, FB obtained marketing approval for episil® (SP-03) from the Singapore authorities, and product supply from our company to FB has commenced.

In August 2025, we entered into an exclusive license agreement with Daiichi Sankyo Brasil Farmacêutica Ltda. (headquartered in São Paulo, Federative Republic of Brazil; President: Marcelo Gonçalves; a wholly owned subsidiary of Daiichi Sankyo Co., Ltd.), granting exclusive rights for product sales in Brazil.

［**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 the information obtained from the results of previous animal studies, in collaboration with licensor Egetis Therapeutics, we have conducted animal study in Japan and have obtained positive results in terms of peripheral neuropathic pain and pathological evaluation of neuronal cells in the test animals. With a view to future clinical trials, we have also conducted an additional new animal study to reinforce these results.

［**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 the development of this pipeline product. In 2024, Isofol has decided to resume development of SP-05, and we have also decided resume development in Japan.

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).

At the Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI) held in the United States in January this year, the details of the post ad-hoc analysis results of the AGENT study were reported, and it was reported that when only the patient group that strictly followed the study protocol was analyzed, the SP-05 administration group showed higher efficacy than the control group that received leucovorin.

These are thought to further increase the possibility of obtaining positive data in the upcoming Phase Ib/II clinical trial currently in progress.

In March of this year, Isofol received approval from the German regulator BfArM (Federal Agency for Pharmaceuticals and Medical Devices) to start a Phase Ib/II clinical trial of SP-05. In September of this year, Isofol announced the completion of the second cohort of the dose escalation in the ongoing phase Ib/II clinical study with arfolitixorin that has been carried out since April of this year at Charité – Universitätsmedizin Berlin. The third cohort in the dose-escalating part of the study is currently ongoing. The company plan to participate in the Phase II part of the study.

In July 2025, Isofol Medical AB initiated a capital raise to fund the future development of SP-05 through a rights issue of units with preferential rights for existing shareholders, as well as an overallotment option. In response to a funding request, we invested 77 million yen. Through this investment, we aim to strengthen our collaboration with Isofol in the development of SP-05 and expect to share in the economic value generated from development progress outside Japan.

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. 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, product sales are struggling to grow. As a result, our financial performance during the nine months ended September 30, 2025, was as follows.

[Revenue, Gross profit]

During the nine months ended September 30, 2025, revenue totaled 91 million yen. Revenue mainly came

from the sales of pipeline products of DARVIAS® (SP-02) and episil® (SP-03), as well as upfront payments for out-licensing of episil® (SP-03) in Brazil. In addition, gross profit amounted to 60 million yen. Revenue from the license agreement with FIREBIRD BIOLOGICS PTE LTD has not yet been recognized.

Breakdown of R&D and SG&A expenses

(Millions of yen)

	Nine months ended September 30, 2024	Nine months ended September 30, 2025	Year-on-year
R&D expenses	317	314	(3)
SG&A expenses	580	459	(120)
Total	898	774	(123)
(Breakdown) Personnel expenses	314	302	(12)
Outsourcing expenses	344	327	(17)
Depreciation and amortization of intangible assets	161	28	(133)
Other	77	116	38

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

R&D expenses amounted to 314 million yen. This amount mainly reflected costs for reducing the 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 459 million yen, down 120 million yen year on year.

The Company incurred an operating loss of 713 million yen.

The Company incurred an overall loss of 726 million yen.

2) Cash flows

(Millions of yen)

	Nine months ended September 30, 2024	Nine months ended September 30, 2025	Year-on-year
Net cash provided by (used in) operating activities	(865)	(296)	568
Net cash provided by (used in) investing activities	(0)	(79)	(78)
Net cash provided by (used in) financing activities	1,182	1,339	156

[Cash flows from operating activities]

Net cash used in operating activities amounted to 296 million yen (compared with 865 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 725 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 79 million yen (compared with 0 million yen used in these activities in the corresponding period of the previous fiscal year). This figure was mainly attributable to 77 million yen in purchase of investment securities , specifically shares in Isofol Medical AB.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 1,339 million yen (compared with 1,182 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 1,363 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) R&D activities

R&D expenses amounted to 314 million yen. This amount mainly reflected reflected costs for reducing the 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.

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, 2025, total assets amounted to 2,340 million yen, up 977 million yen from the previous year-end. Current assets were 2,076 million yen, including 1,832 million yen in cash and cash equivalents 75 million in trade and other receivables. Non-current assets came to 264 million yen, mainly due to 105 million yen in right-of-use assets and 139 million yen in other financial assets. Total liabilities totaled 543 million yen, up 337 million yen from the previous year-end. Current liabilities were 454 million yen, including 378 million yen in trade and other payables. Non-current liabilities amounted to 89 million yen, mainly due to 73 million yen in lease liabilities.

Total equity equaled 1,796 million yen, up 640 million yen from the previous year-end. The increase was mainly attributable to 1,363 million yen in proceeds from issuance of new shares by the exercise of warrants. The decrease was mainly attributable to the overall loss of 726 million yen.

In addition, In May of the year, the Company reduced its share capital and legal capital surplus by a total of 3.633 billion yen to cover a loss brought forward.

