

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 10, 2021

## Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2021 (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 10, 2021

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, 2021 (from January 1, 2021 to September 30, 2021)

#### (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, 2021	283	(1.5)	(2,063)	–	(2,084)	–	(2,111)	–
September 30, 2020	287	(1.3)	(1,902)	–	(1,928)	–	(1,937)	–

	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, 2021	(2,111)	–	(2,099)	–	(16.36)	(16.36)
September 30, 2020	(1,937)	–	(1,938)	–	(16.64)	(16.64)

#### (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, 2021	3,713	2,956	2,956	79.6	22.14
December 31, 2020	5,775	3,652	3,652	63.2	29.78

### 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, 2020	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2021	–	0.00	–		
Fiscal year ending December 31, 2021 (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, 2021  
(from January 1, 2021 to December 31, 2021)**

(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, 2021	600	32.1	(2,500)	–	(2,500)	–	(2,500)	–	(2,500)	–	(18.73)

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, 2021	133,946,210 shares
As of December 31, 2020	123,081,210 shares

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

As of September 30, 2021	440,000 shares
As of December 31, 2020	440,000 shares

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

For the Nine months ended September 30, 2021	129,017,987 shares
For the Nine months ended September 30, 2020	116,447,636 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, 2020	Nine months ended September 30, 2021	Year-on-year
Revenue	287	283	(4)
Gross profit	186	125	(60)
Operating profit (loss)	(1,902)	(2,063)	(161)
Profit (loss)	(1,937)	(2,111)	(173)

The Group intends to focus business operations on expanding its oncology development pipeline, which consists of two 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, 2021.

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

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

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

The COVID-19 pandemic significantly restrained marketing activities of the Group's and sales partners' medical representatives (MRs), including their access to medical sites. This in turn had an impact on the prescription and delivery volumes of Sancuso® (SP-01) and episil® (SP-03), which were mainly sold in China.

#### **[Pipeline products in the clinical study and later phase]**

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

In 2020, the Company achieved the primary endpoint (antitumor effect) in the Global Phase II clinical trial (pivotal study) of our pipeline product SP-02. In September 30, 2021, we filed a New Drug Application (NDA) for the drug with the regulatory authority in Japan.

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

Based on the interim analysis of the global Phase III clinical trial of SP-05, a pivotal study before filing for regulatory approval, the target number of patients enrolled in the study should be 440, the minimum number specified in the trial protocol. As of the submission date of this document, the Company is continuing the trial with the minimum target number of patients with the aim of bringing the product to market.

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

##### **SP-04 (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 are conducting additional animal studies to investigate the product's potential in treating taxane-induced peripheral neuropathy.

As indicated above, we have focused on achieving progress in terms of both our products and pipeline products. On the financial front, however, 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, 2021, was as follows.

[Revenue, Gross profit]

During the nine months ended September 30, 2021, revenue totaled 283 million yen. Revenue mainly came from the sales of pipeline products of Sancuso® (SP-01) and episil® (SP-03). In addition, gross profit amounted to 125 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year
R&D expenses	1,003	822	(181)
SG&A expenses	1,085	1,367	281
Total	2,089	2,189	100
(Breakdown)			
Personnel expenses	458	581	122
Outsourcing expenses	1,117	1,051	(66)
Depreciation and amortization of intangible assets	372	371	(0)
Other	140	185	44

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

R&D expenses amounted to 822 million yen. This amount is mainly attributable to expenses incurred for a multinational phase II clinical study (pivotal study) and the submission cost of New Drug Application for SP-02 and a multinational phase III clinical study of SP-05. SG&A expenses amounted to 1,367million yen, up 281 million yen year on year.

The Company incurred an operating loss of 2,063 million yen.

The Company incurred an overall loss of 2,111 million yen.

