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August 14, 2024

**Consolidated Financial Results for the First Six Months of
the Fiscal Year Ending December 31, 2024
(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 14, 2024
 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 first six months of the fiscal year ending December 31, 2024 (from January 1, 2024 to June 30, 2024)

(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, 2024	72	(86.4)	(611)	–	(627)	–	(611)	–
June 30, 2023	529	179.5	(462)	–	(450)	–	(437)	–

	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, 2024	(611)	–	(600)	–	(3.35)	(3.35)
June 30, 2023	(437)	–	(430)	–	(2.61)	(2.61)

(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
June 30, 2024	2,299	1,965	1,965	85.5	9.85
December 31, 2023	2,229	1,875	1,875	84.1	10.78

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, 2023	–	0.00	–	0.00	0.00
Fiscal year ending December 31, 2024	–	0.00			
Fiscal year ending December 31, 2024 (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, 2024
(from January 1, 2024 to December 31, 2024)**

(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, 2024	1,250	102.5	(800)	—	(800)	—	(800)	—	(800)	—	(4.01)
	~	~	~	~	~	~	~	~	~	~	~
	1,500	143.0	(550)	—	(550)	—	(550)	—	(550)	—	(2.76)

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, 2024	199,944,010 shares
As of December 31, 2023	174,373,910 shares

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

As of June 30, 2024	409,110 shares
As of December 31, 2023	430,910 shares

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

For the Six months ended June 30, 2024	182,514,316 shares
For the Six months ended June 30, 2023	167,977,702 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 15, 2024 for institutional investors and analysts.

The presentation materials used at the meeting will be available on our website.

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1. Qualitative information regarding results for the first six months

(1) Explanation of operating results

1) Overview of results

Operating results

	Six months ended June 30, 2023	Six months ended June 30, 2024	(Millions of yen) Year-on-year
Revenue	529	72	(457)
Gross profit	289	2	(286)
Operating profit (loss)	(462)	(611)	(148)
Profit (loss)	(437)	(611)	(173)

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 six months ended June 30, 2024.

[Launched products (development completed)]

SP-01 (Indication: Chemotherapy-induced nausea and vomiting)

SP-03 (Indication: Oral mucositis/stomatitis caused by chemotherapy and radiotherapy)

Sales of Sancuso® (SP-01) and episil® (SP-03), which are mainly sold in China, were substantially lower than in the corresponding period of the previous fiscal year, due to the restricted shipment of Sancuso®(SP-01) and episil®(SP-03) resulting from the relocation of the manufacturing facility in a bid to lower costs. The regulatory procedures for the transfer of the Sancuso® manufacturing facility in China have been completed. An application for regulatory approval for episil® has been submitted for the transfer of manufacturing site in Japan.

SP-02 (Indication: 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 investigating new targeting hematologic cancers other than Relapsed or Refractory peripheral T-cell lymphoma with an eye to expanding the drug's indications.

The Company is continuing 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.

Pipeline product (development stopped temporarily)]

SP-05 (Target Indication: Increase in antitumor efficacy of fluorouracil)

In 2022, it was found out that neither the primary endpoint nor the key secondary endpoint showed

statistically significant differences as the final results of the international Phase III AGENT Study including Japan in colorectal cancer. We have decided to stop to the development of this pipeline product.

The developed product's licensor, Isofol, has been conducting a detailed analysis of the AGENT study results with external professionals and new non-clinical studies since 2023 with a view to resuming clinical development of SP-05, and has concluded that these overall evaluations show that SP-05 (arfolitixorin) is different from that used in the AGENT study in the study concluded that these overall evaluations indicate that SP-05 (arfolitixorin) is clinically effective at new doses and dosages different from those used in the AGENT study.

In February 2024, Isofol's Board of Directors decided to prepare a new clinical development program for SP-05 and to initiate a new clinical trial as soon as possible. In conjunction with this decision, Isofol also announced that it plans to conduct small clinical trials in a time- and cost-efficient manner to demonstrate the clinical efficacy of SP-05 using the new dosage and administration compared to standard therapy as the first approach.

The Company has been in regular communication with Isofol since the suspension of the development of SP-05. In light of Isofol's recent decision to resume development of SP-05 and its plans to conduct a small clinical trial, we will continue to exchange information with Isofol and evaluate the results of the new non-clinical study and the content of the clinical trial plan in order to decide on the resumption of development in Japan and Isofol's plan to participate in a new development program.

