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Consolidated Financial Results for the Six Months Ended July 31, 2025 [Japanese GAAP]



September 12, 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
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 Scheduled date of filing semi-annual securities report: September 12, 2025
 Scheduled date of commencing dividend payments: —
 Availability of supplementary briefing material on financial results: No
 Schedule of financial results briefing session: Yes (for institutional investors and analysts)

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

1. Consolidated Financial Results for the Six Months Ended July 31, 2025 (February 1, 2025 to July 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 | |
|--------------------------------|-------------------|---|------------------|---|-----------------|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % |
| Six months ended July 31, 2025 | — | — | (1,888) | — | (2,481) | — | (1,997) | — |
| July 31, 2024 | — | — | (1,571) | — | (1,186) | — | (1,309) | — |

(Note) Comprehensive income: Six months ended July 31, 2025: ¥(1,501) million [—%]

Six months ended July 31, 2024: ¥(1,715) million [—%]

| | Net income per share | Diluted net income per share |
|--------------------------------|----------------------|------------------------------|
| | Yen | Yen |
| Six months ended July 31, 2025 | (27.80) | — |
| July 31, 2024 | (19.10) | — |

(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 July 31, 2025 | 3,219 | 1,294 | 33.5 | 14.97 |
| As of January 31, 2025 | 3,447 | 1,762 | 45.1 | 21.93 |

(Reference) Equity: As of July 31, 2025: ¥1,078 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 | — | 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: Yes

Notes:

- (1) Significant changes in the scope of consolidation during the period under review: No
- (2) Accounting policies adopted specially for the preparation of semi-annual 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. Semi-annual Consolidated Financial Statements and Primary Notes, (4) Notes to the Semi-annual Consolidated Financial Statements, (Notes on changes in accounting policies)” on page 10 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):
 - July 31, 2025: 72,027,931 shares
 - January 31, 2025: 70,927,202 shares
 - 2) Total number of treasury shares at the end of the period:
 - July 31, 2025: 538 shares
 - January 31, 2025: 518 shares
 - 3) Average number of shares during the period:
 - Six months ended July 31, 2025: 71,835,733 shares
 - Six months ended July 31, 2024: 68,536,829 shares

* These semi-annual financial results are outside the scope of review by a certified public accountant or an audit corporation.

*** 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 5 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 July 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 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 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® 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 already, the manufactured product has met all standard values in specification testing and characteristic analysis, being deemed compliant. Accordingly, in June 2025, the Company has completed filing a partial change application of marketing approval of AKUUGO®. The application will be reviewed by the regulatory authorities and the committee, with approval expected in the second half of the fiscal year ending January 2026 (August 2025–January 2026). 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 six months ended July 31, 2025, the Company recorded ¥1,346 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 ¥1,888 million (operating loss of ¥1,571 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥518 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 ¥2,481 million (ordinary loss of ¥1,186 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,997 million (net loss attributable to owners of parent of ¥1,309 million for the same period in the previous fiscal year). During the six months ended July 31, 2025, the Company 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

1) Assets, liabilities and net assets

(Current assets)

The balance of current assets at the end of the semi-annual period of the fiscal year under review was ¥3,111 million, a decrease of ¥223 million compared to the end of the previous fiscal year (¥3,335 million), mainly due to a decrease of ¥183 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the semi-annual period of the fiscal year under review was ¥107 million, a decrease of ¥4 million compared to the end of the previous fiscal year (¥111 million).

(Current liabilities)

The balance of current liabilities at the end of semi-annual period of the fiscal year under review was ¥493 million, a decrease of ¥238 million compared to the end of the previous fiscal year (¥732 million), mainly due to a decrease of ¥274 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of semi-annual period of the fiscal year under review was ¥1,431 million, an increase of ¥479 million compared to the end of the previous fiscal year (¥952 million), mainly due to an increase of ¥1,093 million in convertible bonds with stock acquisition rights, despite decreases of ¥129 million in long-term loans payable and ¥485 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of semi-annual period of the fiscal year under review were ¥1,294 million, a decrease of ¥468 million compared to the end of the previous fiscal year (¥1,762 million), mainly due to the recording of ¥1,997 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 ¥495 million in foreign currency translation adjustment.

2) Cash flows

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the semi-annual period of the fiscal year under review were ¥2,372 million, a decrease of ¥480 million compared to the end of the previous fiscal year (¥2,853 million). Cash flows in each area of activity and their respective contributing factors are as follows.

(Cash flows from operating activities)

Net cash used in operating activities for the six months ended July 31, 2025 was ¥2,052 million (an outflow of ¥1,703 million for the same period in the previous fiscal year). This was primarily due to the recording of a loss before income taxes of ¥2,481 million, foreign exchange losses of ¥521 million, and a decrease of ¥264 million in accrued expenses.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2025 was ¥301 million (an outflow of ¥3 million for the same period in the previous fiscal year). This was primarily due to an outflow of ¥400 million for payments into time deposits and an inflow of ¥100 million from proceeds from withdrawal of time deposits.

