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August 13, 2025

## Consolidated Financial Results for the First Six Months of the Fiscal Year Ending December 31, 2025 (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 13, 2025  
 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 six months ended June 30, 2025 (from January 1, 2025 to June 30, 2025)

#### (1) Consolidated operating results (cumulative) (Percentages indicate year-on-year changes.)

	Sales		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Total comprehensive income	
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
June 30, 2025	49	(31.3)	(537)	—	(555)	—	(555)	—	(555)	—	(567)	—
June 30, 2024	72	(86.4)	(611)	—	(627)	—	(611)	—	(611)	—	(600)	—

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
June 30, 2025	(2.54)	(2.54)
June 30, 2024	(3.35)	(3.35)

#### (2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of parent	Equity attributable to owners of parent to total assets ratio	Equity attributable to owners of parent per share
As of	Millions of yen	Millions of yen	Millions of yen	%	Yen
June 30, 2025	1,864	1,276	1,276	68.5	5.75
December 31, 2024	1,362	1,156	1,156	84.9	5.30

### 2. Cash dividends

	Annual dividend				
	First quarter	Second quarter	Third quarter	Year end	Annual
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2024	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2025	—	0.00			
Fiscal year ending December 31, 2025 (Forecast)			—	0.00	0.00

Note: Revisions to the forecast of cash dividends most recently announced : None

3. Consolidated financial forecast for the fiscal year ending December 31, 2025 (from January 1, 2025 to December 31, 2025)

(Percentages indicate year-on-year changes.)

	Sales		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Basic earnings per share
Fiscal year ending	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
December 31, 2025	1,300	310.2	(650)	—	(650)	—	(650)	—	(650)	—	(2.98)

Note:Revisions to the earnings forecasts most recently announced : None

\* Notes

(1) Significant changes in the scope of consolidation during the period : None

(2) Changes in accounting policies and changes in accounting estimates

(i) Changes in accounting policies required by IFRS : None

(ii) Changes in accounting policies due to other reasons : None

(iii) Changes in accounting estimates : None

(3) Number of issued shares (ordinary shares)

① Number of issued and outstanding shares at the period end (including treasury stock)

As of June 30, 2025	241,609,010shares	As of December 31, 2024	218,458,910shares
As of June 30, 2025	409,143shares	As of December 31, 2024	409,110shares
Six months ended June 30, 2025	218,926,884shares	Six months ended June 30, 2024	182,514,316shares

② Number of treasury stock at the period end

③ Average number of shares

\* Semi-annual financial results reports are exempt from review conducted by certified public accountants or an audit firm.

\* 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 14, 2025 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, 2024	Six months ended June 30, 2025	(Millions of yen) Year-on-year
Revenue	72	49	(22)
Gross profit	2	20	17
Operating profit (loss)	(611)	(537)	74
Profit (loss)	(611)	(555)	55

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, 2025.

#### [Launched products (development completed)]

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

Sales of Sancuso® sharply declined due to shipment constraints following the transfer of manufacturing facility.

The regulatory procedures for the addition of the Sancuso® manufacturing facility in China have been completed.

##### **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 cancers other than Relapsed or Refractory peripheral T-cell lymphoma with an eye to expanding the new indications.

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

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

In December 2024, The Group resolved to cancel the sales partner agreement with Lee's Pharmaceutical (HK) Limited and enter into a new sales partner agreement with Changchun GeneScience Pharmaceutical Co., Ltd. (headquarters: China; hereinafter "GenSci". The contracting party is Gensci Singapore Pte. Ltd., a wholly owned subsidiary of GenSci.) and began shipping to the company during the quarter. The Company is continuing out-licensing activities.

#### [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 trials (POLAR-A study and POLAR-M study) 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 the information obtained from the results of previous animal studies, in collaboration with licensor Egetis Therapeutics, we have conducted animal study in Japan and have obtained positive results in terms of peripheral neuropathic pain and pathological evaluation of neuronal cells in the test animals. With a view to future clinical trials, we have also conducted an additional new animal study to reinforce these results.

**[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 the development of this pipeline product. In 2024, Isofol has decided to resume development of SP-05, and we have also decided resume development in Japan.

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).

At the Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (ASCO-GI) held in the United States in January this year, the details of the post ad-hoc analysis results of the AGENT study were reported, and it was reported that when only the patient group that strictly followed the study protocol was analyzed, the SP-05 administration group showed higher efficacy than the control group that received leucovorin.

