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May 13, 2022

**Consolidated Financial Results for the First Three Months of
the Fiscal Year Ending December 31, 2022
(under IFRS)**

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 Listing: Tokyo Stock Exchange
 Securities code: 4597
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Scheduled date to file quarterly securities report: May 13, 2022

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, 2022
(from January 1, 2022 to March 31, 2022)**

(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, 2022	113	23.5	(600)	–	(606)	–	(615)	–
March 31, 2021	91	(41.1)	(642)	–	(650)	–	(656)	–

	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, 2022	(615)	–	(606)	–	(4.61)	(4.61)
March 31, 2021	(656)	–	(648)	–	(5.22)	(5.22)

(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					
March 31, 2022	3,099	2,630	2,630	84.9	18.52
December 31, 2021	3,144	2,587	2,587	82.3	19.38

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	–				
Fiscal year ending December 31, 2022 (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, 2022
(from January 1, 2022 to December 31, 2022)**

(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, 2022	2,300	311.4	(1,100)	–	(1,100)	–	(1,200)	–	(1,200)	–	(8.45)
	~	~	~	~	~	~	~	~	~	~	~
	3,800	579.8	150	–	150	–	50	–	50	–	0.35

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, 2022	142,451,310 shares
As of December 31, 2021	133,946,210 shares

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

As of March 31, 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 three months ended March 31, 2022	133,528,611 shares
For the three months ended March 31, 2021	125,694,543 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.....	4
(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 three months

(1) Explanation of operating results

1) Overview of results

Operating results

	Three months ended March 31, 2021	Three months ended March 31, 2022	(Millions of yen) Year-on-year
Revenue	91	113	21
Gross profit	50	82	32
Operating profit (loss)	(642)	(600)	42
Profit (loss)	(656)	(615)	41

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 three months ended March 31, 2022.

[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 confirmed that primary endpoints were met in the global Phase II clinical trial (pivotal study) of SP-02, and based on these favorable results, at the end of June 2021 the Company filed a New Drug Application (NDA) for the pipeline product with regulatory authorities in Japan. As of the date of submission of this document, the Company is making necessary preparations with an eye toward obtaining approval in the second quarter of the fiscal year ending December 2022.

SP-05 (Increase in antitumor efficacy of fluorouracil)

For the global Phase III clinical trial (pivotal study) of SP-05, as of the date of submission of this document, Isofol Medical AB (publ) (STO: ISOFOL), Solasia's partner is analyzing the trial data in the aim of obtaining top-line results in the second or third quarter of the fiscal year ending December 2022.

[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.

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 three months ended March 31, 2022, was as follows.

[Revenue, Gross profit]

During the three months ended March 31, 2022, revenue totaled 113 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 82 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Three months ended March 31, 2021	Three months ended March 31, 2022	Year-on-year
R&D expenses	258	177	(80)
SG&A expenses	434	505	70
Total	692	682	(9)
(Breakdown)			
Personnel expenses	190	207	16
Outsourcing expenses	336	290	(45)
Depreciation and amortization of intangible assets	123	124	0
Other	41	60	18

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

R&D expenses amounted to 177 million yen. This amount is mainly attributable to expenses incurred for a multinational phase III clinical study of SP-05. SG&A expenses amounted to 505 million yen, up 70 million yen year on year.

The Company incurred an operating loss of 600 million yen.

The Company incurred an overall loss of 615 million yen.

[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 three months ended March 31, 2022, pipeline investment amounted to 181 million yen. This figure includes the 3 million yen in intangible assets derived from capitalization of such outlays and 177 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 109 million yen during the three months under review. As a result, the balance of intangible assets was 1,973 million yen as of March 31, 2022.

2) Cash flows

	(Millions of yen)		
	Three months ended March 31, 2021	Three months ended March 31, 2022	Year-on-year
Net cash provided by (used in) operating activities	(650)	(569)	81
Net cash provided by (used in) investing activities	(3)	(4)	(1)
Net cash provided by (used in) financing activities	(99)	638	737

[Cash flows from operating activities]

Net cash used in operating activities amounted to 569 million yen (compared with 650 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 606 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 4 million yen (compared with 3 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 4 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 638 million yen (compared with 99 million yen used in these activities in the same period of the previous year). This figure was mainly attributable to 638 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) R&D activities

R&D expenses amounted to 177 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 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 181 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 March 31, 2022, total assets amounted to 3,099 million yen, down 45 million yen from the previous year-end. Current assets were 967 million yen, including 790 million yen in cash and cash equivalents. Non-current assets came to 2,131 million yen. This figure includes 1,973 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 468 million yen, down 87 million yen from the previous year-end. Current liabilities were 415 million yen, including 311 million yen in trade and other payables. Non-current liabilities amounted to 53 million yen, mainly due to 25 million yen in lease liabilities 17 million yen in deferred tax liabilities.

