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Consolidated Financial Results for the First Six 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://www.solasia.co.jp/en/

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Scheduled date to file quarterly securities report: August 15, 2022

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

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
June 30, 2022	189	(31.9)	(1,228)	_	(1,233)	_	(1,247)	-
June 30, 2021	278	15.8	(1,362)	=	(1,383)	-	(1,394)	=

	Profit attribut owners of p		Total comprehensive income		Basic earnings per share	Diluted earnings per share
Six months ended	Millions of yen	%	Millions of yen	%	Yen	Yen
June 30, 2022	(1,247)	-	(1,231)	_	(8.98)	(8.98)
June 30, 2021	(1,394)	_	(1,386)	_	(10.91)	(10.91)

(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
June 30, 2022	3,072	2,590	2,590	84.3	17.31
December 31, 2021	3,144	2,587	2,587	82.3	19.38

2. Cash dividends

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: None

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.)

	Reven	nue	Operating	g profit	Profit bef	ore tax	Prof	fit	Prof attributa owners of	ble to	Basic earnings per share
	Millions	%	Millions	%	Millions	%	Millions	%	Millions	%	Yen
	of yen		of yen		of yen		of yen		of yen		
Fiscal year ending	2,300	311.4	(1,100)	_	(1,100)	_	(1,200)	_	(1,200)	_	(8.02)
, ,	~	~	~	~	~	~	~	~	~	~	~
December 31,2022	3,800	579.8	150	_	150	_	50	_	50	_	0.33

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, 2022	150,092,310 shares
As of December 31, 2021	133,946,210 shares

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

As of June 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 Six months ended June 30, 2022	138,912,094 shares
For the Six months ended June 30, 2021	127,890,216 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 Friday, August 19, 2022 for institutional investors and analysts.

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

[Attached Material]

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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

(Millions of yen)

	Six months ended June 30, 2021	Six months ended June 30, 2022	Year-on-year
Revenue	278	189	(88)
Gross profit	120	127	6
Operating profit (loss)	(1,362)	(1,228)	133
Profit (loss)	(1,394)	(1,247)	147

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

[Launched products (development completed)]

SP-01 (Chemotherapy-induced nausea and vomiting)

SP-03 (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.

[Pipeline products in the clinical study and later phase]

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

The Company confirmed that the primary endpoints of the global Phase II clinical trial (pivotal study) of SP-02 were met in 2020, and on June 30, 2021, filed a New Drug Application (NDA) for the pipeline product with the regulatory authorities; it obtained approval in June 2022. The Company is preparing to launch the product as of the submission date of this document.

SP-05 (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).

[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 have determined to conduct additional animal studies to investigate the product's potential in

treating taxane-induced peripheral neuropathy.

Further, 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.
- 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.
- 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.

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 six months of the fiscal year under review, financial performance was as follows.

[Revenue, Gross profit]

During the six months ended June 30, 2022, revenue totaled 189 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 127 million yen.

Breakdown of R&D and SG&A expenses

(Millions of ven)

			(Williams of year)
	Six months ended June 30, 2021	Six months ended June 30, 2022	Year-on-year
R&D expenses	617	347	(269)
SG&A expenses	865	1,008	142
Total	1,483	1,356	(126)
(Breakdown) Personnel expenses	383	421	37
Outsourcing expenses	760	493	(267)
Depreciation and amortization of intangible assets	247	248	1
Other	90	192	101

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

R&D expenses amounted to 347 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 1,008 million yen, up 142 million yen year on year.

The Company incurred an operating loss of 1,228 million yen.

The Company incurred an overall loss of 1,247 million yen.

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

The Group posted a 6 million yen increase in intangible assets attributable to development costs and inlicensing expenses recognized as assets among pipeline investment outlays. In the six months ended June 30, 2022, pipeline investment amounted to 353 million yen. This figure includes the 6 million yen in intangible assets derived from capitalization of such outlays and 347 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 219 million yen during the six months under review. As a result, the balance of intangible assets was 1,866 million yen as of June 30, 2022.

2) Cash flows

(Millions of yen)

	Six months ended June 30, 2021	Six months ended June 30, 2022	Year-on-year
Net cash provided by (used in) operating activities	(1,222)	(963)	258
Net cash provided by (used in) investing activities	(2)	(20)	(17)
Net cash provided by (used in) financing activities	29	1,211	1,181

[Cash flows from operating activities]

Net cash used in operating activities amounted to 963 million yen (compared with 1,222 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 1,233 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 20 million yen (compared with 2 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 14 million yen in outflows related to Share-based payment transactions,5 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 1,211 million yen (compared with 29 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 1,222 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) R&D activities

R&D expenses amounted to 347 million yen. This amount is mainly attributable to expenses incurred for a multinational phase III clinical study of SP-05. In addition, the Company recorded a 6 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 353 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 June 30, 2022, total assets amounted to 3,072 million yen, down 71 million yen from the previous year-end. Current assets were 1,046 million yen, including 973 million yen in cash and cash equivalents. Non-current assets came to 2,025 million yen. This figure includes 1,866 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 482 million yen, down 74 million yen from the previous year-end. Current liabilities were 442 million yen, including 333 million yen in trade and other payables. Non-current liabilities amounted to 39 million yen, mainly due to 13 million yen in lease liabilities 15 million yen in deferred tax liabilities.

