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Consolidated Financial Results for the Three Months Ended April 30, 2025 [Japanese GAAP]



June 13, 2025

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 Stock exchange listing: Tokyo Stock Exchange
 Code number: 4592
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 Scheduled date of commencing dividend payments: —
 Availability of supplementary briefing material on financial results: No
 Schedule of financial results briefing session: No

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

1. Consolidated Financial Results for the Three Months Ended April 30, 2025 (February 1, 2025 to April 30, 2025)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Three months ended April 30, 2025	—	—	(1,007)	—	(1,750)	—	(1,531)	—
April 30, 2024	—	—	(666)	—	91	—	(144)	—

(Note) Comprehensive income: Three months ended April 30, 2025: ¥(880) million [–%]
 Three months ended April 30, 2024: ¥(883) million [–%]

	Net income per share	Diluted net income per share
	Yen	Yen
Three months ended April 30, 2025	(21.38)	—
April 30, 2024	(2.12)	—

(Note) Diluted net income per share is not stated, as net loss per share was recorded although there are potential shares with dilutive effect.

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of April 30, 2025	4,207	1,895	39.8	23.26
As of January 31, 2025	3,447	1,762	45.1	21.93

(Reference) Equity: As of April 30, 2025: ¥1,674 million
 As of January 31, 2025: ¥1,555 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2025	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2026	—				
Fiscal year ending January 31, 2026 (Forecast)		0.00	—	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Consolidated Financial Results Forecast for the Fiscal Year Ending January 31, 2026 (February 1, 2025 to January 31, 2026)

(% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
First half	—	—	(1,911)	—	(1,943)	—	(1,943)	—	(27.05)
Full year	—	—	(3,509)	—	(3,551)	—	(3,554)	—	(49.41)

(Note) Revision to the financial results forecast announced most recently: No

Notes:

- (1) Significant changes in the scope of consolidation during the period under review: No
- (2) Accounting policies adopted specially for the preparation of quarterly consolidated financial statements: No
- (3) Changes in accounting policies, changes in accounting estimates and retrospective restatement
 - 1) Changes in accounting policies due to the revision of accounting standards: Yes
 - 2) Changes in accounting policies other than 1) above: No
 - 3) Changes in accounting estimates: No
 - 4) Retrospective restatement: No(Note) For details, please refer to “2. Quarterly Consolidated Financial Statements and Primary Notes, (3) Notes to the Quarterly Consolidated Financial Statements, (Notes on changes in accounting policies)” on page 8 of the attachment.
- (4) Total number of issued shares (common shares)
 - 1) Total number of issued shares at the end of the period (including treasury shares):
 - April 30, 2025: 72,015,342 shares
 - January 31, 2025: 70,927,202 shares
 - 2) Total number of treasury shares at the end of the period:
 - April 30, 2025: 538 shares
 - January 31, 2025: 518 shares
 - 3) Average number of shares during the period:
 - Three months ended April 30, 2025: 71,648,029 shares
 - Three months ended April 30, 2024: 68,441,619 shares

*Review of the Japanese-language originals of the attached consolidated quarterly financial statements by certified public accountants or an audit firm: No

*** Explanation of the proper use of the financial results forecast and other notes**

The earnings forecasts and other forward-looking statements herein are based on information available to the Company at the time of preparation and certain assumptions deemed to be reasonable, and the Company does not assure the achievement of any of these. Furthermore, actual results may vary significantly due to various factors. For the assumptions and notes for earnings forecasts, please refer to “1. Overview of Operating Results, etc., (3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information” on page 4 of the attachment.

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1. Overview of Operating Results, etc.

(1) Overview of Operating Results for the Period under Review

In the Japanese regenerative medicine industry, amid ongoing promotion of the industry by implementation of the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Act of November 2014, 21 products were approved for manufacture and marketing as regenerative medicine products by the end of April 2025. In addition, in the US, the Regenerative Medicine Advanced Therapy (RMAT) Designation program was established under the 21st Century Cures Act which was passed in December 2016, which enables expedited approval of regenerative medicine products for the purpose of treatment of serious diseases. In 2021, biologics license applications (BLAs) were approved for three products designated as RMAT, including one that received BLA approval as an RMAT-designated product for the first time, and in 2024, four RMAT-designated items received BLA approval. As described above, the practical application of regenerative medicine has continued to make steady progress in Japan and US.