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

The Group posted a 160 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, 2021, pipeline investment amounted to 982 million yen. This figure includes the 160 million yen in intangible assets derived from capitalization of such outlays and 822 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01) and episil® (SP-03), leading to amortization of 329 million yen during the nine months under review. As a result, the balance of intangible assets was 2,187 million yen as of September 30, 2021.

## 2) Cash flows

	(Millions of yen)		
	Nine months ended September 30, 2020	Nine months ended September 30, 2021	Year-on-year
Net cash provided by (used in) operating activities	(2,243)	(2,049)	193
Net cash provided by (used in) investing activities	(161)	(106)	55
Net cash provided by (used in) financing activities	2,521	372	(2,148)

### [Cash flows from operating activities]

Net cash used in operating activities amounted to 2,049 million yen (compared with 2,243 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 2,084 million yen.

### [Cash flows from investing activities]

Net cash used in investing activities amounted to 106 million yen (compared with 161 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 105 million yen in outflows related to capitalized development investment.

### [Cash flows from financing activities]

Net cash provided by financing activities amounted to 372 million yen (compared with 2,521 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 1,000 million yen from redemption of bonds and 1,403 million yen in proceeds from issuance of new shares by the exercise of warrants.

## 3) R&D activities

R&D expenses amounted to 822 million yen. In addition, the Company recorded a 160 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 982 million yen.

Summaries regarding progress achieved with pipeline products—those in the clinical study or later phase—are as follows.

	As of January 1, 2021	Nine months ended September 30, 2021	As of today
SP-01 Sancuso® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-02 darinaparsin Japan etc.	Preparing for NDA filing	Application for approval filed (in June 2021)	Application for approval filed (in June 2021)
SP-03 episil® Japan China Korea	Ongoing sale	Ongoing sale	Ongoing sale
SP-05 arfolitixorin Japan	Global Phase III clinical study in progress. Preparing for an interim analysis of data obtained from 330 patients Patient enrollment reached 440	Global Phase III clinical study in progress. Determined to continue the study with the minimum target number of patients based on interim analysis	Global Phase III clinical study in progress. Completion of patient enrollment

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, 2021, total assets amounted to 3,713 million yen, down 2,061 million yen from the previous year-end. Current assets were 1,345 million yen, including 1,204 million yen in cash and cash equivalents. Non-current assets came to 2,368 million yen. This figure includes 2,187 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 757 million yen, down 1,365 million yen from the previous year-end. Current liabilities were 678 million yen, including 574 million yen in trade and other payables. Non-current liabilities amounted to 78 million yen, mainly due to 49 million yen in lease liabilities 18 million yen in deferred tax liabilities.

Total equity equaled 2,956 million yen, down 696 million yen from the previous year-end. The increase was mainly attributable to 1,403 million yen in proceeds from issuance of new shares. The decrease was mainly attributable to the overall loss of 2,111 million yen.

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

The Company has revised the consolidated earnings forecasts for the fiscal year ending December 31, 2021 (announced on February 10, 2021), mainly due to the spread of the COVID-19 pandemic continues longer than anticipated, it made a stronger impact on product sales, out-licensing its pipeline products, and other elements of our business than initially estimated.

Details are 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, 2020	As of September 30, 2021
<b>Assets</b>		
Current assets		
Cash and cash equivalents	2,964	1,204
Trade and other receivables	173	50
Inventories	4	2
Other current assets	126	87
Total current assets	<u>3,269</u>	<u>1,345</u>
Non-current assets		
Property, plant and equipment	43	37
Light-of-use asset	59	94
Intangible assets	2,356	2,187
Other non-current assets	46	48
Total non-current assets	<u>2,506</u>	<u>2,368</u>
Total assets	<u><u>5,775</u></u>	<u><u>3,713</u></u>
<b>Liabilities and equity</b>		
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	987	574
Bonds payable	1,000	—
Lease liabilities	39	46
Other current liabilities	52	57
Total current liabilities	<u>2,079</u>	<u>678</u>
Non-current liabilities		
Deferred tax liabilities	11	18
Lease liabilities	21	49
Other non-current liabilities	10	10
Total non-current liabilities	<u>43</u>	<u>78</u>
Total liabilities	<u>2,123</u>	<u>757</u>
<b>Equity</b>		
Share capital	1,402	2,110
Capital surplus	5,043	5,746
Retained earnings	(2,726)	(4,837)
Treasury stock	(70)	(70)
Other components of equity	2	7
Total equity	<u>3,652</u>	<u>2,956</u>
Total liabilities and equity	<u><u>5,775</u></u>	<u><u>3,713</u></u>



