

**Consolidated Financial Results**  
**for the Nine Months Ended October 31, 2024**  
**[Japanese GAAP]**



December 16, 2024

Company name: SanBio Company Limited  
 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 Nine Months Ended October 31, 2024 (February 1, 2024 to October 31, 2024)**

(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                                 | % |
| Nine months ended October 31, 2024 | —                 | — | (2,482)          | — | (1,999)         | — | (2,152)                                     | — |
| October 31, 2023                   | —                 | — | (3,725)          | — | (1,837)         | — | (1,883)                                     | — |

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

Nine months ended October 31, 2023: ¥(3,502) million [-%]

|                                    | Net income per share |  | Diluted net income per share |  |
|------------------------------------|----------------------|--|------------------------------|--|
|                                    | Yen                  |  | Yen                          |  |
| Nine months ended October 31, 2024 | (31.39)              |  | —                            |  |
| October 31, 2023                   | (28.99)              |  | —                            |  |

(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, 2024 | 2,562        |  | 616         |  | 15.8         |  | 5.89                 |  |
| As of January 31, 2024 | 5,047        |  | 2,792       |  | 51.3         |  | 38.08                |  |

(Reference) Equity: As of October 31, 2024: ¥404 million

As of January 31, 2024: ¥2,586 million

## 2. Dividends

|  | Annual dividends |                 |                 |             |             |
|--|------------------|-----------------|-----------------|-------------|-------------|
|  | 1st quarter-end  | 2nd quarter-end | 3rd quarter-end | Year-end    | Total       |
| Fiscal year ended January 31, 2024             | Yen<br>—         | Yen<br>0.00     | Yen<br>—        | Yen<br>0.00 | Yen<br>0.00 |
| Fiscal year ending January 31, 2025            | —                | 0.00            | —               |             |             |
| Fiscal year ending January 31, 2025 (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, 2025 (February 1, 2024 to January 31, 2025)

(% 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 | —                 | — | (3,339)          | — | (3,359)         | — | (3,359)                                     | — | (49.45)              |

(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: No
  - 2) Changes in accounting policies other than 1) above: No
  - 3) Changes in accounting estimates: No
  - 4) Retrospective restatement: No
- (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, 2024: 68,631,602 shares
    - January 31, 2024: 67,929,202 shares
  - 2) Total number of treasury shares at the end of the period:
    - October 31, 2024: 518 shares
    - January 31, 2024: 278 shares
  - 3) Average number of shares during the period:
    - Nine months ended October 31, 2024: 68,568,452 shares
    - Nine months ended October 31, 2023: 64,949,133 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 November 2024. 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, three 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.” Since the designation, under the framework of the SAKIGAKE Designation System, the Company has negotiated with the Pharmaceuticals and Medical Devices Agency (PMDA), completed the SAKIGAKE comprehensive evaluation consultation in January 2022, and submitted the application for approval of manufacture and marketing of regenerative medicine products in Japan in March 2022. Thereafter, 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.” Although the Company assumed that it would confirm the equivalence and homogeneity of AKUUGO®, one of the conditions for the approval, by implementing manufacturing of commercially available products about two times, the results of the first production run did not meet the specification standards. However, while one specification value was non-compliant, all other specification values were compliant. The results of the characteristic analysis were also equivalent to those of the clinical trials product. Furthermore, the yield results of the subsequent second production run have been confirmed with the expected yield obtained. If all standards are met in specification tests and characteristic analysis, the second production run will be deemed compliant with the required specifications. It will take several months to obtain the results of the specification tests and characteristic analysis. As a result, the expected timeline for the Company to begin the shipment of AKUUGO® has been delayed by a quarter, from the initial timeline of the first quarter of the fiscal year ending January 31, 2026 (February 2025 to April 2025) to the second quarter of the same fiscal year (May 2025 to July 2025). 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.

Moreover, there have been no changes in the Company’s policy, where the Company will go back to its vision of “Globally promoting regenerative medicine originating in Japan,” which has not changed since its foundation, and proceed again with its global business. The Company will focus on the US, which will be the

largest market, and plans to negotiate with regulatory authorities in Japan and the US toward implementing new clinical trials for chronic ischemic stroke and other diseases based on the results of AKUUGO® in Japan.

Under these circumstances, during the nine months ended October 31, 2024, the Company recorded ¥1,666 million in research and development expenses mainly consisting of manufacturing-related costs incurred to obtain approval with respect to the SB623 development program for treatment of chronic traumatic brain injury. As a result, operating loss was ¥2,482 million (operating loss of ¥3,725 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥499 million in foreign exchange gains as non-operating income, owing to the foreign exchange gains resulting from fluctuations in foreign exchange rates. Furthermore, ordinary loss was ¥1,999 million (ordinary loss of ¥1,837 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥2,152 million (net loss attributable to owners of parent of ¥1,883 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 third quarter of the fiscal year under review was ¥2,447 million, a decrease of ¥2,490 million compared to the end of the previous fiscal year (¥4,937 million), mainly due to a decrease of ¥2,416 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 ¥115 million, an increase of ¥5 million compared to the end of the previous fiscal year (¥109 million).

