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November 13, 2023

## Consolidated Financial Results for the Nine 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: November 13, 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 nine months of the fiscal year ending December 31, 2023 (from January 1, 2023 to September 30, 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	%
Nine months ended September 30, 2023	602	24.3	(787)	–	(784)	–	(768)	–
September 30, 2022	485	71.3	(1,952)	–	(1,973)	–	(2,049)	–

	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
Nine months ended September 30, 2023	(768)	–	(756)	–	(4.57)	(4.57)
September 30, 2022	(2,049)	–	(2,032)	–	(13.98)	(13.98)

#### (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 September 30, 2023	2,278	1,913	1,913	84.0	11.37
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	–	0.00	–		
Fiscal year ending December 31, 2023 (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, 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)	—	(6.83)
	~ 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 September 30, 2023	168,743,910 shares
As of December 31, 2022	168,402,310 shares

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

As of September 30, 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 Nine months ended September 30, 2023	168,058,069 shares
For the Nine months ended September 30, 2022	146,635,496 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 nine months

### (1) Explanation of operating results

#### 1) Overview of results

##### Operating results

	(Millions of yen)		
	Nine months ended September 30, 2022	Nine months ended September 30, 2023	Year-on-year
Revenue	485	602	117
Gross profit	352	331	(21)
Operating profit (loss)	(1,952)	(787)	1,164
Profit (loss)	(2,049)	(768)	1,280

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 nine months ended September 30, 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<sup>®</sup> (SP-01) and episil<sup>®</sup> (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 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.

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.

The Company is conducting out-licensing activities for marketing and other rights in China and other regions.

#### **[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 have started new animal studies in Japan 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 nine months

ended September,30, 2023, was as follows.

[Revenue, Gross profit]

During the nine months ended September 30, 2023, revenue totaled 602 million yen. Revenue mainly came from the sales of pipeline products of Sancuso® (SP-01) ,DARVIAS® (SP-02) and episil® (SP-03). In addition, gross profit amounted to 331 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Nine months ended September 30, 2022	Nine months ended September 30, 2023	Year-on-year
R&D expenses	766	308	(458)
SG&A expenses	1,538	810	(728)
Total	2,304	1,118	(1,186)
(Breakdown)			
Personnel expenses	545	349	(195)
Outsourcing expenses	920	322	(597)
Depreciation and amortization of intangible assets	389	378	(11)
Other	449	68	(381)

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

R&D expenses amounted to 308 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), animal studies for SP-04, and investments in new development candidates. SG&A expenses amounted to 810 million yen, down 728 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 787 million yen.

The Company incurred an overall loss of 768 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 nine months ended September 30, 2023, pipeline investment amounted to 308 million yen. This figure is 308 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01) and ,DARVIAS® (SP-02), leading to amortization of 339 million yen during the nine months under review. As a result, the balance of intangible assets was 1,230 million yen as of September 30, 2023.

## 2) Cash flows

	(Millions of yen)		
	Nine months ended September 30, 2022	Nine months ended September 30, 2023	Year-on-year
Net cash provided by (used in) operating activities	(1,096)	(262)	834
Net cash provided by (used in) investing activities	(418)	(0)	418
Net cash provided by (used in) financing activities	2,581	(27)	(2,609)

### [Cash flows from operating activities]

Net cash used in operating activities amounted to 1,096 million yen (compared with 262 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 784 million yen.

### [Cash flows from investing activities]

Net cash used in investing activities amounted to 0 million yen (compared with 418 million yen used in these activities in the corresponding period of the previous fiscal year, mainly attributable to 403 million yen in outflows related to capitalized development investment).

### [Cash flows from financing activities]

Net cash used in financing activities amounted to 27 million yen (compared with 2,581 million yen provided by these activities in the same period of the previous year. This figure was mainly attributable to 2,608 million yen in proceeds from issuance of new shares by third party allotment and the exercise of warrants).

## 3) R&D activities

R&D expenses amounted to 308 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), animal studies for SP-04, and investments in new development 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 September 30, 2023, total assets amounted to 2,278 million yen, down 855 million yen from the previous year-end. Current assets were 897 million yen, including 520 million yen in cash and cash equivalents, 206 million yen in trade and other receivables. Non-current assets came to 1,381 million yen. This figure includes 1,230 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 365 million yen, down 106 million yen from the previous year-end. Current liabilities were 287 million yen, including 212 million yen in trade and other payables. Non-current liabilities amounted to 77 million yen, mainly due to 36 million yen in lease liabilities 30 million yen in deferred tax liabilities.