(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021
Revenue	287	283
Cost of sales	100	157
Gross profit	186	125
Research and development expenses	1,003	822
Selling, general and administrative expenses	1,085	1,367
Operating profit (loss)	(1,902)	(2,063)
Finance income	0	0
Finance costs	27	21
Other income	–	0
Other costs	0	–
Profit (loss) before tax	(1,928)	(2,084)
Income taxes	8	26
Profit (loss)	(1,937)	(2,111)
Profit (loss) attributable to:		
Owners of parent	(1,937)	(2,111)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(16.64)	(16.36)
Diluted earnings (loss) per share [yen]	(16.64)	(16.36)

## (3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021
Profit (loss)	(1,937)	(2,111)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(0)	11
Subtotal	(0)	11
Total other comprehensive income	(0)	11
Comprehensive income	(1,938)	(2,099)
Comprehensive income attributable to:		
Owners of parent	(1,938)	(2,099)

## (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, 2020	960	4,630	1,400	(70)	(4)	–	(4)	6,917
Comprehensive income								
Profit (loss)	–	–	(1,937)	–	–	–	–	(1,937)
Other comprehensive income	–	–	–	–	(0)	–	(0)	(0)
Total comprehensive income	–	–	(1,937)	–	(0)	–	(0)	(1,938)
Transactions with owners								
Exercise of share acquisition rights	154	139	–	–	–	(1)	(1)	292
Issuance of share acquisition rights	–	–	–	–	–	13	13	13
Total transactions with owners	154	139	–	–	–	12	12	306
Balance at September 30, 2020	1,115	4,769	(536)	(70)	(5)	12	6	5,285
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	2,110	5,746	(4,837)	(70)	4	3	7	2,956

## (5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2020	Nine months ended September 30, 2021
Cash flows from operating activities		
Profit (loss) before tax	(1,928)	(2,084)
Depreciation and amortization	372	371
Finance income	(0)	(0)
Finance costs	27	21
Decrease (increase) in trade and other receivables	(79)	122
Decrease (increase) in inventories	(3)	2
Increase (decrease) in trade and other payables	(556)	(486)
Other	(60)	27
Subtotal	<u>(2,228)</u>	<u>(2,026)</u>
Interest received	0	0
Interest paid	(0)	(1)
Income taxes paid	(14)	(21)
Net cash provided by (used in) operating activities	<u>(2,243)</u>	<u>(2,049)</u>
Cash flows from investing activities		
Purchase of property, plant and equipment	(2)	(1)
Purchase of intangible assets	(159)	(105)
Other	(0)	—
Net cash provided by (used in) investing activities	<u>(161)</u>	<u>(106)</u>
Cash flows from financing activities		
Proceeds from issuance of bonds	2,500	—
Redemption of bonds	(250)	(1,000)
Proceeds from issuance of new shares	292	1,403
Proceeds from issuance of share acquisition rights	13	—
Repayment of lease liabilities	(34)	(30)
Net cash provided by (used in) financing activities	<u>2,521</u>	<u>372</u>
Net increase (decrease) in cash and cash equivalents	<u>116</u>	<u>(1,783)</u>
Cash and cash equivalents at beginning of period	<u>4,116</u>	<u>2,964</u>
Effect of exchange rate changes on cash and cash equivalents	(12)	23
Cash and cash equivalents at end of period	<u>4,221</u>	<u>1,204</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.