(Cash flows from financing activities)

Net cash provided by financing activities for the six months ended July 31, 2025 was ¥1,895 million (an inflow of ¥340 million for the same period in the previous fiscal year). This was primarily due to an outflow of ¥134 million for repayments of long-term loans payable, an inflow of ¥1,080 million from proceeds from issuance of convertible bonds with stock acquisition rights, and an inflow of ¥ 975 million from proceeds from issuance of shares.

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

With regard to the consolidated financial results forecast for the fiscal year ending January 31, 2026, the forecast figures announced on March 17, 2025 have been revised. For details, please refer to "Revision of Consolidated Earnings Forecast for the Fiscal Year Ending January 2026" released today.

2. Semi-annual Consolidated Financial Statements and Primary Notes

(1) Semi-annual Consolidated Balance Sheets

(Thousand yen)

| | As of January 31, 2025 | As of July 31, 2025 |
|---|------------------------|---------------------|
| Assets | | |
| Current assets | | |
| Cash and deposits | 2,921,402 | 2,738,369 |
| Advance payments | 269,881 | 263,158 |
| Other | 144,296 | 110,178 |
| Total current assets | 3,335,580 | 3,111,706 |
| Non-current assets | | |
| Property, plant and equipment | 40,319 | 40,553 |
| Intangible assets | 43,891 | 43,891 |
| Investments and other assets | 27,547 | 23,097 |
| Total non-current assets | 111,759 | 107,542 |
| Total assets | 3,447,339 | 3,219,248 |
| Liabilities | | |
| Current liabilities | | |
| Current portion of long-term loans payable | 268,000 | 263,000 |
| Accounts payable - other | 139,077 | 131,483 |
| Accrued expenses | 304,830 | 30,812 |
| Income taxes payable | 345 | 605 |
| Provision for bonuses | 9,593 | 59,732 |
| Other | 10,230 | 8,076 |
| Total current liabilities | 732,076 | 493,708 |
| Non-current liabilities | | |
| Convertible bond-type bonds with stock acquisition rights | – | 1,093,500 |
| Long-term loans payable | 129,000 | – |
| Deferred tax liabilities | 823,340 | 337,866 |
| Total non-current liabilities | 952,340 | 1,431,366 |
| Total liabilities | 1,684,417 | 1,925,075 |
| Net assets | | |
| Shareholders' equity | | |
| Capital stock | 2,496,192 | 1,235,760 |
| Capital surplus | 6,207,634 | 4,947,202 |
| Retained earnings | (698,901) | 849,467 |
| Treasury shares | (1,128) | (1,161) |
| Total shareholders' equity | 8,003,796 | 7,031,269 |
| Accumulated other comprehensive income | | |
| Foreign currency translation adjustment | (6,448,629) | (5,952,916) |
| Total accumulated other comprehensive income | (6,448,629) | (5,952,916) |
| Subscription rights to shares | 207,754 | 215,820 |
| Total net assets | 1,762,921 | 1,294,173 |
| Total liabilities and net assets | 3,447,339 | 3,219,248 |

(2) Semi-annual Consolidated Statements of Income and Comprehensive Income

Semi-annual Consolidated Statements of Income

(Thousand yen)

| | For the six months ended July 31, 2024 | For the six months ended July 31, 2025 |
|--|---|---|
| Operating revenue | – | – |
| Operating expenses | | |
| Research and development expenses | 1,024,418 | 1,346,768 |
| Other selling, general and administrative expenses | 547,505 | 541,354 |
| Total operating expenses | 1,571,923 | 1,888,122 |
| Operating loss | (1,571,923) | (1,888,122) |
| Non-operating income | | |
| Interest income | 1,036 | 1,644 |
| Foreign exchange gains | 397,932 | – |
| Other | 2,349 | 78 |
| Total non-operating income | 401,318 | 1,723 |
| Non-operating expenses | | |
| Interest expenses | 4,299 | 3,540 |
| Interest expenses on bonds | – | 13,500 |
| Foreign exchange losses | – | 518,514 |
| Financing expenses | 6,382 | 34,300 |
| Share issuance costs | 4,821 | 23,929 |
| Other | – | 1,800 |
| Total non-operating expenses | 15,502 | 595,585 |
| Ordinary loss | (1,186,107) | (2,481,984) |
| Loss before income taxes | (1,186,107) | (2,481,984) |
| Income taxes - current | 788 | 734 |
| Income taxes - deferred | 122,230 | (485,474) |
| Total income taxes | 123,019 | (484,739) |
| Net loss | (1,309,126) | (1,997,245) |
| Net loss attributable to owners of parent | (1,309,126) | (1,997,245) |