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

The consolidated earnings forecasts are unchanged from the forecasts announced on February 12, 2025

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2024	As of September 30, 2025
Assets		
Current assets		
Cash and cash equivalents	886	1,832
Trade and other receivables	232	75
Inventories	128	138
Other current assets	19	29
Total current assets	1,266	2,076
Non-current assets		
Property, plant and equipment	19	17
Right-of-use assets	28	105
Investments accounted for using equity method	1	1
Other financial assets	46	139
Total non-current assets	96	264
Total assets	1,362	2,340
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	121	378
Lease liabilities	25	31
Other current liabilities	47	44
Total current liabilities	193	454
Non-current liabilities		
Deferred tax liabilities	0	5
Lease liabilities	0	73
Other non-current liabilities	10	11
Total non-current liabilities	12	89
Total liabilities	206	543
Equity		
Share capital	2,211	788
Capital surplus	2,255	1,408
Retained earnings	(3,277)	(370)
Treasury shares	(65)	(65)
Other components of equity	33	36
Total equity	1,156	1,796
Total liabilities and equity	1,362	2,340

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2024	Nine months ended September 30, 2025
Revenue	81	91
Cost of sales	76	30
Gross profit	5	60
Research and development expenses	317	314
Selling, general and administrative expenses	580	459
Operating profit (loss)	(892)	(713)
Finance income	5	1
Finance costs	0	13
Other expenses	0	—
Share of profit (loss) of investments accounted for using equity method	(3)	(0)
Profit (loss) before tax	(892)	(725)
Income tax expense	(21)	0
Profit (loss)	(871)	(726)
Profit (loss) attributable to		
Owners of parent	(871)	(726)
Earnings (loss) per share		
Basic earnings (loss) per share	(4.53)	(3.16)
Diluted earnings (loss) per share	(4.53)	(3.16)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2024	Nine months ended September 30, 2025
Profit (loss)	(871)	(726)
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	—	10
Total of items that will not be reclassified to profit or loss	—	10
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(2)	(6)
Total of items that may be reclassified to profit or loss	(2)	(6)
Total other comprehensive income	(2)	3
Comprehensive income	(873)	(722)
Comprehensive income attributable to		
Owners of parent	(873)	(722)

(4) Condensed consolidated statement of changes in equity

(Millions of yen)

	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity				Total
					Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	Exchange differences on translation of foreign operations	Share acquisition rights	Total	
Balance at beginning of period	1,596	1,657	(1,336)	(69)	—	25	1	26	1,875
Comprehensive income									
Profit (loss)	—	—	(871)	—	—	—	—	—	(871)
Other comprehensive income	—	—	—	—	—	(2)	—	(2)	(2)
Comprehensive income	—	—	(871)	—	—	(2)	—	(2)	(873)
Transactions with owners									
Exercise of share acquisition rights	611	597	—	—	—	—	—	—	1,209
Cancellation of share acquitision 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 end of period	2,208	2,251	(2,207)	(65)	—	22	—	22	2,209

(Millions of yen)

	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity				Total
					Net change in fair value of equity instruments designated as measured at fair value through other comprehensive income	Exchange differences on translation of foreign operations	Share acquisition rights	Total	
Balance at beginning of period	2,211	2,255	(3,277)	(65)	—	33	—	33	1,156
Comprehensive income									
Profit (loss)	—	—	(726)	—	—	—	—	—	(726)
Other comprehensive income	—	—	—	—	10	(6)	—	3	3
Comprehensive income	—	—	(726)	—	10	(6)	—	3	(722)
Transactions with owners									
Exercise of share acquisition rights	688	674	—	—	—	—	—	—	1,363
Capital reduction	(2,111)	2,111	—	—	—	—	—	—	—
Deficit disposition	—	(3,633)	3,633	—	—	—	—	—	—
Purchase of treasury shares	—	—	—	(0)	—	—	—	—	(0)
Total transactions with owners	(1,423)	(847)	3,633	(0)	—	—	—	—	1,363
Balance at end of period	788	1,408	(370)	(65)	10	26	—	36	1,796

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2024	Nine months ended September 30, 2025
Cash flows from operating activities		
Profit (loss) before tax	(892)	(725)
Depreciation and amortization of intangible assets	161	28
Finance income	(1)	(1)
Finance costs	0	11
Share of loss (profit) of investments accounted for using equity method	3	0
Decrease (increase) in trade and other receivables	26	157
Decrease (increase) in inventories	(52)	(10)
Increase (decrease) in trade and other payables	(142)	257
Other	31	(13)
Subtotal	(864)	(296)
Interest received	0	1
Interest paid	(0)	(1)
Income taxes refund (paid)	(0)	(0)
Net cash provided by (used in) operating activities	(865)	(296)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Purchase of investment securities	―	(77)
Other	―	(0)
Net cash provided by (used in) investing activities	(0)	(79)
Cash flows from financing activities		
Proceeds from issuance of bonds	500	―
Redemption of bonds	(500)	―
Proceeds from issuance of shares	1,209	1,363
Purchase of share acquisition rights	(1)	―
Repayments of lease liabilities	(24)	(24)
Other	―	0
Net cash provided by (used in) financing activities	1,182	1,339
Net increase (decrease) in cash and cash equivalents	316	963
Cash and cash equivalents at beginning of period	728	886
Effect of exchange rate changes on cash and cash equivalents	(0)	(17)
Cash and cash equivalents at end of period	1,043	1,832

(6) Notes to condensed quarterly consolidated financial statements

(Notes on premise of going concern)

No items to report.

(Segment information)

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

(Change in presentation method)

In the previous consolidated fiscal year. “Other financial assets,” which had previously been included under “Other non-current assets,” have been separately presented due to increased materiality.
To reflect this change in presentation, a reclassification has been made in the consolidated statement of financial position for the previous fiscal year.
As a result, the amount of 46 million yen, previously presented under "Other non-current assets," has been reclassified and is now presented as "Other financial assets."