In July 2024, Isofol has announced results from a post hoc per-Protocol analysis of the AGENT Study and two preclinical studies that support the dose-response relationship for SP-05(arfolitixorin). The results show even the likely suboptimal dosing regimen used in the Phase III AGENT study results in a numerical advantage for SP-05(arfolitixorin). Additionally, previous studies suggest that an optimized dosing regimen could generate even better efficacy. These preclinical studies confirm previous findings and thereby provide further support for Isofol's strategy to conduct a clinical study with an optimized dosing regimen of arfolitixorin, where higher doses than the one used in the Phase III AGENT study are tested. This is considered to further increase the likelihood of generating positive data in the Phase Ib/II study, which is anticipated to start before the end of 2024,

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 the year before last 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 six months ended June 30, 2024, was as follows.

[Revenue, Gross profit]

During the six months ended June 30, 2024, revenue totaled 72 million yen. Currently, procedures are underway to change the manufacturing site of the drug in a bid to lower manufacturing costs, and we expect prescription volume of the drug to fall temporarily until the procedures are complete. Revenue mainly came from the sales of pipeline products of DARVIAS® (SP-02). In addition, gross profit amounted to 2 million yen.

Breakdown of R&D and SG&A expenses

(Millions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year
R&D expenses	192	223	31
SG&A expenses	559	390	(169)
Total	751	614	(137)
(Breakdown)			
Personnel expenses	236	209	(26)
Outsourcing expenses	218	224	5
Depreciation and amortization of intangible assets	252	127	(125)
Other	44	52	8

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

R&D expenses amounted to 223 million yen. This amount mainly reflected costs for changing the manufacturing site to lower manufacturing costs, R&D aimed at preparing the clinical studies and expanding the indications for DARVIAS[®] (SP-02), animal studies for SP-04, and investments in new development candidates. SG&A expenses amounted to 390 million yen, down 169 million yen year on year.

The Company incurred an operating loss of 611 million yen.

The Company incurred an overall loss of 611 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 six months ended June 30, 2024, pipeline investment amounted to 223 million yen. This figure is 223 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 108 million yen during the six months under review. As a result, the balance of intangible assets was 1,008 million yen as of June 30, 2024.

2) Cash flows

	(Millions of yen)		
	Six months ended June 30, 2023	Six months ended June 30, 2024	Year-on-year
Net cash provided by (used in) operating activities	(330)	(474)	(143)
Net cash provided by (used in) investing activities	(0)	(0)	(0)
Net cash provided by (used in) financing activities	(23)	675	698

[Cash flows from operating activities]

Net cash used in operating activities amounted to 474 million yen (compared with 330 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 627 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 0 million yen (compared with 0 million yen used in these activities in the corresponding period of the previous fiscal year).

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 675 million yen (compared with 23 million yen used in these activities in the same period of the previous year). This figure was mainly attributable to 692 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) R&D activities

R&D expenses amounted to 223 million yen. This amount mainly reflected costs for changing the manufacturing site to lower manufacturing costs, R&D aimed at preparing the clinical studies and 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 June 30, 2024, total assets amounted to 2,299 million yen, up 69 million yen from the previous year-end. Current assets were 1,173 million yen, including 942 million yen in cash and cash equivalents 56 million in trade and other receivables. Non-current assets came to 1,125 million yen. This figure includes 1,008 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 333 million yen, down 20 million yen from the previous year-end. Current liabilities were 303 million yen, including 226 million yen in trade and other payables. Non-current liabilities amounted to 30 million yen, mainly due to 11 million yen in lease liabilities 5 million yen in deferred tax liabilities.

