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May 15, 2023

**Consolidated Financial Results for the First Three Months of
the Fiscal Year Ending December 31, 2023
(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 15, 2023

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, 2023
(from January 1, 2023 to March 31, 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	%
Three months ended								
March 31, 2023	220	93.8	(245)	–	(247)	–	(241)	–
March 31, 2022	113	23.5	(600)	–	(606)	–	(615)	–

	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, 2023	(241)	–	(237)	–	(1.44)	(1.44)
March 31, 2022	(615)	–	(606)	–	(4.61)	(4.61)

(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
March 31, 2023	2,989	2,424	2,424	81.1	14.44
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
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2022	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2023	–				
Fiscal year ending December 31, 2023 (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, 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)	—	(6.85)
	~	~	~	~	~	~	~	~	~	~	~
	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 March 31, 2023	168,402,310 shares
As of December 31, 2022	168,402,310 shares

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

As of March 31, 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 three months ended March 31, 2023	167,966,100 shares
For the three months ended March 31, 2022	133,528,611 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.

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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, 2022	Three months ended March 31, 2023	(Millions of yen) Year-on-year
Revenue	113	220	106
Gross profit	82	128	45
Operating profit (loss)	(600)	(245)	354
Profit (loss)	(615)	(241)	373

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 three months ended March 31, 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 three months ended March 31, 2023, was as follows.

[Revenue, Gross profit]

During the three months ended March 31, 2023, revenue totaled 220 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 128 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Three months ended March 31, 2022	Three months ended March 31, 2023	Year-on-year
R&D expenses	177	93	(84)
SG&A expenses	505	280	(225)
Total	682	373	(309)
(Breakdown)			
Personnel expenses	207	119	(88)
Outsourcing expenses	290	104	(185)
Depreciation and amortization of intangible assets	124	126	2
Other	60	22	(37)

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

R&D expenses amounted to 93 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 280 million yen, down 225 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 245 million yen.

The Company incurred an overall loss of 241 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 three months ended March 31, 2023, pipeline investment amounted to 93 million yen. This figure is 93 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso[®] (SP-01), DARVIAS[®] (SP-02) and episil[®] (SP-03), leading to amortization of 113 million yen during the three months under review. As a result, the balance of intangible assets was 1,456 million yen as of March 31, 2023.

2) Cash flows

	(Millions of yen)		
	Three months ended March 31, 2022	Three months ended March 31, 2023	Year-on-year
Net cash provided by (used in) operating activities	(569)	223	792
Net cash provided by (used in) investing activities	(4)	(0)	3
Net cash provided by (used in) financing activities	638	(12)	(650)

[Cash flows from operating activities]

Net cash provided by operating activities amounted to 223 million yen (compared with 569 million yen in net cash used in these activities in the corresponding period of the previous fiscal year), which was mainly attributable to decrease in trade and other receivables of 332 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 0 million yen (compared with 4 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 12 million yen (compared with 638 million yen provided by these activities in the same period of the previous year).

3) R&D activities

R&D expenses amounted to 93 million yen. This amount is mainly attributable to expenses incurred for new drug and technology 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 March 31, 2023, total assets amounted to 2,989 million yen, down 145 million yen from the previous year-end. Current assets were 1,353 million yen, including 1,016 million yen in cash and cash equivalents. Non-current assets came to 1,635 million yen. This figure includes 1,456 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 564 million yen, up 92 million yen from the previous year-end. Current liabilities were 455 million yen, including 374 million yen in trade and other payables. Non-current liabilities amounted to 109 million yen, mainly due to 52 million yen in lease liabilities 45 million yen in deferred tax liabilities.