Semi-annual Consolidated Statements of Comprehensive Income

(Thousand yen)

| | For the six months ended July 31, 2024 | For the six months ended July 31, 2025 |
|--|---|---|
| Net loss | (1,309,126) | (1,997,245) |
| Other comprehensive income | | |
| Foreign currency translation adjustment | (406,629) | 495,713 |
| Total other comprehensive income | (406,629) | 495,713 |
| Comprehensive income | (1,715,756) | (1,501,531) |
| Comprehensive income attributable to: | | |
| Comprehensive income attributable to owners of parent | (1,715,756) | (1,501,531) |
| Comprehensive income attributable to non-controlling interests | — | — |

(3) Semi-annual Consolidated Statements of Cash Flows

(Thousand yen)

| | For the six months ended July 31, 2024 | For the six months ended July 31, 2025 |
|---|---|---|
| Cash flows from operating activities | | |
| Loss before income taxes | (1,186,107) | (2,481,984) |
| Depreciation | 4,943 | 3,832 |
| Share based compensation expenses | 9,704 | 17,621 |
| Increase (decrease) in provision for bonuses | 46,719 | 50,138 |
| Interest and dividend income | (1,036) | (1,644) |
| Foreign exchange losses (gains) | (399,123) | 521,439 |
| Interest expenses | 4,299 | 3,540 |
| Interest expenses on bonds | – | 13,500 |
| Financing expenses | 6,382 | 34,300 |
| Share issuance costs | 4,821 | 23,929 |
| Decrease (increase) in advance payments | 86,068 | (2,050) |
| Increase (decrease) in accounts payable - other | 85,896 | (6,583) |
| Increase (decrease) in accrued expenses | (388,351) | (264,935) |
| Other | 36,114 | 34,121 |
| Subtotal | (1,689,669) | (2,054,773) |
| Interest and dividends received | 1,036 | 1,390 |
| Interest expenses paid | (4,299) | (3,544) |
| Income taxes paid | (10,879) | (474) |
| Income taxes refund | – | 4,737 |
| Net cash provided by (used in) operating activities | (1,703,812) | (2,052,664) |
| Cash flows from investing activities | | |
| Payments into time deposits | – | (400,000) |
| Proceeds from withdrawal of time deposits | – | 100,000 |
| Purchase of property, plant and equipment | (3,555) | (2,530) |
| Proceeds from sale of property, plant and equipment | – | 1,020 |
| Payments of leasehold deposits | (200) | (20) |
| Net cash provided by (used in) investing activities | (3,755) | (301,529) |
| Cash flows from financing activities | | |
| Repayments of long-term loans payable | (134,000) | (134,000) |
| Payments of financing expenses | (6,390) | (41,030) |
| Proceeds from issuance of convertible bond-type bonds with stock acquisition rights | – | 1,080,000 |
| Proceeds from issuance of shares | – | 975,819 |
| Proceeds from issuance of shares resulting from exercise of subscription rights to shares | 480,980 | 15,193 |
| Other | (147) | (32) |
| Net cash provided by (used in) financing activities | 340,441 | 1,895,950 |
| Effect of exchange rate change on cash and cash equivalents | (8,052) | (22,572) |
| Net increase (decrease) in cash and cash equivalents | (1,375,178) | (480,816) |
| Cash and cash equivalents at beginning of period | 4,389,520 | 2,853,132 |
| Cash and cash equivalents at end of period | 3,014,341 | 2,372,315 |

(4) Notes to the Semi-annual 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 semi-annual period ended July 31, 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 semi-annual 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 semi-annual period ended July 31, 2025. The change in accounting policies was applied retrospectively and the semi-annual consolidated financial statements for the semi-annual period 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 semi-annual consolidated financial statements for the semi-annual period 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 six months ended July 31, 2024 (from February 1, 2024 to July 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 six months ended July 31, 2025 (from February 1, 2025 to July 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 six months ended July 31, 2024 (from February 1, 2024 to July 31, 2024)

During the six months ended July 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 ¥1,329 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 semi-annual period of the fiscal year ended January 31, 2025, capital stock, capital surplus, and retained earnings were ¥1,495,595 thousand, ¥5,207,038 thousand, and ¥874,857 thousand, respectively.

II For the six months ended July 31, 2025 (from February 1, 2025 to July 31, 2025)

During the six months ended July 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 ¥12,375 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 semi-annual period of the fiscal year ending January 31, 2026, capital stock, capital surplus, and retained earnings were ¥1,235,760 thousand, ¥4,947,202 thousand, and ¥859,052 thousand, respectively.

(Notes on going concern assumption)

None