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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 | |
|--------------------------------------|------------------------|-----------|--------------------------|--------|--------------------------|--------|--------------------------|--------|
| Three months ended March 31, 2022 | Millions of yen 113 | % 23.5 | Millions of yen (600) | % — | Millions of yen (606) | % — | Millions of yen (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 | |
|--------------------------------------|--|--------|-------------------------------|--------|-----------------------------|---------------|-------------------------------|---------------|
| Three months ended March 31, 2022 | Millions of yen (615) | % — | Millions of yen (606) | % — | | Yen (4.61) | | Yen (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 | |
|-------------------------|--------------------------|--|--------------------------|--|--|--|---|--|---|--|
| As of March 31, 2022 | Millions of yen 3,099 | | Millions of yen 2,630 | | Millions of yen 2,630 | | % 84.9 | | Yen 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 |
| Fiscal year ended December 31, 2021 | Yen — | Yen 0.00 | Yen — | Yen 0.00 | Yen 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) |
| | ~ | ~ | ~ | ~ | ~ | ~ | ~ | ~ | ~ | ~ | 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.

[Attached Material]**Index**

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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, 2021 | Three months ended March 31, 2022 | 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

| | Three months ended March 31, 2021 | Three months ended March 31, 2022 | (Millions of yen) 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

| | Three months ended March 31, 2021 | Three months ended March 31, 2022 | (Millions of yen) 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 | <u>894</u> | <u>967</u> |
| 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 | <u>2,249</u> | <u>2,131</u> |
| Total assets | <u>3,144</u> | <u>3,099</u> |
| Liabilities and equity | | |
| Liabilities | | |
| Current liabilities | | |
| Trade and other payables | 386 | 311 |
| Lease liabilities | 47 | 48 |
| Other current liabilities | 55 | 55 |
| Total current liabilities | <u>489</u> | <u>415</u> |
| Non-current liabilities | | |
| Deferred tax liabilities | 18 | 17 |
| Lease liabilities | 37 | 25 |
| Other non-current liabilities | 10 | 10 |
| Total non-current liabilities | <u>67</u> | <u>53</u> |
| Total liabilities | <u>556</u> | <u>468</u> |
| 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 | <u>2,587</u> | <u>2,630</u> |
| Total liabilities and equity | <u>3,144</u> | <u>3,099</u> |

(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 | (648) | (556) |
| Interest received | 0 | 0 |
| Interest paid | (0) | (0) |
| Income taxes paid | (1) | (12) |
| Net cash provided by (used in) operating activities | (650) | (569) |
| 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 | (3) | (4) |
| 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 | (99) | 638 |
| Net increase (decrease) in cash and cash equivalents | (753) | 64 |
| Cash and cash equivalents at beginning of period | 2,964 | 714 |
| Effect of exchange rate changes on cash and cash equivalents | 15 | 11 |
| Cash and cash equivalents at end of period | 2,226 | 790 |

(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.