In this environment, the Group (hereinafter referring to two companies: the Company and SanBio, Inc. of Oakland, California, US) has promoted research and development aiming at the commercialization of its unique cell therapeutic agent, SB623, mainly for central nervous system diseases with high unmet medical needs.

For the SB623 development program for treatment of chronic traumatic brain injury (hereinafter the “Program”), in the Phase 2 global clinical trial including Japan and involving 61 patients, the Group obtained positive results in November 2018 that the “patients treated with SB623 cells demonstrated a statistically significant improvement in their motor function compared to the control group, and the primary endpoint was met.” In April 2019, the Program in Japan was chosen as a designated regenerative medical product by the Ministry of Health, Labour and Welfare under the “SAKIGAKE Designation System.” Thereafter, under the designation framework, the Company submitted the application for approval of manufacture and marketing of regenerative medicine products in Japan in March 2022, and in June 2024, the Pharmaceutical Affairs Council’s Subcommittee on Regenerative Medicine Products concluded that approval may be granted, subject to conditions and time limit, to the Program as “AKUUGO® suspension for intracranial implantation; hereinafter ‘AKUUGO®,’” the therapeutic agent for improving chronic motor paralysis resulting from traumatic brain injury. On July 31, the Company received, from the Ministry of Health, Labour and Welfare, the approval of manufacture and marketing of AKUUGO® in Japan with conditions and a time limit attached, of which efficacy/effectiveness is “to improve chronic motor paralysis associated with traumatic brain injury.” Since then, the Company manufactured AKUUGO® for the purpose of obtaining conformity for about two times of commercially available products to confirm the equivalence and homogeneity of the product, one of the conditions for the approval. Twice to date, the manufactured product has met all standard values in specification testing and characteristic analysis, being deemed compliant. Accordingly, the Company has completed filing a partial change application of marketing approval of AKUUGO®. While the judgment depends on the regulatory authorities, the Company continue to expect shipments of AKUUGO® to commence in the second quarter of the fiscal year ending January 31, 2026 (May–July 2025), in line with our previous projections. Going forward, the Company plans to obtain the official approval of the Program by vitalizing the promotion of AKUUGO® in Japan, and in tandem with this initiative, implementing the clinical trial for post manufacture and marketing period and other trials within the seven years of the time limit for approval of manufacture and marketing, the second condition for the approval.

As described above, the Company has been making steady progress toward launching AKUUGO® as a result of its efforts by concentrating its management resources in the domestic business. In these circumstances, the Company will make efforts with a keener awareness of the concept of going back to its original vision, which has been stated as an important pillar of the medium- to long-term growth strategy since the previous fiscal year. Specifically, the Company will promote business activities targeting the two diseases—chronic ischemic stroke and chronic traumatic brain injury in the US market, which has a large number of patients. The Company already restarted to negotiate with regulatory authorities in the US toward implementing new clinical trials for chronic traumatic brain injury based on the results of AKUUGO® in Japan. Also the Company plans to negotiate with regulatory authorities in Japan and the US toward implementing new clinical trials for chronic ischemic stroke.

The Company will go back to its vision of “Globally promoting regenerative medicine originating in Japan,” which has not changed since its foundation, and work on maximizing corporate value in the course of aiming to become a global leader in the field of regenerative medicine.

Under these circumstances, during the three months ended April 30, 2025, the Company recorded ¥723 million in research and development expenses mainly consisting of those related to receiving the approval of partial changes to the items that have been approved for the manufacture and marketing for AKUUGO®. As a result, operating loss was ¥1,007 million (operating loss of ¥666 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥711 million in foreign exchange losses as non-operating expenses, owing to the foreign exchange losses resulting from fluctuations in foreign exchange rates. Furthermore, ordinary loss was ¥1,750 million (ordinary income of ¥91 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,531 million (net loss attributable to owners of parent of ¥144 million for the same period in the previous fiscal year).

The Group consists of a single business segment, cell therapeutic agent using modified allogeneic stem cells. Therefore, description of business performance by segment is omitted.

(2) Overview of Financial Position for the Period under Review

(Current assets)

The balance of current assets at the end of the first quarter of the fiscal year under review was ¥3,997 million, an increase of ¥661 million compared to the end of the previous fiscal year (¥3,335 million), mainly due to an increase of ¥665 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the first quarter of the fiscal year under review was ¥209 million, an increase of ¥98 million compared to the end of the previous fiscal year (¥111 million), mainly due to an increase of ¥100 million in long-term time deposits.

