

English Translation:
This is a translation of the original release in Japanese. In the event of any discrepancy, the original release in Japanese shall prevail.

Non-consolidated Financial Results for the Six Months Ended January 31, 2025 [Japanese GAAP]

March 12, 2025

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 Stock exchange listing: Tokyo Stock Exchange
 Stock code: 4599
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Scheduled date of commencing dividend payments: —
 Scheduled date of commencing dividend payments: —
 Supplementary briefing materials on financial results: None
 Explanatory meeting on financial results: None

(Amounts of less than one million yen are rounded down)

1. Financial Results for the Six Months Ended January 31, 2025 (August 1, 2024 to January 31, 2025)

(1) Operating results

	Operating revenue		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Six months ended January 31, 2025	—	—	(1,066)	—	(1,065)	—	(1,048)	—
January 31, 2024	—	—	(1,033)	—	(1,033)	—	(1,005)	—

	Earnings per share Basic		Earnings per share diluted	
	Yen	Yen	Yen	Yen
Six months ended January 31, 2025	(17.00)	—	—	—
January 31, 2024	(16.45)	—	—	—

Note: Earnings per share diluted is not stated because of a net loss per share.

(2) Financial position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of January 31, 2025	8,369	8,157	80.6
As of July 31, 2024	9,080	8,894	83.5

(Reference) Equity capital: As of January 31, 2025 6,742 Million yen
 As of July 31, 2024 7,579 Million yen

2. Payment of Dividends

	Annual dividends				
	End Q1	End Q2	End Q3	Year-end	Total
Fiscal year ended	Yen	Yen	Yen	Yen	Yen
July 31, 2024	—	0.00	—	0.00	0.00
July 31, 2025	—	0.00	—	—	—
July 31, 2025 (forecast)	—	—	—	0.00	0.00

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

3. Financial Forecasts for the Fiscal Year Ending July 31, 2025 (August 1, 2024 to July 31, 2025)

Most of the Company's current operating revenue comes from milestone revenues associated with the progress of development, and these revenues are highly dependent on the development strategies and schedules of our business partners. Therefore, it is difficult to predict when the Company will receive milestone revenues, and the amount of business revenue for each fiscal year may fluctuate significantly. Hence, the Company has not provided a forecast for the fiscal year ending July 31, 2025.

The Company will continue to research and develop the "Regeneration-Inducing Medicine™" Redasemtide (a peptide medicine created from HMGB1) in the fiscal year ending July 31, 2025. In addition, the Company expects to continue to progress the development of Regeneration-Inducing Medicine™ candidate that follows Redasemtide for the clinical trials and negotiations for licensing out.

The cash outflow for the fiscal year ending July 31, 2025, is expected to be as follows.

- Forecast cash R&D expenses in the range of 1,200 million yen to 1,600 million yen.
- Forecast cash other selling, general and administrative expenses in the range of 230 million yen to 310 million yen.
- There is a possibility that upfront payments related to new partnerships.
- There is a possibility that milestone payments from existing partners for out-licensed pipelines.

The Company has secured sufficient funds for research and development activities through 2028.

*Notes

(1) Application of specific accounting for preparing the semi-annual semi-annual non-consolidated financial statements: None

(2) Changes in accounting policies, changes in accounting estimates and retrospective restatements

- (a) Changes in accounting policies due to amendment to the accounting standards, etc. : None
- (b) Changes in accounting policies other than (a) above : None
- (c) Changes in accounting estimates : None
- (d) Retrospective restatements : None

(3) Number of shares issued (common stock)

(a) Number of shares issued at the end of the period (including treasury stock)

As of January 31, 2025	62,136,200 shares
As of July 31, 2024	61,523,200 shares

(b) Number of treasury stock at the end of the period

As of January 31, 2025	121 shares
As of July 31, 2024	121 shares

(c) Average number of shares during the period

Six months ended January 31, 2025	61,696,622 shares
Six months ended January 31, 2024	61,130,694 shares

* Review of the accompanying semi-annual semi-annual financial statements by a certified public accountant or auditing firm: None

* Explanation of the appropriate use of business forecasts and other special instructions

The forward-looking statements in this document are based on information currently available to the Company and certain assumptions deemed to be reasonable, and the Company does not assure the achievement of any of these. Furthermore, actual results may differ significantly due to various factors.

