



August 12, 2020

Consolidated Financial Results for the Six Months of the Fiscal Year Ending December 31, 2020 (under IFRS)

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 Listing: Tokyo Stock Exchange
 Securities code: 4597
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Scheduled date to file quarterly securities report: August 12, 2020
 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 six months of the fiscal year ending December 31, 2020 (from January 1, 2020 to June 30, 2020)

(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, 2020	240	83.6	(1,268)	–	(1,283)	–	(1,272)	–
June 30, 2019	130	54.9	(1,010)	–	(1,036)	–	(1,093)	–

	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, 2020	(1,272)	–	(1,274)	–	(10.93)	(10.93)
June 30, 2019	(1,093)	–	(1,094)	–	(10.42)	(10.42)

(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, 2020	6,130	5,643	5,643	92.1	48.47
December 31, 2019	7,946	6,917	6,917	87.0	59.43

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, 2019	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2020	–	0.00			
Fiscal year ending December 31, 2020 (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, 2020 (from January 1, 2020 to December 31, 2020)

(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, 2020	500	(61.8)	(2,900)	–	(2,900)	–	(2,900)	–	(2,900)	–	(24.91)
	to	To	to	to	to	to	to	to	to	to	to
	2,000	52.6	(2,000)	–	(2,000)	–	(2,000)	–	(2,000)	–	(17.18)

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, 2020	116,879,961 shares
As of December 31, 2019	116,835,795 shares

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

As of June 30, 2020	440,000 shares
As of December 31, 2019	440,000 shares

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

For the six months ended June 30, 2020	116,855,905 shares
For the six months ended June 30, 2019	104,952,884 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 20, 2020 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 six months

(1) Explanation of operating results

1) Overview of results

Operating results

	Six months ended June 30, 2019	Six months ended June 30, 2020	(Millions of yen) Year-on-year
Revenue	130	240	109
Gross profit	111	175	64
Operating profit (loss)	(1,010)	(1,268)	(258)
Profit (loss)	(1,093)	(1,272)	(179)

In the six months ended June 30, 2020, Solasia Pharma K.K. (the “Company”) and its group company (collectively, the “Group”) focused on enhancing the pharmaceutical business, as well as strengthening and commercializing the drug development pipeline, while weathering impact from the spread of the novel coronavirus disease.

The spread of the novel coronavirus disease greatly hindered access to medical sites and various activities performed by Group medical representatives (MRs) responsible for promoting sales of Sancuso® (SP-01) and episil® (SP-03), which were launched in China during the previous fiscal year. However, as of the submission date of this document, MRs are gradually regaining permission to visit hospitals and contact medical personnel in the Company’s sales areas(exclude Beijing) in China.

Aside from products that have been successfully commercialized, two pipeline products reached the final stages of clinical development. In June, 2020, we achieved the primary endpoint (antitumor effect) in the Phase II clinical trial (pivotal study) of our pipeline product SP-02. As of the submission date of this document, we are preparing for the NDA Filing in different countries. Development of SP-04 has reached the Phase III clinical trial stage. As of the submission date of this document, 590 patients had been enrolled for the trial (out of a target of 700). However, we have decided to suspend both new patient enrollment and study drug administration in March and April 2020 and to bring this trial to its conclusion after making an early cut-off of case data collection (data cut-off) in the third quarter of 2020. Starting in the fourth quarter of the fiscal year ending December 31, 2020, we will conduct detailed and robust evaluations of the safety and effectiveness of SP-04 focusing on information acquired through the completion of trial. The decision was taken after a recommendation from the independent Drug Safety Monitoring Board (DSMB) to stop the studies due to a number of severe allergic reactions, which have been observed after repeated dosing. Afterward, we will formulate further plans for SP-04.

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 six months ended June 30, 2020, was as follows.