These are thought to further increase the possibility of obtaining positive data in the Phase Ib/II clinical trial scheduled to begin in the first half of this year.

In March of this year, Isofol received approval from the German regulator BfArM (Federal Agency for Pharmaceuticals and Medical Devices) to start a Phase Ib/II clinical trial of SP-05. In June of this year, Isofol announced the completion of the first cohort of the dose escalation in the ongoing phase Ib/II clinical study with arfolitixorin that has been carried out since April of this year at Charité – Universitätsmedizin Berlin. The company is now waiting for patient enrollment to initiate the next cohort in the dose-escalating part of the study. The company plan to participate in the Phase II part of the study.

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. However, in the short term, upfront expenditures for pipeline product development continue to exceed earnings from product sales due to the impact of competing products, product sales are struggling to grow. As a result, our financial performance during the six months ended June 30, 2025, was as follows.

**[Revenue, Gross profit]**

During the six months ended June 30, 2025, revenue totaled 49 million yen. Revenue mainly came from the sales of pipeline products of DARVIAS® (SP-02) and episil® (SP-03). In addition, gross profit amounted to 20 million yen.

## Breakdown of R&D and SG&A expenses

(Millions of yen)

	Six months ended June 30, 2024	Six months ended June 30, 2025	Year-on-year
R&D expenses	223	232	8
SG&A expenses	390	325	(64)
Total	614	557	(56)
(Breakdown)			
Personnel expenses	209	202	(7)
Outsourcing expenses	224	245	21
Depreciation and amortization of intangible assets	127	18	(108)
Other	52	90	37

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

R&D expenses amounted to 232 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<sup>®</sup> (SP-02), animal studies for SP-04, and investments in new development candidates. SG&A expenses amounted to 325 million yen, down 64 million yen year on year.

The Company incurred an operating loss of 537 million yen.

The Company incurred an overall loss of 555 million yen.

## 2) Cash flows

	(Millions of yen)		
	Six months ended June 30, 2024	Six months ended June 30, 2025	Year-on-year
Net cash provided by (used in) operating activities	(474)	(32)	442
Net cash provided by (used in) investing activities	(0)	(1)	(0)
Net cash provided by (used in) financing activities	675	672	(2)

### [Cash flows from operating activities]

Net cash used in operating activities amounted to 32 million yen (compared with 474 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 555 million yen.

### [Cash flows from investing activities]

Net cash used in investing activities amounted to 1 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 672 million yen (compared with 675 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 688 million yen in proceeds from issuance of new shares by the exercise of warrants.

## 3) R&D activities

R&D expenses amounted to 232 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<sup>®</sup> (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, 2025, total assets amounted to 1,864 million yen, up 501 million yen from the previous year-end. Current assets were 1,682 million

yen, including 1,486 million yen in cash and cash equivalents 26 million in trade and other receivables. Non-current assets came to 181 million yen.

Total liabilities totaled 587 million yen, up 381 million yen from the previous year-end. Current liabilities were 492 million yen, including 416 million yen in trade and other payables. Non-current liabilities amounted to 94 million yen, mainly due to 81 million yen in lease liabilities.

Total equity equaled 1,276 million yen, up 120 million yen from the previous year-end. The increase was mainly attributable to 688 million yen in proceeds from issuance of new shares by the exercise of warrants. The decrease was mainly attributable to the overall loss of 555 million yen.

In addition, In May of the year, the Company reduced its share capital and legal capital surplus by a total of 3.633 billion yen to cover a loss brought forward.

## (3) Explanation of consolidated earnings forecasts and other forward-looking statements

The consolidated earnings forecasts are unchanged from the forecasts announced on February 12, 2025

## 2. Condensed quarterly consolidated financial statements and significant notes thereto

### (1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2024	As of June 30, 2025
Assets		
Current assets		
Cash and cash equivalents	886	1,486
Trade and other receivables	232	26
Inventories	128	114
Other current assets	19	55
Total current assets	1,266	1,682
Non-current assets		
Property, plant and equipment	19	17
Right-of-use assets	28	114
Investments accounted for using equity method	1	2
Other non-current assets	46	46
Total non-current assets	96	181
Total assets	1,362	1,864
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	121	416
Lease liabilities	25	30
Other current liabilities	47	45
Total current liabilities	193	492
Non-current liabilities		
Deferred tax liabilities	0	0
Lease liabilities	0	81
Other non-current liabilities	10	12
Total non-current liabilities	12	94
Total liabilities	206	587
Equity		
Share capital	2,211	450
Capital surplus	2,255	1,071
Retained earnings	(3,277)	(200)
Treasury shares	(65)	(65)
Other components of equity	33	20
Total equity	1,156	1,276
Total liabilities and equity	1,362	1,864



