

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.



November 14, 2022

Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2022 (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 file quarterly securities report: November 14, 2022

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, 2022 (from January 1, 2022 to September 30, 2022)

(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, 2022 | 485 | 71.3 | (1,952) | – | (1,973) | – | (2,049) | – |
| September 30, 2021 | 283 | (1.5) | (2,063) | – | (2,084) | – | (2,111) | – |

| | 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, 2022 | (2,049) | – | (2,032) | – | (13.98) | (13.98) |
| September 30, 2021 | (2,111) | – | (2,099) | – | (16.36) | (16.36) |

(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, 2022 | 4,281 | 3,169 | 3,169 | 74.0 | 18.89 |
| December 31, 2021 | 3,144 | 2,587 | 2,587 | 82.3 | 19.38 |

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, 2021 | – | 0.00 | – | 0.00 | 0.00 |
| Fiscal year ending December 31, 2022 | – | 0.00 | – | | |
| Fiscal year ending December 31, 2022 (Forecast) | | | | 0.00 | 0.00 |

Note: Revisions to the forecast of cash dividends most recently announced: Yes

**3. Consolidated earnings forecasts for the fiscal year ending December 31, 2022
(from January 1, 2022 to December 31, 2022)**

(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, 2022 | 1,150 | 105.7 | (2,150) | – | (2,175) | – | (2,250) | – | (2,250) | – | (13.41) |

Note: Revisions to the consolidated earnings forecasts most recently announced: Yes

* 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, 2022 | 168,252,310 shares |
| As of December 31, 2021 | 133,946,210 shares |

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

| | |
|--------------------------|----------------|
| As of September 30, 2022 | 436,210 shares |
| As of December 31, 2021 | 440,010 shares |

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

| | |
|--|--------------------|
| For the Nine months ended September 30, 2022 | 146,635,496 shares |
| For the Nine months ended September 30, 2021 | 129,017,987 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.

Index

| | |
|--|----|
| 1. Qualitative information regarding results for the first three months | 2 |
| (1) Explanation of operating results | 2 |
| (2) Explanation of financial position..... | 5 |
| (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..... | 8 |
| (5) Condensed consolidated statement of cash flows..... | 9 |
| (6) Notes to condensed quarterly consolidated financial statements..... | 10 |

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, 2021 | Nine months ended September 30, 2022 | Year-on-year |
| Revenue | 283 | 485 | 201 |
| Gross profit | 125 | 352 | 226 |
| Operating profit (loss) | (2,063) | (1,952) | 111 |
| Profit (loss) | (2,111) | (2,049) | 61 |

The Group intends to focus business operations on expanding its oncology development pipeline, which consists of three products that have already been launched and two in the later stage of development. Under this goal, the Group primarily engaged in the following business activities in the nine months ended September 30, 2022.

[Launched products (development completed)]

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

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

Prescription and delivery volumes of Sancuso[®] (SP-01) and episil[®] (SP-03), which are mainly sold in China, were adversely affected by the spread of COVID-19 and related city-wide lockdowns in the country. Specifically, the pandemic and lockdowns resulted in temporary closures of cancer treatment centers and significant reductions in patient treatments. Further, marketing activities of the Group's and sales partners' medical representatives (MRs), including their access to medical institutions, were restrained. Prescription and shipment volumes of the two products were also affected by changes in the sales structure in the three Chinese cities made during the third quarter of the fiscal year under review.

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

The Company obtained marketing approval for SP-02 in Japan on June 20, 2022, and began sales on August 22.

[Pipeline products in the clinical study and later phase]

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

In August 2022, the Company announced results that neither the primary endpoint of Overall Response Rate (ORR) nor the key secondary endpoint in Progression Free Survival (PFS) achieved statistical significance in the multi-center, international Phase III AGENT Study of arfolitixorin in combination with 5-FU, oxaliplatin and bevacizumab in metastatic colorectal cancer (mCRC). The Company plans to reanalyze PFS, a secondary endpoint of the Phase III study, and conduct gene expression and other subgroup analyses and safety information analysis in phases, with the goal of releasing the results of these analyses in the fourth quarter of the fiscal year under review.

[Pipeline products in the non-clinical study phase]

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

Based on the results of the Phase III clinical trial 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 plan to conduct new animal studies in collaboration with licensor Egetis Therapeutics through 2023.

[Other]

Solasia implemented the following measures to improve its business structure and relationship with partners.

