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Consolidated Financial Results for the Nine Months Ended October 31, 2025 [Japanese GAAP]

December 15, 2025

Company name: SanBio Company Limited
Stock exchange listing: Tokyo Stock Exchange
Code number: 4592
URL: https://www.sanbio.com/
Representative: Keita Mori, Representative Director and President
Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
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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 Nine Months Ended October 31, 2025 (February 1, 2025 to October 31, 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	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
October 31, 2025	–	–	(2,673)	–	(3,159)	–	(2,713)	–
October 31, 2024	–	–	(2,482)	–	(1,999)	–	(2,152)	–

(Note) Comprehensive income: Nine months ended October 31, 2025: ¥(2,307) million [–%]
Nine months ended October 31, 2024: ¥(2,675) million [–%]

	Net income per share	Diluted net income per share
Nine months ended	Yen	Yen
October 31, 2025	(37.75)	–
October 31, 2024	(31.39)	–

(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 October 31, 2025	2,406	492	11.3	3.78
As of January 31, 2025	3,447	1,762	45.1	21.93

(Reference) Equity: As of October 31 2025: ¥272 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
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended January 31, 2025	–	0.00	–	0.00	0.00
Fiscal year ending January 31, 2026	–	0.00	–		
Fiscal year ending January 31, 2026 (Forecast)			–	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
Full year	–	–	(3,920)	–	(4,530)	–	(4,045)	–	(56.17)

(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):
October 31, 2025: 72,028,331 shares
January 31, 2025: 70,927,202 shares

2) Total number of treasury shares at the end of the period:
October 31, 2025: 538 shares
January 31, 2025: 518 shares

3) Average number of shares during the period:
Nine months ended October 31, 2025: 71,900,457 shares
Nine months ended October 31, 2024: 68,568,452 shares

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

<u>* Explanation of the proper use of the financial results forecast and other notes</u>

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, 23 products were approved for manufacture and marketing as regenerative medicine products by the end of October 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 2025, one RMAT-designated item 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 July 2024, as "AKUUGO® suspension for intracranial implantation; hereinafter 'AKUUGO®'," the therapeutic agent for improving chronic motor paralysis resulting from traumatic brain injury, the Program received conditional and time-limited approval of manufacture and marketing of AKUUGO® in Japan. Since then, the Company manufactured AKUUGO® to obtain conformity of commercially available products to confirm the equivalence and homogeneity which are among the conditions for the approval. As a result, the manufactured product has met all standard values twice in specification testing and characteristic analysis, being deemed compliant.

Following these results, in June 2025, the Company completed filing a partial change application of marketing approval of AKUUGO®. In October 2025, at the Pharmaceutical Affairs Council's Subcommittee on Regenerative Medicine Products and Biological Technologies under the Ministry of Health, Labour and Welfare (MHLW), the proposal titled "Partial change to the marketing approval and revision of the approval conditions for the regenerative medicine product AKUUGO® suspension for intracranial implantation" was reviewed, and it was concluded that the change and revision would be accepted.

Accordingly, in December 2025, the MHLW approved the partial change to the marketing approval and revised the associated approval conditions. Going forward, after the NHI price listing, the Company plans to launch AKUUGO®. The Company also 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® in Japan. Going forward, in line with its medium- to long-term growth strategy, the Company will advance business activities targeting traumatic brain injury in the US market. The Company has already obtained consent from the U.S. Food and Drug Administration (FDA) for the Phase 3 clinical trial design for its traumatic brain injury program and plans to proceed with preparations for the clinical trial in the next fiscal year. In Japan, the Company also plans to initiate discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) regarding clinical trials for its

ischemic stroke program in the next fiscal year. The Company will work on maximizing corporate value, aiming to become a global leader in the field of regenerative medicine.

Under these circumstances, during the nine months ended October 31, 2025, the Company recorded ¥1,920 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 ¥2,673 million (operating loss of ¥2,482 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥395 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 ¥3,159 million (ordinary loss of ¥1,999 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥2,713 million (net loss attributable to owners of parent of ¥2,152 million for the same period in the previous fiscal year). Up to today, the Company has entered into committed credit line agreements with banks and raised funds through the issuance of new shares and convertible bonds. Going forward, the Company aims to maintain sound financial health by securing financing at appropriate times through the most suitable methods.

