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August 10, 2023

**Consolidated Financial Results for the First Six Months of
the Fiscal Year Ending December 31, 2023
(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: August 10, 2023
 Scheduled date to commence dividend payments: –
 Preparation of supplementary material on quarterly financial results: Yes
 Holding of quarterly financial results presentation meeting: Yes (for institutional investors and analysts)

(Millions of yen with fractional amounts discarded, unless otherwise noted)

1. Consolidated financial results for the first six months of the fiscal year ending December 31, 2023 (from January 1, 2023 to June 30, 2023)

(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	%
Six months ended June 30, 2023	529	179.5	(462)	–	(450)	–	(437)	–
June 30, 2022	189	(31.9)	(1,228)	–	(1,233)	–	(1,247)	–

	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
Six months ended June 30, 2023	(437)	–	(430)	–	(2.61)	(2.61)
June 30, 2022	(1,247)	–	(1,231)	–	(8.98)	(8.98)

(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 June 30, 2023	2,678	2,233	2,233	83.3	13.29
December 31, 2022	3,134	2,662	2,662	84.9	15.85

2. Cash dividends

	Annual cash dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
Fiscal year ended December 31, 2022	Yen –	Yen 0.00	Yen –	Yen 0.00	Yen 0.00
Fiscal year ending December 31, 2023	–	0.00			
Fiscal year ending December 31, 2023 (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, 2023
(from January 1, 2023 to December 31, 2023)**

(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, 2023	1,000	(8.5)	(1,150)	—	(1,150)	—	(1,150)	—	(1,150)	—	(6.84)
	~	~	~	~	~	~	~	~	~	~	~
	1,800	64.7	(350)	—	(350)	—	(350)	—	(350)	—	(2.08)

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 June 30, 2023	168,472,310 shares
As of December 31, 2022	168,402,310 shares

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

As of June 30, 2023	436,210 shares
As of December 31, 2022	436,210 shares

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

For the Six months ended June 30, 2023	167,977,702 shares
For the Six months ended June 30, 2022	138,912,094 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.

A financial results presentation meeting will be held on thursday, August 17, 2023 for institutional investors and analysts.

The presentation materials used at the meeting will be available on our website immediately after the meeting.

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1. Qualitative information regarding results for the first six months

(1) Explanation of operating results

1) Overview of results

Operating results

	Six months ended June 30, 2022	Six months ended June 30, 2023	(Millions of yen) Year-on-year
Revenue	189	529	340
Gross profit	127	289	161
Operating profit (loss)	(1,228)	(462)	765
Profit (loss)	(1,247)	(437)	809

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 six months ended June 30, 2023..

[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 affected by the spread of COVID-19 so far, but owing to the easing of various restrictions imposed under China's zero-COVID policy, treatment opportunities for cancer patients and promotional activities by medical representatives (MRs) of sales partners, including their access to medical institutions, recovered. As a result, sales gradually expanded.

[Pipeline products in the clinical study and later phase]

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

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

In March 2023, the Company completed preparations for providing the drug under the Named Patient Program, primarily in Europe, among other regions.

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

[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 plan to conduct new animal studies in collaboration with licensor Egetis Therapeutics .

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 last

year 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 six months ended June 30, 2023, was as follows.

[Revenue, Gross profit]

During the six months ended June 30, 2023, revenue totaled 529 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 289 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Six months ended June 30, 2022	Six months ended June 30, 2023	Year-on-year
R&D expenses	347	192	(155)
SG&A expenses	1,008	559	(448)
Total	1,356	751	(604)
(Breakdown)			
Personnel expenses	421	236	(185)
Outsourcing expenses	493	218	(275)
Depreciation and amortization of intangible assets	248	252	4
Other	192	44	(147)

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

R&D expenses amounted to 192 million yen. This amount mainly reflected costs for changing the manufacturing site to lower manufacturing costs, R&D aimed at expanding the indications for DARVIAS® (SP-02), and investments in new development candidates. SG&A expenses amounted to 559 million yen, down 448 million yen year on year, as ongoing company-wide efforts to cut costs related to the dissolution of the in-house sales structure in China.

The Company incurred an operating loss of 462 million yen.

The Company incurred an overall loss of 437 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 six months ended June 30, 2023, pipeline investment amounted to 192 million yen. This figure is 192 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 226 million yen during the six months under review. As a result, the balance of intangible assets was 1,343 million yen as of June 30, 2023.

2) Cash flows

	(Millions of yen)		
	Six months ended June 30, 2022	Six months ended June 30, 2023	Year-on-year
Net cash provided by (used in) operating activities	(963)	(330)	632
Net cash provided by (used in) investing activities	(20)	(0)	20
Net cash provided by (used in) financing activities	1,211	(23)	(1,234)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 330 million yen (compared with 963 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 450 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 0 million yen (compared with 20 million yen used in these activities in the corresponding period of the previous fiscal year).

[Cash flows from financing activities]

Net cash used in financing activities amounted to 23 million yen (compared with 1,211million yen provided by these activities in the same period of the previous year).