- On June 30, 2022, the Company resolved to dissolve its sales structure in China, which had been the main cause of the Group's losses, primarily for the purposes of reducing fixed costs and managing country risk of operating in China, including soaring labor costs and lockdowns in metropolitan areas. In specific, the Company decided to dissolve its sales organization operated by wholly-owned subsidiary Solasia Medical Information Consulting (Shanghai) Co., Ltd. in Beijing, Shanghai, and Guangzhou (hereafter, the "three cities") by the end of July 2022, which will bring down the number of Group employees from 77 (as of March 31, 2022) to around 27 (as of submission date).
- Following the abovementioned decision to dissolve its own sales structure in China, on the same day, the Company entered into a sublicense agreement with Lee's Pharmaceutical (HK) Limited, granting the latter marketing rights to Sancuso® and episil® in the three cities in China. As a result, the Company's sales of the two products in all of China will now be made to Lee's.
- To lower product procurement costs and ensure stable supply of products, on July 8, 2022, the Company concluded an agreement with Camurus AB, under which it acquired from the latter global licensing rights, including manufacturing rights, to episil® (SP-03) oral liquid.
- On June 28, 2022, Solasia entered into a capital and business partnership agreement with Nippon Kayaku Co., Ltd., its partner for SP-02. The purpose of the partnership was to secure stable financial resources for the long term necessary for the Company's continued active engagement in the development of new cancer treatments to meet the expectations of cancer patients, patients suffering from adverse effects of existing anticancer drugs, and healthcare providers.

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 aimed at improving earnings. However, in the short term, upfront expenditures for pipeline product development and investments in establishing sales structures continue to exceed earnings from product sales due to the impact of COVID-19-related lockdowns in China, the Company's main market, and product sales still being in the early stage. As a result, in the first nine months of the fiscal year under review, financial performance was as follows.

[Revenue, Gross profit]

During the nine months ended September 30, 2022, revenue totaled 485 million yen. Revenue mainly came from the sales of pipeline products of Sancuso® (SP-01), DARVIAS® (SP-02) and episil® (SP-03). In addition, gross profit amounted to 352 million yen

Breakdown of R&D and SG&A expenses

(Millions of yen)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 | Year-on-year |
|---|---|---|--------------|
| R&D expenses | 822 | 766 | (55) |
| SG&A expenses | 1,367 | 1,538 | 170 |
| Total | 2,189 | 2,304 | 115 |
| (Breakdown) | | | |
| Personnel expenses | 581 | 545 | (36) |
| Outsourcing expenses | 1,051 | 920 | (131) |
| Depreciation and amortization of intangible assets | 371 | 389 | 18 |
| Other | 185 | 449 | 264 |

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

R&D expenses amounted to 766 million yen, mainly comprising expenses for obtaining marketing approval for SP-02 and conducting a Phase III clinical trial (pivotal study) for SP-05. SG&A expenses amounted to 1,538 million yen, up 170 million yen year on year, as ongoing company-wide efforts to cut costs could not fully offset one-time costs (312 million yen) related to the dissolution of the in-house sales structure in China. The Company incurred an operating loss of 1,952 million yen. The Company incurred an overall loss of 2,049 million yen.

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

The Group posted a 401 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, 2022, pipeline investment amounted to 1,168 million yen. This figure includes the 401 million yen in intangible assets derived from capitalization of such outlays and 766 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01), DARVIAS® (SP-02) and episil® (SP-03), leading to amortization of 345 million yen during the nine months under review. As a result, the balance of intangible assets was 2,135 million yen as of September 30, 2022.

2) Cash flows

(Millions of yen)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 | Year-on-year |
|--|---|---|--------------|
| Net cash provided by (used in) operating activities | (2,049) | (1,096) | 952 |
| Net cash provided by (used in) investing activities | (106) | (418) | (311) |
| Net cash provided by (used in) financing activities | 372 | 2,581 | (2,209) |

[Cash flows from operating activities]

Net cash used in operating activities amounted to 1,096 million yen (compared with 2,049 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 1,973 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 418 million yen (compared with 106 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 403 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 2,581 million yen (compared with 372 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 2,608 million yen in proceeds from issuance of new shares by third party allotment and the exercise of warrants.

3) R&D activities

R&D expenses amounted to 766 million yen. In addition, the Company recorded a 401 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 1,168 million yen.

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, 2022, total assets amounted to 4,281 million yen, up 1,137million yen from the previous year-end. Current assets were 2,002 million yen, including 1,812 million yen in cash and cash equivalents. Non-current assets came to 2,278 million yen. This figure includes 2,135 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 1,111 million yen, up 555 million yen from the previous year-end. Current liabilities were 1,025 million yen, including 924 million yen in trade and other payables. Non-current liabilities amounted to 86 million yen, mainly due to 3 million yen in lease liabilities 72 million yen in deferred tax liabilities.