## (2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Six months ended June 30, 2024	Six months ended June 30, 2025
Revenue	72	49
Cost of sales	69	29
Gross profit	2	20
Research and development expenses	223	232
Selling, general and administrative expenses	390	325
Operating profit (loss)	(611)	(537)
Finance income	0	0
Finance costs	14	19
Share of profit (loss) of investments accounted for using equity method	(2)	0
Profit (loss) before tax	(627)	(555)
Income tax expense	(16)	0
Profit (loss)	(611)	(555)
Profit (loss) attributable to Owners of parent	(611)	(555)
Earnings (loss) per share		
Basic earnings (loss) per share	(3.35)	(2.54)
Diluted earnings (loss) per share	(3.35)	(2.54)

### (3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Six months ended June 30, 2024	Six months ended June 30, 2025
Profit (loss)	(611)	(555)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	10	(12)
Total	10	(12)
Total other comprehensive income	10	(12)
Comprehensive income	(600)	(567)
Comprehensive income attributable to Owners of parent	(600)	(567)

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

(Millions of yen)

	Other components of equity							Total
	Share capital	Capital surplus	Retained earnings	Treasury shares	Exchange differences on translation of foreign operations	Share acquisition on rights	Total	
Balance at beginning of period	1,596	1,657	(1,336)	(69)	25	1	26	1,875
Comprehensive income								
Profit (loss)	—	—	(611)	—	—	—	—	(611)
Other comprehensive income	—	—	—	—	10	—	10	10
Comprehensive income	—	—	(611)	—	10	—	10	(600)
Transactions with owners								
Exercise of share acquisition rights	351	340	—	—	—	—	—	692
Cancellation 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 end of period	1,948	1,994	(1,947)	(65)	35	—	35	1,965

(Millions of yen)

	Other components of equity							Total
	Share capital	Capital surplus	Retained earnings	Treasury shares	Exchange differences on translation of foreign operations	Share acquisition on rights	Total	
Balance at beginning of period	2,211	2,255	(3,277)	(65)	33	—	33	1,156
Comprehensive income								
Profit (loss)	—	—	(555)	—	—	—	—	(555)
Other comprehensive income	—	—	—	—	(12)	—	(12)	(12)
Comprehensive income	—	—	(555)	—	(12)	—	(12)	(567)
Transactions with owners								
Exercise of share acquisition rights	350	338	—	—	—	—	—	688
Capital reduction	(2,111)	2,111	—	—	—	—	—	—
Deficit disposition	—	(3,633)	3,633	—	—	—	—	—
Purchase of treasury shares	—	—	—	(0)	—	—	—	(0)
Total transactions with owners	(1,761)	(1,183)	3,633	(0)	—	—	—	688
Balance at end of period	450	1,071	(200)	(65)	20	—	20	1,276

## (5) Condensed consolidated statement of cash flows

(Millions of yen)

	Six months ended June 30, 2024	Six months ended June 30, 2025
Cash flows from operating activities		
Profit (loss) before tax	(627)	(555)
Depreciation and amortization of intangible assets	127	18
Finance income	(3)	(0)
Finance costs	0	27
Share of loss (profit) of investments accounted for using equity method	2	(0)
Decrease (increase) in trade and other receivables	11	206
Decrease (increase) in inventories	(15)	13
Increase (decrease) in trade and other payables	12	295
Other	19	(38)
Subtotal	(473)	(32)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes refund (paid)	(0)	(0)
Net cash provided by (used in) operating activities	(474)	(32)
Cash flows from investing activities		
Purchase of property, plant and equipment	(0)	(0)
Other	—	(0)
Net cash provided by (used in) investing activities	(0)	(1)
Cash flows from financing activities		
Proceeds from issuance of bonds	500	—
Redemption of bonds	(500)	—
Proceeds from issuance of shares	692	688
Purchase of share acquisition rights	(1)	—
Repayments of lease liabilities	(16)	(16)
Other	1	1
Net cash provided by (used in) financing activities	675	672
Net increase (decrease) in cash and cash equivalents	200	639
Cash and cash equivalents at beginning of period	728	886
Effect of exchange rate changes on cash and cash equivalents	13	(39)
Cash and cash equivalents at end of period	942	1,486

(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.