Total equity equaled 1,965 million yen, up 89 million yen from the previous year-end. The increase was mainly attributable to 692 million yen in proceeds from issuance of new shares by the exercise of warrants. The decrease was mainly attributable to the overall loss of 611 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, 2024

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2023	As of June 30, 2024
Assets		
Current assets		
Cash and cash equivalents	728	942
Trade and other receivables	67	56
Inventories	122	138
Other current assets	58	36
Total current assets	976	1,173
Non-current assets		
Property, plant and equipment	21	20
Light-of-use asset	60	44
Intangible assets	1,117	1,008
Investments accounted for using equity method	6	4
Other non-current assets	46	47
Total non-current assets	1,252	1,125
Total assets	2,229	2,299
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	213	226
Lease liabilities	33	33
Other current liabilities	45	43
Total current liabilities	293	303
Non-current liabilities		
Deferred tax liabilities	22	5
Lease liabilities	27	11
Other non-current liabilities	10	12
Total non-current liabilities	61	30
Total liabilities	354	333
Equity		
Share capital	1,596	1,948
Capital surplus	1,657	1,994
Retained earnings	(1,336)	(1,947)
Treasury stock	(69)	(65)
Other components of equity	26	35
Total equity	1,875	1,965
Total liabilities and equity	2,229	2,299

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Revenue	529	72
Cost of sales	240	69
Gross profit	289	2
Research and development expenses	192	223
Selling, general and administrative expenses	559	390
Operating profit (loss)	(462)	(611)
Finance income	15	0
Finance costs	0	14
Share of profit (loss) of investments accounted for using equity method	(3)	(2)
Profit (loss) before tax	(450)	(627)
Income taxes	(13)	(16)
Profit (loss)	(437)	(611)
Profit (loss) attributable to:		
Owners of parent	(437)	(611)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(2.61)	(3.35)
Diluted earnings (loss) per share [yen]	(2.61)	(3.35)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Profit (loss)	(437)	(611)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	7	10
Subtotal	7	10
Total other comprehensive income	7	10
Comprehensive income	(430)	(600)
Comprehensive income attributable to:		
Owners of parent	(430)	(600)

(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, 2023	1,436	1,500	(223)	(70)	15	3	19	2,662
Comprehensive income								
Profit (loss)	—	—	(437)	—	—	—	—	(437)
Other comprehensive income	—	—	—	—	7	—	7	7
Total comprehensive income	—	—	(437)	—	7	—	7	(430)
Transactions with owners								
Exercise of share acquisition rights	0	0	—	—	—	—	—	1
Total transactions with owners	0	0	—	—	—	—	—	1
Balance at June 30, 2023	1,436	1,501	(661)	(70)	23	3	26	2,233
Balance at January 1, 2024	1,596	1,657	(1,336)	(69)	25	1	26	1,875
Comprehensive income								
Profit (loss)	—	—	(611)	—	—	—	—	(611)
Other comprehensive income	—	—	—	—	10	—	10	10
Total comprehensive income	—	—	(611)	—	10	—	10	(600)
Transactions with owners								
Exercise of share acquisition rights	351	340	—	—	—	—	—	692
Disposal of share acquisition rights	—	—	—	—	—	(1)	(1)	(1)
Disposal of treasury shares	—	—	—	3	—	—	—	3
Share-based payment transactions	—	(3)	—	—	—	—	—	(3)
Total transactions with owners	351	336	—	3	—	(1)	(1)	690
Balance at June 30, 2024	1,948	1,994	(1,947)	(65)	35	—	35	1,965

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Six months ended June 30, 2023	Six months ended June 30, 2024
Cash flows from operating activities		
Profit (loss) before tax	(450)	(627)
Depreciation and amortization	252	127
Finance income	(15)	(3)
Finance costs	0	0
Share of loss (profit) of investments accounted for using equity method	3	2
Decrease (increase) in trade and other receivables	62	11
Decrease (increase) in inventories	(103)	(15)
Increase (decrease) in trade and other payables	(52)	12
Other	(1)	19
Subtotal	(304)	(473)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	(25)	(0)
Net cash provided by (used in) operating activities	(330)	(474)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Purchase of intangible assets	—	—
Share-based payment transactions	—	—
Net cash provided by (used in) investing activities	(0)	(0)
Cash flows from financing activities		
Proceeds from issuance of bonds	—	500
Redemption of bonds	—	(500)
Proceeds from issuance of new shares	1	692
Acquisition of share acquisition rights	—	(1)
Repayment of lease liabilities	(24)	(16)
Other	—	1
Net cash provided by (used in) financing activities	(23)	675
Net increase (decrease) in cash and cash equivalents	(354)	200
Cash and cash equivalents at beginning of period	803	728
Effect of exchange rate changes on cash and cash equivalents	3	13
Cash and cash equivalents at end of period	453	942

(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.