[Revenue,Gross profit]

During the six months ended June 30, 2020, revenue totaled 240 million yen, up 109 million yen from the first six months of the preceding fiscal year. Revenue mainly came from the sales of pipeline products of Sancuso® (SP-01) and episil® (SP-03). In addition, gross profit amounted to 175 million yen, up 64 million yen from the first six months of the preceding fiscal year. The increase was attributable to the aforementioned growth in revenue.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Six months ended June 30, 2019	Six months ended June 30, 2020	Year-on-year
R&D expenses	455	719	263
SG&A expenses	666	724	58
Total	1,121	1,444	322
(Breakdown)			
Personnel expenses	265	304	38
Outsourcing expenses	514	794	280
Depreciation and amortization of intangible assets	225	248	23
Other	116	96	(19)

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

R&D expenses amounted to 719 million yen. This amount is mainly attributable to expenses incurred for a multinational phase II clinical study (pivotal study) of SP-02 and a multinational phase III clinical study (pivotal study) of SP-04 (initiated in December 2018). SG&A expenses amounted to 724 million yen, up 58 million yen year on year, as a result of building of an independent sales structure in China by strengthening organization of personnel and amortization of intangible assets.

The Company incurred an operating loss of 1,268 million yen, which is a increase of 258 million yen year on year.

The Company incurred an overall loss of 1,272million yen, mainly as a consequence of having posted the aforementioned operating loss.

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

The Group posted a 3 million yen 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, 2020, pipeline investment amounted to 723 million yen. This figure includes the 3 million yen in intangible assets derived from capitalization of such outlays and 719 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 3,269 million yen as of June 30, 2020.

2) Cash flows

	(Millions of yen)		
	Six months ended June 30, 2019	Six months ended June 30, 2020	Year-on-year
Net cash provided by (used in) operating activities	(803)	(1,651)	(848)
Net cash provided by (used in) investing activities	(676)	(56)	619
Net cash provided by (used in) financing activities	(10)	(22)	(11)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 1,651 million yen (compared with 803 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 1,283 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 56 million yen (down from 676 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 54 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash used in financing activities amounted to 22 million yen (up from 10 million yen used in these activities in the same period of the previous year). This figure was mainly attributable to 23 million yen in outflows related to repayments of lease liabilities.

3) R&D activities

R&D expenses amounted to 719 million yen. In addition, the Company recorded a 3 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 723 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2020	Six months ended June 30, 2020	As of today
SP-01 Sancuso® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-02 darinaparsin Japan etc.	Multinational phase II clinical study (final clinical study) in progress; Completion of subject-enrollment	Achieved the primary endpoint (antitumor effect) in multinational phase II clinical study (final clinical study)	Preparing for NDA Filing
SP-03 episil® Japan	Ongoing sale	Ongoing sale	Ongoing sale
SP-03 episil® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-04 PledOx® Japan etc.	Multinational phase III clinical study (completion of subject-enrollment for POLAR-A study) in progress	Decision reached to suspend patient recruitment and the study drug administration in the multinational phase III clinical study, and to make an early cut-off of case data collection in the third quarter of 2020	Decision reached to suspend patient recruitment and the study drug administration in the multinational phase III clinical study, and to make an early cut-off of case data collection in the third quarter of 2020

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, 2020, total assets amounted to 6,130 million yen, down 1,816 million yen from the previous

year-end. Current assets were 2,729million yen, including 2,377 million yen in cash and cash equivalents. Non-current assets came to 3,400 million yen. This figure includes 3,269 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 486 million yen, down 542 million yen from the previous year-end. Current liabilities were 410 million yen, including 322 million yen in trade and other payables. Non-current liabilities amounted to 76 million yen, mainly due to 54 million yen in deferred tax liabilities.

Total equity equaled 5,643 million yen, down 1,273 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 1,272 million yen.

As of today, the overdraft and committed credit line with domestic banks total 3.5 billion yen. The entire amount is unused.