Total equity equaled 2,590 million yen, up 2 million yen from the previous year-end. The increase was mainly attributable to 1,222 million yen in proceeds from issuance of new shares. The decrease was mainly attributable to the overall loss of 1,247 million yen.

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

The consolidated earnings forecasts for the fiscal year ending December 31, 2022 (announced on February 9, 2022) reflect the impact of the COVID-19 pandemic to some extent, and the Company has made no change to its forecasts as of the date this document was published. However, if the spread of the virus continues longer than anticipated, we cannot deny the possibility that it could have a stronger impact on product sales, out-licensing its pipeline products, development (primarily clinical development), and other elements of our business than initially estimated. We will promptly disclose any potential impact on our earnings forecasts as soon as the Company becomes clear.

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	973
Trade and other receivables	126	35
Inventories	0	2
Other current assets	53	34
Total current assets	894	1,046
Non-current assets		
Property, plant and equipment	36	32
Light-of-use asset	84	62
Intangible assets	2,079	1,866
Investments accounted for using equity method	_	14
Other non-current assets	49	50
Total non-current assets	2,249	2,025
Total assets	3,144	3,072
Liabilities and equity Liabilities		
Current liabilities		
Trade and other payables	386	333
Lease liabilities	47	49
Other current liabilities	55	58
Total current liabilities	489	442
Non-current liabilities		
Deferred tax liabilities	18	15
Lease liabilities	37	13
Other non-current liabilities	10	10
Total non-current liabilities	67	39
Total liabilities	556	482
Equity		
Share capital	2,110	724
Capital surplus	5,738	822
Retained earnings	(5,204)	1,077
Treasury stock	(70)	(70)
Other components of equity	13	35
Total equity	2,587	2,590
Total liabilities and equity	3,144	3,072

(2) Condensed consolidated statement of profit or loss

		(Millions of yen)
	Six months ended June 30, 2021	Six months ended June 30, 2022
Revenue	278	189
Cost of sales	157	61
Gross profit	120	127
Research and development expenses	617	347
Selling, general and administrative expenses	865	1,008
Operating profit (loss)	(1,362)	(1,228)
Finance income	0	2
Finance costs	21	7
Share of profit (loss) of investments accounted for using equity method	_	(0)
Profit (loss) before tax	(1,383)	(1,233)
Income taxes	11	13
Profit (loss)	(1,394)	(1,247)
Profit (loss) attributable to:		
Owners of parent	(1,394)	(1,247)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(10.91)	(8.98)
Diluted earnings (loss) per share [yen]	(10.91)	(8.98)

(3) Condensed consolidated statement of comprehensive income

		(Millions of yen)
	Six months ended June 30, 2021	Six months ended June 30, 2022
Profit (loss)	(1,394)	(1,247)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	8	16
Subtotal	8	16
Total other comprehensive income	8	16
Comprehensive income	(1,386)	(1,231)
Comprehensive income attributable to: Owners of parent	(1,386)	(1,231)

(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 acomponents 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)	_	_	(1,394)	_	_	_	_	(1,394)
Other comprehensive income					8		8	8
Total comprehensive income		_	(1,394)	_	8	_	8	(1,386)
Transactions with owners								
Exercise of share acquisition rights	529	525	_	_	_	(4)	(4)	1,050
Total transactions with owners	529	525	_	_	_	(4)	(4)	1,050
Balance at June 30, 2021	1,932	5,569	(4,121)	(70)	1	5	6	3,316
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

(5) Condensed consolidated statement of cash flows

June 30, 2022		
_		
(1,233)		
248		
(2)		
7		
0		
90		
(1)		
(56)		
12		
(935)		
0		
(0)		

(Millions of yen)

	Six months ended June 30, 2021	Six months ended June 30, 2022
Cash flows from operating activities		
Profit (loss) before tax	(1,383)	(1,233)
Depreciation and amortization	247	248
Finance income	(0)	(2)
Finance costs	21	7
Share of loss (profit) of investments accounted for using equity method	_	0
Decrease (increase) in trade and other receivables	(12)	90
Decrease (increase) in inventories	2	(1)
Increase (decrease) in trade and other payables	(83)	(56)
Other _	7	12
Subtotal	(1,200)	(935)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	(20)	(27)
Net cash provided by (used in) operating activities	(1,222)	(963)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Purchase of intangible assets	(2)	(5)
Share-based payment transactions	_	(14)
Net cash provided by (used in) investing activities	(2)	(20)
Cash flows from financing activities		
Proceeds from issuance of bonds	_	500
Redemption of bonds	(1,000)	(500)
Proceeds from issuance of new shares	1,050	1,222
Proceeds from issuance of share acquisition rights	_	10
Repayment of lease liabilities	(20)	(22)
Net cash provided by (used in) financing activities	30	1,211
Net increase (decrease) in cash and cash equivalents	(1,195)	226
Cash and cash equivalents at beginning of period	2,964	714
Effect of exchange rate changes on cash and cash equivalents	21	29
Cash and cash equivalents at end of period	1,790	973

(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.