Total equity equaled 3,169 million yen, up 582 million yen from the previous year-end. The increase was mainly attributable to 2,608 million yen in proceeds from issuance of new shares by third party allotment and the exercise of warrants. The decrease was mainly attributable to the overall loss of 2,049 million yen.

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

The Company revised the consolidated earnings forecast for the fiscal year ending December 31, 2022 in light of the impact of the prolonged pandemic on product sales, the status of out-licensing activities for SP-02, pending subgroup analysis results for SP-05, and one-time expenses related to the dissolution of its in-house sales structure in China. For details, please refer to today's news release, entitled "Solasia Announces Revision to Full-Year Earnings Forecast."

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Millions of yen)

| | As of December 31, 2021 | As of June 30, 2022 |
|---|-------------------------|---------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | 714 | 1,812 |
| Trade and other receivables | 126 | 71 |
| Inventories | 0 | 2 |
| Other current assets | 53 | 116 |
| Total current assets | 894 | 2,002 |
| Non-current assets | | |
| Property, plant and equipment | 36 | 28 |
| Light-of-use asset | 84 | 50 |
| Intangible assets | 2,079 | 2,135 |
| Investments accounted for using equity method | — | 13 |
| Other non-current assets | 49 | 50 |
| Total non-current assets | 2,249 | 2,278 |
| Total assets | 3,144 | 4,281 |
| Liabilities and equity | | |
| Liabilities | | |
| Current liabilities | | |
| Trade and other payables | 386 | 924 |
| Lease liabilities | 47 | 48 |
| Other current liabilities | 55 | 51 |
| Total current liabilities | 489 | 1,025 |
| Non-current liabilities | | |
| Deferred tax liabilities | 18 | 72 |
| Lease liabilities | 37 | 3 |
| Other non-current liabilities | 10 | 10 |
| Total non-current liabilities | 67 | 86 |
| Total liabilities | 556 | 1,111 |
| Equity | | |
| Share capital | 2,110 | 1,431 |
| Capital surplus | 5,738 | 1,501 |
| Retained earnings | (5,204) | 275 |
| Treasury stock | (70) | (70) |
| Other components of equity | 13 | 30 |
| Total equity | 2,587 | 3,169 |
| Total liabilities and equity | 3,144 | 4,281 |

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 |
|---|---|---|
| Revenue | 283 | 485 |
| Cost of sales | 157 | 132 |
| Gross profit | 125 | 352 |
| Research and development expenses | 822 | 766 |
| Selling, general and administrative expenses | 1,367 | 1,538 |
| Operating profit (loss) | (2,063) | (1,952) |
| Finance income | 0 | 0 |
| Finance costs | 21 | 19 |
| Other income | 0 | — |
| Share of profit (loss) of investments accounted for using equity method | — | (1) |
| Profit (loss) before tax | (2,084) | (1,973) |
| Income taxes | 26 | 75 |
| Profit (loss) | (2,111) | (2,049) |
| Profit (loss) attributable to: | | |
| Owners of parent | (2,111) | (2,049) |
| Earnings (loss) per share | | |
| Basic earnings (loss) per share [yen] | (16.36) | (13.98) |
| Diluted earnings (loss) per share [yen] | (16.36) | (13.98) |

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 |
|---|---|---|
| Profit (loss) | (2,111) | (2,049) |
| Other comprehensive income | | |
| Items that may be reclassified to profit or loss | | |
| Exchange differences on translation of foreign operations | 11 | 16 |
| Subtotal | 11 | 16 |
| Total other comprehensive income | 11 | 16 |
| Comprehensive income | <u>(2,099)</u> | <u>(2,032)</u> |
| Comprehensive income attributable to: | | |
| Owners of parent | (2,099) | (2,032) |