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 third quarter of the fiscal year under review was ¥ 2,301 million, a decrease of ¥1,034 million compared to the end of the previous fiscal year (¥3,335 million), mainly due to a decrease of ¥1,015 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the third quarter of the fiscal year under review was ¥104 million, a decrease of ¥7 million compared to the end of the previous fiscal year (¥111 million).

(Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥435 million, a decrease of ¥296 million compared to the end of the previous fiscal year (¥732 million), mainly due to a decrease of ¥289 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥1,478 million, an increase of ¥525 million compared to the end of the previous fiscal year (¥952 million), mainly due to an increase of ¥1,101 million in convertible bond-type bonds with stock acquisition rights, despite decreases of ¥129 million in long-term loans payable and ¥446 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥ 492 million, a decrease of ¥1,270 million compared to the end of the previous fiscal year (¥1,762 million), mainly due to the recording of ¥2,713 million in net loss attributable to owners of parent, despite increases of ¥512 million in capital stock and capital surplus respectively resulting from issuance of new shares by third-party allotment and exercise of subscription rights to shares, and an increase of ¥405 million in foreign currency translation adjustment.

(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 full year of the fiscal year under review, as released on September 12, 2025.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2025	As of October 31, 2025
Assets		
Current assets		
Cash and deposits	2,921,402	1,905,912
Advance payments	269,881	265,841
Other	144,296	129,790
Total current assets	3,335,580	2,301,544
Non-current assets		
Property, plant and equipment	40,319	39,636
Intangible assets	43,891	43,891
Investments and other assets	27,547	21,131
Total non-current assets	111,759	104,659
Total assets	3,447,339	2,406,203
Liabilities		
Current liabilities		
Current portion of long-term loans payable	268,000	196,000
Accounts payable - other	139,077	124,643
Accrued expenses	304,830	15,122
Income taxes payable	345	907
Provision for bonuses	9,593	87,698
Other	10,230	11,426
Total current liabilities	732,076	435,798
Non-current liabilities		
Convertible bond-type bonds with stock acquisition rights	–	1,101,600
Long-term loans payable	129,000	–
Deferred tax liabilities	823,340	376,618
Total non-current liabilities	952,340	1,478,218
Total liabilities	1,684,417	1,914,016
Net assets		
Shareholders' equity		
Capital stock	2,496,192	1,236,068
Capital surplus	6,207,634	4,947,511
Retained earnings	(698,901)	132,822
Treasury shares	(1,128)	(1,161)
Total shareholders' equity	8,003,796	6,315,241
Accumulated other comprehensive income		
Foreign currency translation adjustment	(6,448,629)	(6,042,700)
Total accumulated other comprehensive income	(6,448,629)	(6,042,700)
Subscription rights to shares	207,754	219,646
Total net assets	1,762,921	492,187
Total liabilities and net assets	3,447,339	2,406,203

(2) Quarterly Consolidated Statements of Income and Comprehensive Income

Quarterly Consolidated Statements of Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2024	For the nine months ended October 31, 2025
Operating revenue	–	–
Operating expenses		
Research and development expenses	1,666,389	1,920,108
Other selling, general and administrative expenses	816,548	753,861
Total operating expenses	2,482,938	2,673,969
Operating loss	(2,482,938)	(2,673,969)
Non-operating income		
Interest income	1,662	2,215
Foreign exchange gains	499,993	–
Other	2,311	78
Total non-operating income	503,967	2,294
Non-operating expenses		
Interest expenses	6,384	4,839
Interest expenses on bonds	–	21,600
Foreign exchange losses	–	395,787
Financing expenses	9,608	39,921
Share issuance costs	4,821	23,929
Other	–	1,800
Total non-operating expenses	20,814	487,877
Ordinary loss	(1,999,784)	(3,159,552)
Extraordinary income		
Gain on sale of non-current assets	2,424	–
Total extraordinary income	2,424	–
Loss before income taxes	(1,997,359)	(3,159,552)
Income taxes - current	1,087	1,059
Income taxes - deferred	153,922	(446,722)
Total income taxes	155,010	(445,663)
Net loss	(2,152,369)	(2,713,889)
Net loss attributable to owners of parent	(2,152,369)	(2,713,889)

Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2024	For the nine months ended October 31, 2025
Net loss	(2,152,369)	(2,713,889)
Other comprehensive income		
Foreign currency translation adjustment	(523,419)	405,929
Total other comprehensive income	(523,419)	405,929
Comprehensive income	(2,675,789)	(2,307,960)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(2,675,789)	(2,307,960)
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 nine months ended October 31, 2024 (from February 1, 2024 to October 31, 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 nine months ended October 31, 2025 (from February 1, 2025 to October 31, 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 nine months ended October 31, 2024 (from February 1, 2024 to October 31, 2024)

During the nine months ended October 31, 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 ¥1,963 thousand due to the exercise of share acquisition rights as stock options.

Capital stock and capital surplus each decreased by ¥2,066,993 thousand and retained earnings increased by ¥4,133,986 thousand as a result of covering the deficit in retained earnings brought forward as of June 6, 2024 based on the resolution of the 11th Annual General Meeting of Shareholders held on April 24, 2024.

As a result, at the end of the third quarter of the fiscal year ended January 31, 2025, capital stock, capital surplus, and retained earnings were ¥1,496,228 thousand, ¥5,207,671 thousand, and ¥31,613 thousand, respectively.

II For the nine months ended October 31, 2025 (from February 1, 2025 to October 31, 2025)

During the nine months ended October 31, 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. In addition, capital stock and capital reserves each increased by ¥12,683 thousand due to the exercise of share acquisition rights as stock options.

Capital stock and capital surplus each decreased by ¥1,772,807 thousand and retained earnings increased by ¥3,545,614 thousand as a result of covering the deficit in retained earnings brought forward as of June 6, 2025 based on the resolution of the 12th Annual General Meeting of Shareholders held on April 23, 2025.

As a result, at the end of the third quarter of the fiscal year ending January 31, 2026, capital stock, capital surplus, and retained earnings were ¥1,236,068 thousand, ¥4,947,511 thousand, and ¥132,822 thousand, respectively.

(Notes on going concern assumption)

None

(Notes to quarterly consolidated statements of cash flows)

Quarterly consolidated statements of cash flows for the nine months ended October 31, 2025 are not prepared. Depreciation for the nine months ended October 31, which includes amortization of intangible assets, is as follows:

(Thousand yen)

	For the nine months ended October 31, 2024	For the nine months ended October 31 2025
Depreciation	7,428	5,770

(Notes on significant subsequent events)

(Issuance of new shares through an international offering)

At the Board of Directors' meeting held on November 6, 2025, the Company passed a resolution for issuance of new shares through an international offering, as described below, and its payment was completed on November 21, 2025.

(1) Class and number of shares offered	6,000,000 shares of common stock
(2) Issue price	2,487 yen per share
(3) Total amount of issue price	14,922,000,000 yen
(4) Amount paid in	2,377.64 yen per share
(5) Total amount paid in	14,265,840,000 yen
(6) Amount of capital stock and capital reserves increased	Amount of increase in capital stock: 7,132,920,000 yen Amount of increase in capital reserves: 7,132,920,000 yen
(7) Payment date	November 21, 2025
(8) Method of offering	International offering in overseas markets, mainly in Europe and Asia (excluding the United States and Canada).
(9) Use of funds	(i) Establishment of the promotion structure of AKUUGO® in Japan—preparation and implementation of post-marketing clinical trials and their data analysis, as well as the establishment of mechanisms and structure to ensure the safe and appropriate use of AKUUGO®
	(ii) Costs pertaining to clinical trials for the SB623 traumatic brain injury program in the US market
	(iii) Costs pertaining to clinical trials for the SB623 ischemic stroke program in Japan