### (Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥643 million, a decrease of ¥262 million compared to the end of the previous fiscal year (¥905 million), mainly due to a decrease of ¥372 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 ¥1,302 million, a decrease of ¥47 million compared to the end of the previous fiscal year (¥1,349 million), mainly due to a decrease of ¥201 million in long-term loans payable, despite an increase of ¥153 million in deferred tax liabilities.

### (Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥616 million, a decrease of ¥2,175 million compared to the end of the previous fiscal year (¥2,792 million), mainly due to the recording of ¥2,152 million in net loss attributable to owners of parent and a decrease of ¥523 million in foreign currency translation adjustment, despite increases of ¥246 million in capital stock and capital surplus respectively resulting from exercise of subscription rights to shares.

## (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 March 18, 2024.

## 2. Quarterly Consolidated Financial Statements and Primary Notes

### (1) Quarterly Consolidated Balance Sheets

(Thousand yen)

|  | As of January 31, 2024 | As of October 31, 2024 |
|--|------------------------|------------------------|
| <b>Assets</b>                                |                        |                        |
| Current assets                               |                        |                        |
| Cash and deposits                            | 4,454,716              | 2,038,170              |
| Advance payments                             | 358,924                | 294,482                |
| Other  | 123,729                | 114,515                |
| Total current assets                         | 4,937,370              | 2,447,168              |
| Non-current assets                           |                        |                        |
| Property, plant and equipment                | 44,320                 | 41,672                 |
| Intangible assets                            | 43,891                 | 43,891                 |
| Investments and other assets                 | 21,708                 | 29,612                 |
| Total non-current assets                     | 109,920                | 115,177                |
| Total assets                                 | 5,047,291              | 2,562,345              |
| <b>Liabilities</b>                           |                        |                        |
| Current liabilities                          |                        |                        |
| Current portion of long-term loans payable   | 268,000                | 268,000                |
| Accounts payable - other                     | 115,347                | 173,867                |
| Accrued expenses                             | 486,534                | 114,470                |
| Income taxes payable                         | 18,510                 | 302                    |
| Provision for bonuses                        | 8,313                  | 77,874                 |
| Other  | 8,933                  | 8,969                  |
| Total current liabilities                    | 905,639                | 643,485                |
| Non-current liabilities                      |                        |                        |
| Long-term loans payable                      | 397,000                | 196,000                |
| Deferred tax liabilities                     | 952,253                | 1,106,175              |
| Total non-current liabilities                | 1,349,253              | 1,302,175              |
| Total liabilities                            | 2,254,892              | 1,945,661              |
| <b>Net assets</b>                            |                        |                        |
| Shareholders' equity                         |                        |                        |
| Capital stock                                | 3,316,504              | 1,496,228              |
| Capital surplus                              | 7,027,946              | 5,207,671              |
| Retained earnings                            | (1,950,003)            | 31,613                 |
| Treasury shares                              | (933)                  | (1,128)                |
| Total shareholders' equity                   | 8,393,514              | 6,734,385              |
| Accumulated other comprehensive income       |                        |                        |
| Foreign currency translation adjustment      | (5,806,567)            | (6,329,987)            |
| Total accumulated other comprehensive income | (5,806,567)            | (6,329,987)            |
| Subscription rights to shares                | 205,451                | 212,285                |
| Total net assets                             | 2,792,398              | 616,684                |
| Total liabilities and net assets             | 5,047,291              | 2,562,345              |



(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<br>October 31, 2023 | For the nine months ended<br>October 31, 2024 |
|--|---|---|
| Operating revenue                                  | –   | –   |
| Operating expenses                                 |   |   |
| Research and development expenses                  | 2,447,014                                     | 1,666,389                                     |
| Other selling, general and administrative expenses | 1,278,261                                     | 816,548                                       |
| Total operating expenses                           | 3,725,275                                     | 2,482,938                                     |
| Operating loss                                     | (3,725,275)                                   | (2,482,938)                                   |
| Non-operating income                               |   |   |
| Interest income                                    | 1,940   | 1,662   |
| Foreign exchange gains                             | 1,912,494                                     | 499,993                                       |
| Other  | 1,837   | 2,311   |
| Total non-operating income                         | 1,916,272                                     | 503,967                                       |
| Non-operating expenses                             |   |   |
| Interest expenses                                  | 8,207   | 6,384   |
| Financing expenses                                 | 12,039  | 9,608   |
| Share issuance costs                               | 5,471   | 4,821   |
| Other  | 2,424   | –   |
| Total non-operating expenses                       | 28,142  | 20,814  |
| Ordinary loss                                      | (1,837,145)                                   | (1,999,784)                                   |
| Extraordinary income                               |   |   |
| Gain on sale of non-current assets                 | 26,853  | 2,424   |
| Gain on reversal of subscription rights to shares  | 71,350  | –   |
| Total extraordinary income                         | 98,203  | 2,424   |
| Extraordinary losses                               |   |   |
| Loss on retirement of non-current assets           | 3,092   | –   |
| Total extraordinary losses                         | 3,092   | –   |
| Loss before income taxes                           | (1,742,034)                                   | (1,997,359)                                   |
| Income taxes - current                             | 907   | 1,087   |
| Income taxes - deferred                            | 140,109                                       | 153,922                                       |
| Total income taxes                                 | 141,017                                       | 155,010                                       |
| Net loss   | (1,883,051)                                   | (2,152,369)                                   |
| Net loss attributable to owners of parent          | (1,883,051)                                   | (2,152,369)                                   |