Attached Documents

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1. Qualitative Information on Semi-AnnualSemi-Annual Financial Results for the Period under Review

(1) Explanation of operating results

The forward-looking statements in the text are based on the Company's judgment as of the date of submission.

During the six months ended January 31, 2025 (August 1, 2024, to January 31, 2025) in Japan, research and development for the creation of innovative drugs with new modalities had advanced in the pharmaceutical and regenerative medicine industries, accelerating the commercialization of innovative treatments. The Japanese government has been implementing the support policy to strengthen drug discovery capabilities, and the Ministry of Health, Labour and Welfare (MHLW) is seeking to secure \$344 million (53.5 billion yen) in biotechnology-related budgets in FY2025. Their focus areas are the expansion of the drug discovery ecosystems, the facilitation of the new modalities, and the support for the medical device developments. In particular, they are seeking to fund \$19 million (3 billion yen) for the commercialization of drug seeds, \$45.10 million (7 billion yen) for the improvement of drug discovery cluster infrastructure, and \$22.55 million (3.5 billion yen) for the enhancement of AI-driven drug discovery platforms.

In addition, the Ministry of Economy, Trade, and Industry (METI) is planning to launch a new project to support capital investment and talent development for contract development and manufacturing organizations (CDMOs) committed to regenerative medicine and gene therapy in Japan. For this purpose, METI is seeking to secure \$64.44 million (10 billion yen) for the FY2024 supplementary budget. This initiative is expected to strengthen the drug discovery infrastructure and improve the research environment for regenerative medicine in Japan.

Furthermore, the Regenerative Medicine Safety Securing Act was amended in 2024, and in vivo gene therapy and genome editing technologies were incorporated in the regulatory framework. This revision is expected to further ensure the safety of advanced medical technologies.

On the other hand, due to the changes in the global financial environment, the financing environment for biotech companies remains challenging, making selection and concentration of the development pipelines increasingly more important. In addition, because of the amendment of the Regenerative Medicine Safety Securing Act and the stricter review policy for regenerative medicine and gene therapy, the quality of evidence and the design of clinical trials are becoming more important.

The global market size of regenerative medicine had reached \$26.7 billion (4 trillion yen) in 2024, and it is predicted to grow to \$130.4 billion (19.54 trillion yen) by 2033. Therefore, the demand for regenerative medicine will also steadily increase.

Under these circumstances, our company has continued to make progress in the research and development of "Regeneration-Inducing Medicine™" called Redasemtide (a peptide medicine created from HMGB1), toward the initiation of new clinical trials. Additionally, for next-generation "Regeneration-Inducing Medicine™", TRIM3 and TRIM4, non-clinical development and business development activities aimed at licensing out have also shown continued progress.

"Regeneration-Inducing Medicine™" is a next-generation drug with a completely new mechanism of action, unlike conventional regenerative medicine. It does not require the transplantation of artificially cultured cells but induces mesenchymal stem cell accumulation within the patient's body through drug administration. This allows for easier and more cost-effective tissue regeneration, with effects comparable to or greater than those of traditional regenerative medicine and cell therapy. The administered substances include peptides and proteins, which can be manufactured, transported, stored, and administered using the same methods as traditional pharmaceuticals. As a result, compared to conventional regenerative medicine or cell therapy, it offers a more convenient and cost-effective means of promoting tissue regeneration, while delivering effects that are equal to or potentially greater than those of traditional methods.

Based on the concept of realizing regenerative medicine™regenerative medicine™ and cell therapy without the use of living cells, but through the administration of substances (compounds)," "Regeneration-Inducing Medicine™" is expected to overcome numerous challenges associated with transplantation therapies and conventional regenerative medicine. As an innovative regenerative medical technology, it is anticipated to become a game changer not only in Japan but also globally within the regenerative medicine industry.

The progress of R&D in each pipeline is shown in the figure below.