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

The consolidated earnings forecasts for the fiscal year ending December 31, 2020 (announced on February 13, 2020) reflect the impact of the novel coronavirus disease 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, 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, 2019	As of June 30, 2020
Assets		
Current assets		
Cash and cash equivalents	4,116	2,377
Trade and other receivables	10	131
Inventories	3	33
Other current assets	172	186
Total current assets	4,302	2,729
Non-current assets		
Property, plant and equipment	46	41
Light-of-use asset	66	44
Intangible assets	3,485	3,269
Other non-current assets	45	45
Total non-current assets	3,644	3,400
Total assets	7,946	6,130
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	800	322
Lease liabilities	41	34
Other current liabilities	84	52
Total current liabilities	925	410
Non-current liabilities		
Deferred tax liabilities	65	54
Lease liabilities	27	10
Other non-current liabilities	10	10
Total non-current liabilities	103	76
Total liabilities	1,029	486
Equity		
Share capital	960	961
Capital surplus	4,630	4,630
Retained earnings	1,400	128
Treasury stock	(70)	(70)
Other components of equity	(4)	(6)
Total equity	6,917	5,643
Total liabilities and equity	7,946	6,130

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Six months ended June 30, 2019	Six months ended June 30, 2020
Revenue	130	240
Cost of sales	19	64
Gross profit	111	175
Research and development expenses	455	719
Selling, general and administrative expenses	666	724
Operating profit (loss)	(1,010)	(1,268)
Finance income	0	0
Finance costs	26	14
Other income	0	–
Other costs	–	0
Profit (loss) before tax	(1,036)	(1,283)
Income taxes	56	(11)
Profit (loss)	(1,093)	(1,272)
Profit (loss) attributable to:		
Owners of parent	(1,093)	(1,272)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(10.42)	(10.93)
Diluted earnings (loss) per share [yen]	(10.42)	(10.93)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Six months ended June 30, 2019	Six months ended June 30, 2020
Profit (loss)	(1,093)	(1,272)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(1)	(2)
Subtotal	(1)	(2)
Total other comprehensive income	(1)	(2)
Comprehensive income	(1,094)	(1,274)
Comprehensive income attributable to:		
Owners of parent	(1,094)	(1,274)

(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
Balance at January 1, 2019	7,632	7,483	(7,975)	(48)	(3)	7,087
Comprehensive income						
Profit (loss)	—	—	(1,093)	—	—	(1,093)
Other comprehensive income	—	—	—	—	(1)	(1)
Total comprehensive income	—	—	(1,093)	—	(1)	(1,094)
Transactions with owners						
Issuance of new shares	—	—	—	—	—	—
Exercise of share acquisition rights	5	5	—	—	—	10
Capital reduction	(7,532)	(3,712)	11,244	—	—	—
Total transactions with owners	(7,526)	(3,706)	11,244	—	—	10
Balance at June 30, 2019	105	3,776	2,175	(48)	(4)	6,003
Balance at January 1, 2020	960	4,630	1,400	(70)	(4)	6,917
Comprehensive income						
Profit (loss)	—	—	(1,272)	—	—	(1,272)
Other comprehensive income	—	—	—	—	(2)	(2)
Total comprehensive income	—	—	(1,272)	—	(2)	(1,274)
Transactions with owners						
Issuance of new shares	—	—	—	—	—	—
Exercise of share acquisition rights	0	0	—	—	—	0
Total transactions with owners	0	0	—	—	—	0
Balance at June 30, 2020	961	4,630	128	(70)	(6)	5,643

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Six months ended June 30, 2019	Six months ended June 30, 2020
Cash flows from operating activities		
Profit (loss) before tax	(1,036)	(1,283)
Depreciation and amortization	225	249
Finance income	(0)	(0)
Finance costs	26	14
Decrease (increase) in trade and other receivables	97	(118)
Decrease (increase) in inventories	(2)	(30)
Increase (decrease) in trade and other payables	(99)	(411)
Other	(12)	(58)
Subtotal	(803)	(1,638)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	—	(12)
Net cash provided by (used in) operating activities	(803)	(1,651)
Cash flows from investing activities		
Purchase of property, plant and equipment	(1)	(1)
Purchase of intangible assets	(674)	(54)
Other	0	0
Net cash provided by (used in) investing activities	(676)	(56)
Cash flows from financing activities		
Proceeds from issuance of new shares	10	0
Repayment of lease liabilities	(20)	(23)
Net cash provided by (used in) financing activities	(10)	(22)
Net increase (decrease) in cash and cash equivalents	(1,489)	(1,730)
Cash and cash equivalents at beginning of period	4,046	4,116
Effect of exchange rate changes on cash and cash equivalents	(14)	(8)
Cash and cash equivalents at end of period	2,541	2,377

(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.