Quarterly Consolidated Statements of Comprehensive Income  
For the Nine Months Ended October 31

(Thousand yen)

|  | For the nine months ended<br>October 31, 2023 | For the nine months ended<br>October 31, 2024 |
|--|---|---|
| Net loss   | (1,883,051)                                   | (2,152,369)                                   |
| Other comprehensive income                                     |   |   |
| Foreign currency translation adjustment                        | (1,619,180)                                   | (523,419)                                     |
| Total other comprehensive income                               | (1,619,180)                                   | (523,419)                                     |
| Comprehensive income   | (3,502,232)                                   | (2,675,789)                                   |
| Comprehensive income attributable to:                          |   |   |
| Comprehensive income attributable to owners of parent          | (3,502,232)                                   | (2,675,789)                                   |
| Comprehensive income attributable to non-controlling interests | —   | —   |

### (3) Notes to the Quarterly Consolidated Financial Statements

(Notes on segment information, etc.)

<Segment information>

#### I For the nine months ended October 31, 2023 (from February 1, 2023 to October 31, 2023)

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, 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.

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

#### I For the nine months ended October 31, 2023 (from February 1, 2023 to October 31, 2023)

During the nine months ended October 31, 2023, 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 ¥500,499 thousand. In addition, capital stock and capital reserves each increased by ¥1,797 thousand due to the exercise of share acquisition rights as stock options.

Capital stock and capital surplus each decreased by ¥4,435,693 thousand and retained earnings increased by ¥8,871,387 thousand as a result of covering the deficit in retained earnings brought forward as of June 6, 2023 based on the resolution of the 10th Annual General Meeting of Shareholders held on April 26, 2023.

As a result, at the end of the third quarter of the fiscal year ended January 31, 2024, capital stock, capital surplus, and retained earnings were ¥2,473,793 thousand, ¥6,185,235 thousand, and ¥(1,188,722) thousand, respectively.

#### II 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 ending January 31, 2025, capital stock, capital surplus, and retained earnings were ¥1,496,228 thousand, ¥5,207,671 thousand, and ¥31,613 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, 2024 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<br>October 31, 2023 | For the nine months ended<br>October 31, 2024 |
| Depreciation | 12,112  | 7,428   |

(Notes on significant subsequent events)

(Issuance of new shares by third-party allotment)

At a meeting of the Board of Directors on December 2, 2024, the Company resolved to issue new shares to Athos Asia Event Driven Master Fund, a scheduled subscriber, through a third-party allotment.

1. Subscription details

|     |   |   |
|-----|---|---|
| (1) | Date of payment   | December 18, 2024   |
| (2) | Number of new shares to be issued                         | 2,295,600 shares  |
| (3) | Issue price   | 871.2 yen per share   |
| (4) | Amount of funds to be procured                            | 1,999,926,720 yen   |
| (5) | Method of subscription or disposal (scheduled subscriber) | Third-party allotment to Athos Asia Event Driven Master Fund  |
| (6) | Other   | The above items are subject to a notification in accordance with the Financial Instruments and Exchange Act becoming effective. |

2. Details of use of funds to be procured

The estimated net amount to be procured under this procurement of funds is ¥1,900 million, and funds are planned to be used in accordance with the details of the use of funds and the scheduled timing of disbursement of funds as described below.

| Details of use of funds  | Amount (Million yen) | Scheduled timing of disbursement of funds |
|--|----------------------|---|
| (1) Receiving the approval of partial changes to the items that have been approved for AKUUGO®                 | 672                  | April 2025 to June 2025                   |
| (2) Establishing manufacturing structure and ensuring inventory after launching commercially available AKUUGO® | 1,021                | July 2025 to October 2025                 |
| (3) Establishing the promotion structure after launching commercially available AKUUGO®                        | 207                  | April 2025 to October 2025                |
| Total  | 1,900                |   |