Project code	Development candidate	Indication	Investigator	Area	Research	Pre-clinical	Phase 1	Phase 2	Phase 3	Status
Redasemtide (TRIM2)	(HMGB1 cell mobilization domain peptides)	Epidermolysis bullosa	Shionogi & Co., Ltd.							Additional P2 Study Ongoing
		Acute Ischemic Stroke	Shionogi & Co., Ltd.							Global P2b Study Ongoing
		Ischemic Cardiomyopathy	Osaka University							Physician-Initiated P2 Study Ongoing
		Osteoarthritis of the knee	Hirosaki University							Physician-Initiated P2 Study Primary endpoint achieved
		Chronic liver disease	Niigata University							Physician-Initiated P2 Study Primary endpoint achieved
TRIM3	Novel Regeneration-Inducing peptide for Systemic administration	Not disclosed	In-house (partnership is planned)	—						—
TRIM4	Novel Regeneration-Inducing peptide for Systemic administration	Not disclosed	In-house (partnership is planned)	—						—
TRIM5	Novel Regeneration-Inducing peptide for Local administration	Not disclosed	In-house (partnership is planned)	—						—
SR-GT1	Stem cell gene therapy	Epidermolysis bullosa	In-house (partnership is planned)	—						Under preparation for clinical trial

Currently, clinical development is progressing for Redasemtide, candidate licensed out to Shionogi & Co., Ltd. The development targets include dystrophic epidermolysis bullosa, acute ischemic stroke, ischemic cardiomyopathy, osteoarthritis of the knee, and chronic liver disease.

In addition, for the next-generation "Regeneration-Inducing Medicine™" candidates TRIM3 and TRIM4, experimental data have been steadily accumulated using various disease model animals, and business development activities aimed at licensing out have continued to progress.

Furthermore, regarding SR-GT1, a stem cell gene therapy aimed at a curative treatment for epidermolysis bullosa, as disclosed on December 6, 2024, the project has been selected for the fiscal year 2024 "Project for Fundamental Technology Development toward Industrialization of Regenerative Medicine and Gene Therapy" conducted by the Japan Agency for Medical Research and Development (AMED).

This research builds upon the manufacturing framework for genetically modified cell products established in the fiscal year 2022 "Practical Research Project for Rare and Intractable Diseases" and incorporates advice received through the Risk-Based Approach (RS) consultation with the Pharmaceuticals and Medical Devices Agency (PMDA). The objective is to swiftly transition to physician-initiated clinical trials by producing investigational drugs with a focus on clinical application. For this research, two-thirds of the expenses incurred can be covered by subsidies from AMED, with a maximum total grant of 179 million yen over three years.

Under these circumstances, for the six months ended January 31, 2025, operating revenue was nothing (operating revenue was nothing in the same period of the previous year), operating loss was 1,066,080 thousand yen (operating loss of 1,033,708 thousand yen in the same period of the previous year), ordinary loss was 1,065,434 thousand yen (ordinary loss of 1,033,753 thousand yen in the same period of the previous year), and net loss was 1,048,742 thousand yen (net loss of 1,005,612 thousand yen in the same period of the previous year).

(2) Explanation of financial position

Assets

Total current assets at the end of the semi-annual period of the fiscal year under review were 8,147,434 thousand yen, a decrease of 730,054 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 748,060 thousand yen in cash and cash deposits. Total non-current assets were 222,136 thousand yen, an increase of 19,210 thousand yen from the end of the previous fiscal year, mainly due to an increase of 41,360 thousand yen in Building. As a result, total assets amounted to 8,369,570 thousand yen, a decrease of 710,844 thousand yen from the end of the previous fiscal year.

Liabilities

Total current liabilities at the end of the semi-annual period of the fiscal year under review were 93,144 thousand yen, an increase of 25,617 thousand yen from the end of the previous fiscal year, mainly due to an increase of 23,502 thousand yen in income taxes payable and an increase of 12,133 thousand yen in advances received. Total non-current liabilities were 118,439 thousand yen, an increase of 86 thousand yen from the end of the previous fiscal year, due to an increase of 86 thousand yen in asset retirement obligations. As a result, total liabilities amounted to 211,584 thousand yen, an increase of 25,703 thousand yen from the end of the previous fiscal year.

