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May 15, 2024

Consolidated Financial Results for the First Three 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://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 file quarterly securities report: May 15, 2024

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 three months of the fiscal year ending December 31, 2024 (from January 1, 2024 to March 31, 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	%
Three months ended								
March 31, 2024	11	(94.6)	(307)	–	(318)	–	(310)	–
March 31, 2023	220	93.8	(245)	–	(247)	–	(241)	–

	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
Three months ended						
March 31, 2024	(310)	–	(300)	–	(1.78)	(1.78)
March 31, 2023	(241)	–	(237)	–	(1.44)	(1.44)

(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
March 31, 2024	2,708	1,823	1,823	67.3	10.01
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	–				
Fiscal year ending December 31, 2024 (Forecast)		0.00	–	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)	—	(4.39)
	~ 1,500	~ 143.0	~ (550)	~ —	~ (550)	~ —	~ (550)	~ —	~ (550)	~ —	~ (3.02)

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: 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 March 31, 2024	182,494,010 shares
As of December 31, 2023	174,373,910 shares

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

As of March 31, 2024	414,210 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 three months ended March 31, 2024	174,044,528 shares
For the three months ended March 31, 2023	167,966,100 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.

[Attached Material]

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1. Qualitative information regarding results for the first three months

(1) Explanation of operating results

1) Overview of results

Operating results

	Three months ended March 31, 2023	Three months ended March 31, 2024	(Millions of yen) Year-on-year
Revenue	220	11	(208)
Gross profit	128	0	(127)
Operating profit (loss)	(245)	(307)	(62)
Profit (loss)	(241)	(310)	(69)

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 three months ended March 31, 2024.

[Launched products (development completed)]

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

SP-03 (Indication: 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 relocation of the manufacturing facility in a bid to lower costs .

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 trial 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 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 doses and dosages different from those used in the AGENT study.

In February 2024, Isofol's Board of Directors decided to prepare a new 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.

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.

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 product sales still being in the early stage. As a result, our financial performance during the three months ended March 31, 2024, was as follows.

[Revenue, Gross profit]

During the three months ended March 31, 2024, revenue totaled 11million 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 424 thousand yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Three months ended March 31, 2023	Three months ended March 31, 2024	Year-on-year
R&D expenses	93	76	(16)
SG&A expenses	280	232	(48)
Total	373	308	(65)
(Breakdown)			
Personnel expenses	119	102	(16)
Outsourcing expenses	104	86	(18)
Depreciation and amortization of intangible assets	126	93	(33)
Other	22	25	3

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

R&D expenses amounted to 76 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 232 million yen, down 48 million yen year on year.

The Company incurred an operating loss of 307 million yen.

The Company incurred an overall loss of 310 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 three months ended March 31, 2024, pipeline investment amounted to 76 million yen. This figure is 76 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 83 million yen during the three months under review. As a result, the balance of intangible assets was 1,033 million yen as of March 31, 2024.

2) Cash flows

(Millions of yen)

	Three months ended March 31, 2023	Three months ended March 31, 2024	Year-on-year
Net cash provided by (used in) operating activities	223	(164)	(387)
Net cash provided by (used in) investing activities	(0)	—	0
Net cash provided by (used in) financing activities	(12)	743	755

[Cash flows from operating activities]

Net cash used in operating activities amounted to 164 million yen (compared with 223 million yen in net cash provided by these activities in the corresponding period of the previous fiscal year), which was mainly attributable to loss before tax of 318 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to — 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 743 million yen (compared with 12 million yen used in these activities in the same period of the previous year). This figure was mainly attributable to 500 million yen in proceeds from issuance of Bonds and 249 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) R&D activities

R&D expenses amounted to 76 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.

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 March 31, 2024, total assets amounted to 2,708 million yen, up 478 million yen from the previous year-end. Current assets were 1,547 million yen, including 1,319 million yen in cash and cash equivalents. Non-current assets came to 1,160 million yen. This figure includes 1,033 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 884 million yen, up 530 million yen from the previous year-end. Current liabilities were 837 million yen, including 500 million yen in Bonds payables 259 million yen in trade and other payables. Non-current liabilities amounted to 47 million yen, mainly due to 20 million yen in lease liabilities 13 million yen in deferred tax liabilities.