Total equity equaled 1,913 million yen, down 748 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 768 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 September 30, 2023
<b>Assets</b>		
Current assets		
Cash and cash equivalents	803	520
Trade and other receivables	572	206
Inventories	14	120
Other current assets	44	49
Total current assets	1,435	897
Non-current assets		
Property, plant and equipment	26	23
Light-of-use asset	37	69
Intangible assets	1,570	1,230
Investments accounted for using equity method	11	7
Other non-current assets	52	51
Total non-current assets	1,698	1,381
Total assets	3,134	2,278
<b>Liabilities and equity</b>		
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	332	212
Lease liabilities	37	33
Other current liabilities	37	41
Total current liabilities	407	287
Non-current liabilities		
Deferred tax liabilities	53	30
Lease liabilities	0	36
Other non-current liabilities	10	10
Total non-current liabilities	64	77
Total liabilities	472	365
<b>Equity</b>		
Share capital	1,436	1,439
Capital surplus	1,500	1,504
Retained earnings	(223)	(992)
Treasury stock	(70)	(70)
Other components of equity	19	32
Total equity	2,662	1,913
Total liabilities and equity	3,134	2,278



(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2022	Nine months ended September 30, 2023
Revenue	485	602
Cost of sales	132	271
Gross profit	352	331
Research and development expenses	766	308
Selling, general and administrative expenses	1,538	810
Operating profit (loss)	(1,952)	(787)
Finance income	0	8
Finance costs	19	0
Other income	—	—
Share of profit (loss) of investments accounted for using equity method	(1)	(4)
Profit (loss) before tax	(1,973)	(784)
Income taxes	75	(15)
Profit (loss)	(2,049)	(768)
Profit (loss) attributable to:		
Owners of parent	(2,049)	(768)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(13.98)	(4.57)
Diluted earnings (loss) per share [yen]	(13.98)	(4.57)

## (3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2022	Nine months ended September 30, 2023
Profit (loss)	(2,049)	(768)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	16	12
Subtotal	16	12
Total other comprehensive income	16	12
Comprehensive income	<u>(2,032)</u>	<u>(756)</u>
Comprehensive income attributable to:		
Owners of parent	(2,032)	(756)

## (4) Condensed consolidated statement of changes in equity

(Millions of yen)

	Other components of equity							Total equity
	Share capital	Capital surplus	Retained earnings	Treasury shares	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)	—	—	(2,049)	—	—	—	—	(2,049)
Other comprehensive income	—	—	—	—	16	—	16	16
Total comprehensive income	—	—	(2,049)	—	16	—	16	(2,032)
Transactions with owners								
Issuance of new shares	510	477	—	—	—	—	—	987
Exercise of share acquisition rights	821	806	—	—	—	(7)	(7)	1,621
Issuance of share acquisition rights	—	—	—	—	—	10	10	10
Disposal of share acquisition rights	—	—	—	—	—	(3)	(3)	(3)
Capital reduction	(2,010)	(5,519)	7,529	—	—	—	—	—
Disposal of treasury shares	—	—	—	0	—	—	—	0
Share-based payment transactions	—	(0)	—	—	—	—	—	(0)
Total transactions with owners	(678)	(4,236)	7,529	0	—	0	0	2,615
Balance at September 30, 2022	<u>1,431</u>	<u>1,501</u>	<u>275</u>	<u>(70)</u>	<u>27</u>	<u>3</u>	<u>30</u>	<u>3,169</u>
Balance at January 1, 2023	1,436	1,500	(223)	(70)	15	3	19	2,662
Comprehensive income								
Profit (loss)	—	—	(768)	—	—	—	—	(768)
Other comprehensive income	—	—	—	—	12	—	12	12
Total comprehensive income	—	—	(768)	—	12	—	12	(756)
Transactions with owners								
Exercise of share acquisition rights	3	3	—	—	—	—	—	7
Total transactions with owners	3	3	—	—	—	—	—	7
Balance at September 30, 2023	<u>1,439</u>	<u>1,504</u>	<u>(992)</u>	<u>(70)</u>	<u>28</u>	<u>3</u>	<u>32</u>	<u>1,913</u>

## (5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2022	Nine months ended September 30, 2023
Cash flows from operating activities		
Profit (loss) before tax	(1,973)	(784)
Depreciation and amortization	389	378
Finance income	(0)	(8)
Finance costs	19	0
Share of loss (profit) of investments accounted for using equity method	1	4
Decrease (increase) in trade and other receivables	54	402
Decrease (increase) in inventories	(1)	(106)
Increase (decrease) in trade and other payables	517	(123)
Other	(76)	(0)
Subtotal	<u>(1,067)</u>	<u>(237)</u>
Interest received	0	0
Interest paid	(1)	(0)
Income taxes paid	(27)	(25)
Net cash provided by (used in) operating activities	<u>(1,096)</u>	<u>(262)</u>
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Purchase of intangible assets	(403)	—
Share-based payment transactions	(14)	—
Net cash provided by (used in) investing activities	<u>(418)</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	2,608	7
Proceeds from issuance of share acquisition rights	10	—
Acquisition of share acquisition rights	(3)	—
Repayment of lease liabilities	(33)	(34)
Net cash provided by (used in) financing activities	<u>2,581</u>	<u>(27)</u>
Net increase (decrease) in cash and cash equivalents	<u>1,066</u>	<u>(290)</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	31	7
Cash and cash equivalents at end of period	<u><u>1,812</u></u>	<u><u>520</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.