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥560 million, a decrease of ¥171 million compared to the end of the previous fiscal year (¥732 million), mainly due to a decrease of ¥241 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥1,751 million, an increase of ¥799 million compared to the end of the previous fiscal year (¥952 million), mainly due to an increase of ¥1,085 million in convertible bond-type bonds with stock acquisition rights, despite decreases of ¥67 million in long-term loans payable and ¥219 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the first quarter of the fiscal year under review were ¥1,895 million, an increase of ¥132 million compared to the end of the previous fiscal year (¥1,762 million), mainly due to increases of ¥500 million in capital stock and capital surplus respectively resulting from issuance of new shares by third-party allotment and ¥651 million in foreign currency translation adjustment, despite the recording of ¥1,531 million in net loss attributable to owners of parent.

(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information

No revisions have been made to the consolidated financial results forecast for the first half and the full year of the fiscal year under review, as released on March 17, 2025.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2025	As of April 30, 2025
Assets		
Current assets		
Cash and deposits	2,921,402	3,586,412
Advance payments	269,881	317,952
Other	144,296	92,811
Total current assets	3,335,580	3,997,176
Non-current assets		
Property, plant and equipment	40,319	41,211
Intangible assets	43,891	43,891
Investments and other assets	27,547	124,846
Total non-current assets	111,759	209,949
Total assets	3,447,339	4,207,126
Liabilities		
Current liabilities		
Current portion of long-term loans payable	268,000	268,000
Accounts payable - other	139,077	181,314
Accrued expenses	304,830	63,472
Income taxes payable	345	302
Provision for bonuses	9,593	38,357
Other	10,230	9,014
Total current liabilities	732,076	560,462
Non-current liabilities		
Convertible bond-type bonds with stock acquisition rights	—	1,085,400
Long-term loans payable	129,000	62,000
Deferred tax liabilities	823,340	604,246
Total non-current liabilities	952,340	1,751,646
Total liabilities	1,684,417	2,312,108
Net assets		
Shareholders' equity		
Capital stock	2,496,192	2,996,192
Capital surplus	6,207,634	6,707,635
Retained earnings	(698,901)	(2,230,392)
Treasury shares	(1,128)	(1,161)
Total shareholders' equity	8,003,796	7,472,273
Accumulated other comprehensive income		
Foreign currency translation adjustment	(6,448,629)	(5,797,360)
Total accumulated other comprehensive income	(6,448,629)	(5,797,360)
Subscription rights to shares	207,754	220,104
Total net assets	1,762,921	1,895,017
Total liabilities and net assets	3,447,339	4,207,126

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2024	For the three months ended April 30, 2025
Operating revenue	—	—
Operating expenses		
Research and development expenses	387,101	723,135
Other selling, general and administrative expenses	279,482	284,212
Total operating expenses	666,583	1,007,347
Operating loss	(666,583)	(1,007,347)
Non-operating income		
Interest income	532	601
Foreign exchange gains	767,299	—
Other	47	32
Total non-operating income	767,880	634
Non-operating expenses		
Interest expenses	2,096	1,893
Interest expenses on bonds	—	5,400
Foreign exchange losses	—	711,987
Financing expenses	3,156	934
Share issuance costs	4,821	23,353
Total non-operating expenses	10,074	743,569
Ordinary profit (loss)	91,222	(1,750,282)
Profit (loss) before income taxes	91,222	(1,750,282)
Income taxes - current	292	302
Income taxes - deferred	235,780	(219,094)
Total income taxes	236,072	(218,791)
Net loss	(144,850)	(1,531,490)
Net loss attributable to owners of parent	(144,850)	(1,531,490)

Quarterly Consolidated Statements of Comprehensive Income
For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2024	For the three months ended April 30, 2025
Net loss	(144,850)	(1,531,490)
Other comprehensive income		
Foreign currency translation adjustment	(738,554)	651,269
Total other comprehensive income	(738,554)	651,269
Comprehensive income	(883,405)	(880,221)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(883,405)	(880,221)
Comprehensive income attributable to non-controlling interests	—	—

(3) Notes to the Quarterly Consolidated Financial Statements

(Notes on changes in accounting policies)

(Application of “Accounting Standard for Current Income Taxes,” etc.)