Total equity equaled 1,823 million yen, down 52 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 310 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 December 31, 2023	As of March 31, 2024
Assets		
Current assets		
Cash and cash equivalents	728	1,319
Trade and other receivables	67	27
Inventories	122	143
Other current assets	58	57
Total current assets	976	1,547
Non-current assets		
Property, plant and equipment	21	21
Light-of-use asset	60	53
Intangible assets	1,117	1,033
Investments accounted for using equity method	6	5
Other non-current assets	46	47
Total non-current assets	1,252	1,160
Total assets	2,229	2,708
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	213	259
Bonds payable	—	500
Lease liabilities	33	33
Other current liabilities	45	44
Total current liabilities	293	837
Non-current liabilities		
Deferred tax liabilities	22	13
Lease liabilities	27	20
Other non-current liabilities	10	14
Total non-current liabilities	61	47
Total liabilities	354	884
Equity		
Share capital	1,596	1,726
Capital surplus	1,657	1,774
Retained earnings	(1,336)	(1,646)
Treasury stock	(69)	(66)
Other components of equity	26	35
Total equity	1,875	1,823
Total liabilities and equity	2,229	2,708

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Three months ended March 31, 2023	Three months ended March 31, 2024
Revenue	220	11
Cost of sales	91	11
Gross profit	128	0
Research and development expenses	93	76
Selling, general and administrative expenses	280	232
Operating profit (loss)	(245)	(307)
Finance income	0	0
Finance costs	0	10
Share of profit (loss) of investments accounted for using equity method	(1)	(0)
Finance costs		
Profit (loss) before tax	(247)	(318)
Income taxes	(6)	(8)
Profit (loss)	(241)	(310)
Profit (loss) attributable to:		
Owners of parent	(241)	(310)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(1.44)	(1.78)
Diluted earnings (loss) per share [yen]	(1.44)	(1.78)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Three months ended March 31, 2023	Three months ended March 31, 2024
Profit (loss)	(241)	(310)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	3	10
Subtotal	3	10
Total other comprehensive income	3	10
Comprehensive income	(237)	(300)
Comprehensive income attributable to:		
Owners of parent	(237)	(300)

(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)	–	–	(241)	–	–	–	–	(241)
Other comprehensive income	–	–	–	–	3	–	3	3
Total comprehensive income	–	–	(241)	–	3	–	3	(237)
Transactions with owners								
Exercise of share acquisition rights	–	–	–	–	–	–	–	–
Total transactions with owners	–	–	–	–	–	–	–	–
Balance at March 31, 2023	1,436	1,500	(464)	(70)	19	3	22	2,424
Balance at January 1, 2024	1,596	1,657	(1,336)	(69)	25	1	26	1,875
Comprehensive income								
Profit (loss)	–	–	(310)	–	–	–	–	(310)
Other comprehensive income	–	–	–	–	10	–	10	10
Total comprehensive income	–	–	(310)	–	10	–	10	(300)
Transactions with owners								
Exercise of share acquisition rights	129	119	–	–	–	–	–	249
Disposal of share acquisition rights	–	–	–	–	–	(1)	(1)	(1)
Disposal of treasury shares	–	–	–	2	–	–	–	2
Share-based payment transactions	–	(2)	–	–	–	–	–	(2)
Total transactions with owners	129	117	–	2	–	(1)	(1)	247
Balance at March 31, 2024	1,726	1,774	(1,646)	(66)	35	–	35	1,823

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Three months ended March 31, 2023	Three months ended March 31, 2024
Cash flows from operating activities		
Profit (loss) before tax	(247)	(318)
Depreciation and amortization	126	93
Finance income	(0)	(0)
Finance costs	0	10
Share of loss (profit) of investments accounted for using equity method	1	0
Decrease (increase) in trade and other receivables	332	40
Decrease (increase) in inventories	(41)	(20)
Increase (decrease) in trade and other payables	45	32
Other	8	(1)
Subtotal	226	(163)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	(2)	(0)
Net cash provided by (used in) operating activities	223	(164)
Cash flows from investing activities		
Purchase of property, plant and equipment	(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	—	—
Proceeds from issuance of new shares	—	249
Acquisition of share acquisition rights	—	(1)
Repayment of lease liabilities	(12)	(8)
Other	—	3
Net cash provided by (used in) financing activities	(12)	743
Net increase (decrease) in cash and cash equivalents	210	579
Cash and cash equivalents at beginning of period	803	728
Effect of exchange rate changes on cash and cash equivalents	2	11
Cash and cash equivalents at end of period	1,016	1,319

(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.