(4) Condensed consolidated statement of changes in equity

(Millions of yen)

| | Other components of equity | | | | | | | |
|--------------------------------------|----------------------------|--------------------|----------------------|--------------------|--|--------------------------------|--|-----------------|
| | Share capital | Capital surplus | Retained earnings | Treasury shares | Exchange differences on translation of foreign operations | Share acquisition rights | Total Other component s of equity | Total equity |
| Balance at January 1, 2021 | 1,402 | 5,043 | (2,726) | (70) | (6) | 9 | 2 | 3,652 |
| Comprehensive income | | | | | | | | |
| Profit (loss) | — | — | (2,111) | — | — | — | — | (2,111) |
| Other comprehensive income | — | — | — | — | 11 | — | 11 | 11 |
| Total comprehensive income | — | — | (2,111) | — | 11 | — | 11 | (2,099) |
| Transactions with owners | | | | | | | | |
| Exercise of share acquisition rights | 707 | 702 | — | — | — | (6) | (6) | 1,403 |
| Total transactions with owners | 707 | 702 | — | — | — | (6) | (6) | 1,403 |
| Balance at September 30, 2021 | <u>2,110</u> | <u>5,746</u> | <u>(4,837)</u> | <u>(70)</u> | <u>4</u> | <u>3</u> | <u>7</u> | <u>2,956</u> |
| Balance at January 1, 2022 | 2,110 | 5,738 | (5,204) | (70) | 10 | 3 | 13 | 2,587 |
| Comprehensive income | | | | | | | | |
| Profit (loss) | — | — | (2,049) | — | — | — | — | (2,049) |
| Other comprehensive income | — | — | — | — | 16 | — | 16 | 16 |
| Total comprehensive income | — | — | (2,049) | — | 16 | — | 16 | (2,032) |
| Transactions with owners | | | | | | | | |
| Issuance of new shares | 510 | 477 | — | — | — | — | — | 987 |
| Exercise of share acquisition rights | 821 | 806 | — | — | — | (7) | (7) | 1,621 |
| Issuance of share acquisition rights | — | — | — | — | — | 10 | 10 | 10 |
| Disposal of share acquisition rights | — | — | — | — | — | (3) | (3) | (3) |
| Capital reduction | (2,010) | (5,519) | 7,529 | — | — | — | — | — |
| Disposal of treasury shares | — | — | — | 0 | — | — | — | 0 |
| Share-based payment transactions | — | (0) | — | — | — | — | — | (0) |
| Total transactions with owners | <u>(678)</u> | <u>(4,236)</u> | <u>7,529</u> | <u>0</u> | <u>—</u> | <u>0</u> | <u>0</u> | <u>2,615</u> |
| Balance at September 30, 2022 | <u>1,431</u> | <u>1,501</u> | <u>275</u> | <u>(70)</u> | <u>27</u> | <u>3</u> | <u>30</u> | <u>3,169</u> |

(5) Condensed consolidated statement of cash flows

(Millions of yen)

| | Nine months ended September 30, 2021 | Nine months ended September 30, 2022 |
|---|---|---|
| Cash flows from operating activities | | |
| Profit (loss) before tax | (2,084) | (1,973) |
| Depreciation and amortization | 371 | 389 |
| Finance income | (0) | (0) |
| Finance costs | 21 | 19 |
| Share of loss (profit) of investments accounted for using equity method | — | 1 |
| Decrease (increase) in trade and other receivables | 122 | 54 |
| Decrease (increase) in inventories | 2 | (1) |
| Increase (decrease) in trade and other payables | (486) | 517 |
| Other | 27 | (76) |
| Subtotal | <u>(2,026)</u> | <u>(1,067)</u> |
| Interest received | 0 | 0 |
| Interest paid | (1) | (1) |
| Income taxes paid | (21) | (27) |
| Net cash provided by (used in) operating activities | <u>(2,049)</u> | <u>(1,096)</u> |
| Cash flows from investing activities | | |
| Purchase of property, plant and equipment | (1) | (0) |
| Purchase of intangible assets | (105) | (403) |
| Share-based payment transactions | — | (14) |
| Net cash provided by (used in) investing activities | <u>(106)</u> | <u>(418)</u> |
| Cash flows from financing activities | | |
| Proceeds from issuance of bonds | — | 500 |
| Redemption of bonds | (1,000) | (500) |
| Proceeds from issuance of new shares | 1,403 | 2,608 |
| Proceeds from issuance of share acquisition rights | — | 10 |
| Acquisition of share acquisition rights | — | (3) |
| Repayment of lease liabilities | (30) | (33) |
| Net cash provided by (used in) financing activities | <u>372</u> | <u>2,581</u> |
| Net increase (decrease) in cash and cash equivalents | <u>(1,783)</u> | <u>(1,066)</u> |
| Cash and cash equivalents at beginning of period | <u>2,964</u> | <u>714</u> |
| Effect of exchange rate changes on cash and cash equivalents | 23 | 31 |
| Cash and cash equivalents at end of period | <u>1,204</u> | <u>1,812</u> |

(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.