Total equity equaled 2,630 million yen, up 42 million yen from the previous year-end. The increase was mainly attributable to 638 million yen in proceeds from issuance of new shares. The decrease was mainly attributable to the overall loss of 615 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 March 31, 2022
Assets		
Current assets		
Cash and cash equivalents	714	790
Trade and other receivables	126	129
Inventories	0	2
Other current assets	53	44
Total current assets	894	967
Non-current assets		
Property, plant and equipment	36	34
Light-of-use asset	84	73
Intangible assets	2,079	1,973
Other non-current assets	49	49
Total non-current assets	2,249	2,131
Total assets	3,144	3,099
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	386	311
Lease liabilities	47	48
Other current liabilities	55	55
Total current liabilities	489	415
Non-current liabilities		
Deferred tax liabilities	18	17
Lease liabilities	37	25
Other non-current liabilities	10	10
Total non-current liabilities	67	53
Total liabilities	556	468
Equity		
Share capital	2,110	2,435
Capital surplus	5,738	6,053
Retained earnings	(5,204)	(5,819)
Treasury stock	(70)	(70)
Other components of equity	13	30
Total equity	2,587	2,630
Total liabilities and equity	3,144	3,099

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Three months ended March 31, 2021	Three months ended March 31, 2022
Revenue	91	113
Cost of sales	41	30
Gross profit	50	82
Research and development expenses	258	177
Selling, general and administrative expenses	434	505
Operating profit (loss)	(642)	(600)
Finance income	0	0
Finance costs	8	6
Profit (loss) before tax	(650)	(606)
Income taxes	5	8
Profit (loss)	(656)	(615)
Profit (loss) attributable to:		
Owners of parent	(656)	(615)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(5.22)	(4.61)
Diluted earnings (loss) per share [yen]	(5.22)	(4.61)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Three months ended March 31, 2021	Three months ended March 31, 2022
Profit (loss)	(656)	(615)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	7	8
Subtotal	7	8
Total other comprehensive income	7	8
Comprehensive income	(648)	(606)
Comprehensive income attributable to:		
Owners of parent	(648)	(606)

(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 component s of equity	
Balance at January 1, 2021	1,402	5,043	(2,726)	(70)	(6)	9	2	3,652
Comprehensive income								
Profit (loss)	–	–	(656)	–	–	–	–	(656)
Other comprehensive income	–	–	–	–	7	–	7	7
Total comprehensive income	–	–	(656)	–	7	–	7	(648)
Transactions with owners								
Exercise of share acquisition rights	458	455	–	–	–	(4)	(4)	910
Total transactions with owners	458	455	–	–	–	(4)	(4)	910
Balance at March 31, 2021	1,861	5,499	(3,382)	(70)	0	5	6	3,913
Balance at January 1, 2022	2,110	5,738	(5,204)	(70)	10	3	13	2,587
Comprehensive income								
Profit (loss)	–	–	(615)	–	–	–	–	(615)
Other comprehensive income	–	–	–	–	8	–	8	8
Total comprehensive income	–	–	(615)	–	8	–	8	(606)
Transactions with owners								
Exercise of share acquisition rights	325	315	–	–	–	(2)	(2)	638
Issuance of share acquisition rights	–	–	–	–	–	10	10	10
Total transactions with owners	325	315	–	–	–	8	8	649
Balance at March 31, 2022	2,435	6,053	(5,819)	(70)	18	11	30	2,630

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Three months ended March 31, 2021	Three months ended March 31, 2022
Cash flows from operating activities		
Profit (loss) before tax	(650)	(606)
Depreciation and amortization	123	124
Finance income	(0)	(0)
Finance costs	8	6
Decrease (increase) in trade and other receivables	(36)	(3)
Decrease (increase) in inventories	(30)	(2)
Increase (decrease) in trade and other payables	(44)	(78)
Other	(17)	3
Subtotal	<u>(648)</u>	<u>(556)</u>
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	(1)	(12)
Net cash provided by (used in) operating activities	<u>(650)</u>	<u>(569)</u>
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	—
Purchase of intangible assets	(1)	(4)
Other	(1)	—
Net cash provided by (used in) investing activities	<u>(3)</u>	<u>(4)</u>
Cash flows from financing activities		
Proceeds from issuance of bonds	—	500
Redemption of bonds	(1,000)	(500)
Proceeds from issuance of new shares	910	638
Proceeds from issuance of share acquisition rights	—	10
Repayment of lease liabilities	(9)	(10)
Net cash provided by (used in) financing activities	<u>(99)</u>	<u>638</u>
Net increase (decrease) in cash and cash equivalents	<u>(753)</u>	<u>64</u>
Cash and cash equivalents at beginning of period	<u>2,964</u>	<u>714</u>
Effect of exchange rate changes on cash and cash equivalents	15	11
Cash and cash equivalents at end of period	<u><u>2,226</u></u>	<u><u>790</u></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.