Net assets

Total net assets at the end of the semi-annual period of the fiscal year under review were 8,157,985 thousand yen, a decrease of 736,548 thousand yen from the end of the previous fiscal year. This was mainly due to the recording of a net loss for the semi-annual period, an increase in stock acquisition rights, and an increase in capital stock and capital surplus resulting from the issuance of restricted stock compensation to executives.

As a result, capital stock was 116,400 thousand-yen, capital surplus 9,528,475 thousand yen, and retained earnings (2,902,558) thousand yen.

(3) Explanation of cash flows

Cash and cash equivalents at the end of the semi-annual period of the fiscal year under review were 7,662,388 thousand yen, a decrease of 748,060 thousand yen from the end of the previous fiscal year.

Cash flows from operating activities

Net cash used in operating activities was 746,072 thousand yen (outflow of 1,094,238 thousand yen in the same period of the previous fiscal year). This was mainly due to the recording of 1,046,926 thousand yen in net loss before income taxes, the recording of 231,276 thousand yen in stock-based compensation expenses, an increase of 100,454 thousand yen in prepaid expenses, and a decrease of 131,393 thousand yen in consumption taxes receivable.

Cash flows from investing activities

Net cash used in investing activities was 43,238 thousand yen (outflow of 2,386 thousand yen in the same period of the previous fiscal year). This was mainly due to the purchase of property, plant, and equipment amounting to 43,032 thousand yen.

Cash flows from financing activities

Net cash provided by financing activities was 41,250 thousand yen (inflow of 62,800 thousand yen in the same period of the previous fiscal year). This was mainly due to proceeds of 41,250 thousand yen from the issuance of shares.

(4) Financial forecasts for the fiscal year ending July 31, 2025

Most of the Company's current operating revenue comes from milestone revenues associated with the progress of development, and these revenues are highly dependent on the development strategies and schedules of our business partners. Therefore, it is difficult to predict when the Company will receive milestone revenues, and the amount of business revenue for each fiscal year may fluctuate significantly. Hence, the Company has not provided a forecast for the fiscal year ending July 31, 2025.

The Company will continue to research and develop the "Regeneration-Inducing Medicine™" Redasemtide (a peptide medicine created from HMGB1) in the fiscal year ending July 31, 2025. In addition, the Company expects to continue to progress the development of "Regeneration-Inducing Medicine™" candidate that follows Redasemtide for the clinical trials and negotiations for licensing out.

The cash outflow for the fiscal year ending July 31, 2025, is expected to be as follows.

- Forecast cash R&D expenses in the range of 1,200 million yen to 1,600 million yen.
- Forecast cash other selling, general and administrative expenses in the range of 230 million yen to 310 million yen.
- There is a possibility that upfront payments related to new partnerships.
- There is a possibility that milestone payments from existing partners for out-licensed pipelines.

The Company has secured sufficient funds for research and development activities through 2028.

2. Semi-AnnualSemi-Annual Financial Statements and Primary Notes

(1) Semi-AnnualSemi-Annual Balance Sheets

(Thousands of yen)

	As of July 31, 2024	As of January 31, 2025
Assets		
Current assets		
Cash and deposits	8,410,449	7,662,388
Supplies	29,334	23,615
Prepaid expenses	242,326	402,342
Other	195,379	59,087
Total current assets	8,877,489	8,147,434
Non-current assets		
Property, plant, and equipment	185,847	206,394
Intangible assets	2,439	2,045
Investments and other assets	14,638	13,696
Total non-current assets	202,925	222,136
Total assets	9,080,415	8,369,570
Liabilities		
Current liabilities		
Accounts payable-other	35,533	28,061
Accrued expenses	24,365	21,662
Income taxes payable	3,630	27,132
Advances received	—	12,133
Deposits received	3,999	4,153
Total current liabilities	67,527	93,144
Non-current liabilities		
Asset retirement obligations	108,380	108,466
Deferred tax liabilities	9,973	9,973
Total non-current liabilities	118,353	118,439
Total liabilities	185,880	211,584
Net assets		
Shareholders' equity		
Capital stock	10,750	116,400
Capital surplus	9,422,825	9,528,475
Retained earning	(1,853,816)	(2,902,558)
Treasury shares	(118)	(118)
Total shareholders' equity	7,579,640	6,742,198
Stock acquisition rights	1,314,893	1,415,787
Total net assets	8,894,534	8,157,985
Total liabilities and net assets	9,080,415	8,369,570