3) R&D activities

R&D expenses amounted to 192 million yen. This amount mainly reflected costs for changing the manufacturing site to lower manufacturing costs, R&D aimed at expanding the indications for DARVIAS® (SP-02), 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 June 30, 2023, total assets amounted to 2,678 million yen, down 455 million yen from the previous year-end. Current assets were 1,171 million yen, including 453 million yen in cash and cash equivalents, 549 million yen in trade and other receivables. Non-current assets came to 1,507 million yen. This figure includes 1,343 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 445 million yen, down 26 million yen from the previous year-end. Current liabilities were 351 million yen, including 273 million yen in trade and other payables. Non-current liabilities amounted to 93 million yen, mainly due to 44 million yen in lease liabilities 38 million yen in deferred tax liabilities.

Total equity equaled 2,233 million yen, down 428 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 437 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, 2023

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2022	As of June 30, 2023
Assets		
Current assets		
Cash and cash equivalents	803	453
Trade and other receivables	572	549
Inventories	14	117
Other current assets	44	51
Total current assets	1,435	1,171
Non-current assets		
Property, plant and equipment	26	24
Light-of-use asset	37	79
Intangible assets	1,570	1,343
Investments accounted for using equity method	11	8
Other non-current assets	52	50
Total non-current assets	1,698	1,507
Total assets	3,134	2,678
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	332	273
Lease liabilities	37	34
Other current liabilities	37	43
Total current liabilities	407	351
Non-current liabilities		
Deferred tax liabilities	53	38
Lease liabilities	0	44
Other non-current liabilities	10	10
Total non-current liabilities	64	93
Total liabilities	472	445
Equity		
Share capital	1,436	1,436
Capital surplus	1,500	1,501
Retained earnings	(223)	(661)
Treasury stock	(70)	(70)
Other components of equity	19	26
Total equity	2,662	2,233
Total liabilities and equity	3,134	2,678

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Six months ended June 30, 2022	Six months ended June 30, 2023
Revenue	189	529
Cost of sales	61	240
Gross profit	127	289
Research and development expenses	347	192
Selling, general and administrative expenses	1,008	559
Operating profit (loss)	(1,228)	(462)
Finance income	2	15
Finance costs	7	0
Share of profit (loss) of investments accounted for using equity method	(0)	(3)
Profit (loss) before tax	(1,233)	(450)
Income taxes	13	(13)
Profit (loss)	(1,247)	(437)
Profit (loss) attributable to:		
Owners of parent	(1,247)	(437)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(8.98)	(2.61)
Diluted earnings (loss) per share [yen]	(8.98)	(2.61)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Six months ended June 30, 2022	Six months ended June 30, 2023
Profit (loss)	(1,247)	(437)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	16	7
Subtotal	16	7
Total other comprehensive income	16	7
Comprehensive income	(1,231)	(430)
Comprehensive income attributable to:		
Owners of parent	(1,231)	(430)

(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, 2022	2,110	5,738	(5,204)	(70)	10	3	13	2,587
Comprehensive income								
Profit (loss)	–	–	(1,247)	–	–	–	–	(1,247)
Other comprehensive income	–	–	–	–	16	–	16	16
Total comprehensive income	–	–	(1,247)	–	16	–	16	(1,231)
Transactions with owners								
Exercise of share acquisition rights	624	603	–	–	–	(5)	(5)	1,222
Issuance of share acquisition rights	–	–	–	–	–	10	10	10
Capital reduction	(2,010)	(5,519)	7,529	–	–	–	–	–
Disposal of treasury shares	–	–	–	0	–	–	–	0
Share-based payment transactions	–	(0)	–	–	–	–	–	(0)
Total transactions with owners	(1,385)	(4,915)	7,529	0	–	5	5	1,233
Balance at June 30, 2022	724	822	1,077	(70)	26	8	35	2,590
Balance at January 1, 2023	1,436	1,500	(223)	(70)	15	3	19	2,662
Comprehensive income								
Profit (loss)	–	–	(437)	–	–	–	–	(437)
Other comprehensive income	–	–	–	–	7	–	7	7
Total comprehensive income	–	–	(437)	–	7	–	7	(430)
Transactions with owners								
Exercise of share acquisition rights	0	0	–	–	–	–	–	1
Total transactions with owners	0	0	–	–	–	–	–	1
Balance at June 30, 2023	1,436	1,501	(661)	(70)	23	3	26	2,233

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Six months ended June 30, 2022	Six months ended June 30, 2023
Cash flows from operating activities		
Profit (loss) before tax	(1,233)	(450)
Depreciation and amortization	248	252
Finance income	(2)	(15)
Finance costs	7	0
Share of loss (profit) of investments accounted for using equity method	0	3
Decrease (increase) in trade and other receivables	90	62
Decrease (increase) in inventories	(1)	(103)
Increase (decrease) in trade and other payables	(56)	(52)
Other	12	(1)
Subtotal	(935)	(304)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	(27)	(25)
Net cash provided by (used in) operating activities	(963)	(330)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Purchase of intangible assets	(5)	—
Share-based payment transactions	(14)	—
Net cash provided by (used in) investing activities	(20)	(0)
Cash flows from financing activities		
Proceeds from issuance of bonds	500	—
Redemption of bonds	(500)	—
Proceeds from issuance of new shares	1,222	1
Proceeds from issuance of share acquisition rights	10	—
Repayment of lease liabilities	(22)	(24)
Net cash provided by (used in) financing activities	1,211	(23)
Net increase (decrease) in cash and cash equivalents	226	(354)
Cash and cash equivalents at beginning of period	714	803
Effect of exchange rate changes on cash and cash equivalents	29	3
Cash and cash equivalents at end of period	973	453

(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.