The Company has applied the “Accounting Standard for Current Income Taxes” (Accounting Standards Board of Japan (“ASBJ”) Statement No. 27, October 28, 2022; hereinafter referred to as the “Revised Accounting Standard 2022”), etc. from the beginning of the first quarter ended April 30, 2025.

Revisions concerning the categories in which current income taxes should be recorded (taxes on other comprehensive income) are subject to the transitional treatment set forth in the proviso of Paragraph 20-3 of the Revised Accounting Standard 2022 and the transitional treatment set forth in the proviso of Paragraph 65-2 (2) of the “Guidance on Accounting Standard for Tax Effect Accounting” (ASBJ Guidance No. 28, October 28, 2022; hereinafter referred to as the “Revised Guidance 2022”). The change in accounting policies has no impact on the quarterly consolidated financial statements.

With regard to revisions related to changes in the accounting treatment for consolidated financial statements when gains or losses on sale of shares in subsidiaries resulting from transactions between consolidated companies are deferred for tax purposes, the Company has applied the Revised Guidance 2022 from the beginning of the first quarter ended April 30, 2025. The change in accounting policies was applied retrospectively and the quarterly consolidated financial statements for the same quarter of the previous fiscal year and the consolidated financial statements for the previous fiscal year have been modified retrospectively. This change in the accounting policies has no impact on the quarterly consolidated financial statements for the same quarter of the previous fiscal year and the consolidated financial statements for the previous fiscal year.

(Notes on segment information, etc.)

<Segment information>

I For the three months ended April 30, 2024 (from February 1, 2024 to April 30, 2024)

Segment information is omitted as the Group consists of a single business segment, cell therapeutic agent using modified allogeneic stem cells.

II For the three months ended April 30, 2025 (from February 1, 2025 to April 30, 2025)

Segment information is omitted as the Group consists of a single business segment, cell therapeutic agent using modified allogeneic stem cells.

(Notes in the event of significant changes in shareholders' equity)

I For the three months ended April 30, 2024 (from February 1, 2024 to April 30, 2024)

During the three months ended April 30, 2024, the Company received a payment for the issuance of new shares accompanying the exercise of the 34th Share Acquisition Rights (share acquisition rights with exercise price amendment clause by third-party allotment) issued on November 15, 2022, and capital stock and capital reserves each increased by ¥244,755 thousand. In addition, capital stock and capital reserves each increased by ¥777 thousand due to the exercise of share acquisition rights as stock options.

As a result, at the end of the first quarter of the fiscal year ended January 31, 2025, capital stock and capital surplus were ¥3,562,037 thousand and ¥7,273,479 thousand, respectively.

II For the three months ended April 30, 2025 (from February 1, 2025 to April 30, 2025)

During the three months ended April 30, 2025, the Company received a payment for the third-party allotment from CVI Investments, Inc. with March 3, 2025 as the date of payment, and capital stock and capital reserves each increased by ¥500,000 thousand.

As a result, at the end of the first quarter of the fiscal year ending January 31, 2026, capital stock and capital surplus were ¥2,996,192 thousand and ¥6,707,635 thousand, respectively.

(Notes on going concern assumption)

None

(Notes to quarterly consolidated statements of cash flows)

Quarterly consolidated statements of cash flows for the three months ended April 30, 2025 are not prepared. Depreciation for the three months ended April 30, which includes amortization of intangible assets, is as follows:

	For the three months ended April 30, 2024	For the three months ended April 30, 2025
Depreciation	2,442	1,900

(Notes on significant subsequent events)

(Conclusion of a commitment line agreement)

The Company has entered into a commitment line agreement with Mizuho Bank, Ltd., as described below, to fund expenses related to the establishment of manufacturing, logistics, and sales infrastructure for AKUUGO® to be incurred after receiving the approval of partial changes to the items that have been approved for the manufacture and marketing for AKUUGO®.

(i) Form of funding	Commitment line
(ii) Total commitment	¥1.0 billion
(iii) Date of the agreement	June 2025
(iv) Term of the agreement	Until November 2026
(v) Use of funds	Expenses related to the establishment of manufacturing, logistics, and sales infrastructure for AKUUGO®