(2) Semi-AnnualSemi-Annual Statements of Income

For the Six Months Ended January 31, 2025

(Thousands of yen)

	For the six months ended January 31, 2024	For the six months ended January 31, 2025
Operating revenue	—	—
Operating expenses		
Research and development expenses	732,257	739,576
Other selling, general and administrative expenses	301,451	326,504
Total operating expenses	1,033,708	1,066,080
Operating income or loss	(1,033,708)	(1,066,080)
Non-operating income		
Interest and dividend income	0	4
Foreign exchange gains	—	36
Gain on sale of goods	256	20
Refund income	—	579
Other income	—	5
Total non-operating income	256	646
Non-operating expenses		
Interest expenses	1	—
Foreign exchange loss	169	—
Other losses	130	—
Total non-operating expenses	301	—
Ordinary income or loss	(1,033,753)	(1,065,434)
Extraordinary income		
Gain on sale of fixed assets	57	8
Gain on reversal of stock acquisition rights	29,897	18,570
Total extraordinary income	29,955	18,578
Extraordinary loss		
Loss on disposal of fixed assets	—	70
Total extraordinary loss	—	70
Income or Loss before income taxes	(1,003,797)	(1,046,926)
Income taxes - current	1,815	1,815
Total income taxes	1,815	1,815
Net income or loss	(1,005,612)	(1,048,742)

(3) Semi-AnnualSemi-Annual Statements of Cash Flows

(Thousands of yen)

	For the six months ended January 31, 2024	For the six months ended January 31, 2025
Cash flows from operating activities		
Income (loss) before income taxes	(1,003,797)	(1,046,926)
Depreciation	22,105	22,642
Gain(loss)on sale of fixed assets	(57)	(8)
Loss on disposal of fixed assets	—	70
Interest and dividend income	(0)	(4)
Refund income	—	(579)
Interest expenses	1	—
Gain on reversal of share acquisition rights	(29,897)	(18,570)
Share-based compensation expenses	224,196	231,276
Decrease (increase) in supplies	(26,361)	5,718
Decrease (increase) in prepaid expenses	(90,363)	(100,454)
Decrease (increase) in consumption taxes refund receivable	(98,715)	131,393
Increase (decrease) in accounts payable - other	4,220	(7,471)
Increase (decrease) in accrued expenses	1,257	(2,702)
Increase (decrease) in deposits received	(3,592)	154
Increase (decrease) of accrued consumption tax	(117,680)	—
Increase (decrease) in income taxes payable – factor based tax	24,704	25,317
Other	3,374	17,119
Subtotal	(1,090,606)	(743,025)
Interest and dividends received	0	4
Income taxes refund	—	579
Interest expenses paid	(1)	—
Income taxes paid	(3,630)	(3,630)
Net cash provided by (used in) operating activities	(1,094,238)	(746,072)
Cash flows from investing activities		
Purchase of property, plant, and equipment	—	(43,032)
Sale of property, plant, and equipment	58	175
Purchases of intangibles assets	(2,445)	—
Payments for lease and guarantee deposits	—	(381)
Net cash provided by (used in) investing activities	(2,386)	(43,238)
Cash flows from financing activities		
Repayment of lease obligations	(531)	—
Proceeds from issuance of shares	63,332	41,250
Net cash provided by (used in) financing activities	62,800	41,250
Effect of exchange rate change on cash and cash equivalents	—	—
Net increase (decrease) in cash and cash equivalents	(1,033,824)	(748,060)
Cash and cash equivalents at beginning of period	10,217,764	8,410,449
Cash and cash equivalents at end of period	9,183,940	7,662,388

(4) Notes to the Semi-AnnualSemi-Annual Financial Statements

(Notes regarding going concern assumption)

None

(Notes on significant changes in the amount of shareholders' equity)

None

(Segment information, etc.)

[Segment information]

Since the Company is a single segment of the “Regeneration-Inducing Medicine” business, the business results by segment are omitted.