Total equity equaled 2,424 million yen, down 237 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 241 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 March 31, 2023
Assets		
Current assets		
Cash and cash equivalents	803	1,016
Trade and other receivables	572	240
Inventories	14	55
Other current assets	44	39
Total current assets	<u>1,435</u>	<u>1,353</u>
Non-current assets		
Property, plant and equipment	26	25
Light-of-use asset	37	91
Intangible assets	1,570	1,456
Investments accounted for using equity method	11	10
Other non-current assets	52	51
Total non-current assets	<u>1,698</u>	<u>1,635</u>
Total assets	<u><u>3,134</u></u>	<u><u>2,989</u></u>
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	332	374
Lease liabilities	37	38
Other current liabilities	37	41
Total current liabilities	<u>407</u>	<u>455</u>
Non-current liabilities		
Deferred tax liabilities	53	45
Lease liabilities	0	52
Other non-current liabilities	10	10
Total non-current liabilities	<u>64</u>	<u>109</u>
Total liabilities	<u>472</u>	<u>564</u>
Equity		
Share capital	1,436	1,436
Capital surplus	1,500	1,500
Retained earnings	(223)	(464)
Treasury stock	(70)	(70)
Other components of equity	19	22
Total equity	<u>2,662</u>	<u>2,424</u>
Total liabilities and equity	<u><u>3,144</u></u>	<u><u>2,989</u></u>

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Three months ended March 31, 2022	Three months ended March 31, 2023
Revenue	113	220
Cost of sales	30	91
Gross profit	82	128
Research and development expenses	177	93
Selling, general and administrative expenses	505	280
Operating profit (loss)	(600)	(245)
Finance income	0	0
Finance costs	6	0
Share of profit (loss) of investments accounted for using equity method	—	(1)
Finance costs	—	—
Profit (loss) before tax	(606)	(247)
Income taxes	8	(6)
Profit (loss)	(615)	(241)
Profit (loss) attributable to:		
Owners of parent	(615)	(241)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(4.61)	(1.44)
Diluted earnings (loss) per share [yen]	(4.61)	(1.44)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Three months ended March 31, 2022	Three months ended March 31, 2023
Profit (loss)	(615)	(241)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	8	3
Subtotal	8	3
Total other comprehensive income	8	3
Comprehensive income	(606)	(237)
Comprehensive income attributable to:		
Owners of parent	(606)	(237)

(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)	–	–	(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
Balance at January 1, 2023	1,436	1,500	(223)	(70)	15	3	19	2,662
Comprehensive income								
Profit (loss)	–	–	(241)	–	–	–	–	(241)
Other comprehensive income	–	–	–	–	3	–	3	3
Total comprehensive income	–	–	(241)	–	3	–	3	(237)
Transactions with owners								
Exercise of share acquisition rights	–	–	–	–	–	–	–	–
Issuance of share acquisition rights	–	–	–	–	–	–	–	–
Total transactions with owners	–	–	–	–	–	–	–	–
Balance at March 31, 2023	1,436	1,500	(464)	(70)	19	3	22	2,424

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Three months ended March 31, 2022	Three months ended March 31, 2023
Cash flows from operating activities		
Profit (loss) before tax	(606)	(247)
Depreciation and amortization	124	126
Finance income	(0)	(0)
Finance costs	6	0
Share of loss (profit) of investments accounted for using equity method	—	1
Decrease (increase) in trade and other receivables	(3)	332
Decrease (increase) in inventories	(2)	(41)
Increase (decrease) in trade and other payables	(78)	45
Other	3	8
Subtotal	<u>(556)</u>	<u>226</u>
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	<u>(12)</u>	<u>(2)</u>
Net cash provided by (used in) operating activities	<u>(569)</u>	<u>223</u>
Cash flows from investing activities		
Purchase of property, plant and equipment	—	(0)
Purchase of intangible assets	<u>(4)</u>	<u>—</u>
Net cash provided by (used in) investing activities	<u>(4)</u>	<u>(0)</u>
Cash flows from financing activities		
Proceeds from issuance of bonds	500	—
Redemption of bonds	(500)	—
Proceeds from issuance of new shares	638	—
Proceeds from issuance of share acquisition rights	10	—
Repayment of lease liabilities	<u>(10)</u>	<u>(12)</u>
Net cash provided by (used in) financing activities	<u>638</u>	<u>(12)</u>
Net increase (decrease) in cash and cash equivalents	<u>64</u>	<u>210</u>
Cash and cash equivalents at beginning of period	<u>714</u>	<u>803</u>
Effect of exchange rate changes on cash and cash equivalents	<u>11</u>	<u>2</u>
Cash and cash equivalents at end of period	<u><u>790</u></u>	<u><u>1,016</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.