

**Consolidated Financial Results**  
**for the Six Months Ended July 31, 2024**  
**[Japanese GAAP]**



September 17, 2024

Company name: SanBio Company Limited  
 Stock exchange listing: Tokyo Stock Exchange  
 Code number: 4592  
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 Scheduled date of filing semi-annual securities report: September 17, 2024  
 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, 2024 (February 1, 2024 to July 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	%
Six months ended July 31, 2024	—	—	(1,571)	—	(1,186)	—	(1,309)	—
July 31, 2023	—	—	(3,084)	—	(1,930)	—	(1,787)	—

(Note) Comprehensive income: Six months ended July 31, 2024: ¥(1,715) million [–%]  
 Six months ended July 31, 2023: ¥(2,764) million [–%]

	Net income per share		Diluted net income per share	
	Yen		Yen	
Six months ended July 31, 2024	(19.10)		—	
July 31, 2023	(27.59)		—	

(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, 2024	3,558		1,572		38.3		19.86	
As of January 31, 2024	5,047		2,792		51.3		38.08	

(Reference) Equity: As of July 31, 2024: ¥1,363 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 –	Yen 0.00	Yen –	Yen 0.00	Yen 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 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: 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):
    - July 31, 2024: 68,630,802 shares
    - January 31, 2024: 67,929,202 shares
  - 2) Total number of treasury shares at the end of the period:
    - July 31, 2024: 473 shares
    - January 31, 2024: 278 shares
  - 3) Average number of shares during the period:
    - Six months ended July 31, 2024: 68,536,829 shares
    - Six months ended July 31, 2023: 64,781,562 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, 20 products were approved for manufacture and marketing as regenerative medicine products by the end of July 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.” Going forward, 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. In addition, as for the program for treatment of chronic traumatic brain injury, for which the approval has been obtained in Japan with conditions and a time limit attached, the Company will work on launching AKUUGO®. First, the Company will make efforts assuming that it will achieve the situation which enables its shipment in the first quarter of the fiscal year ending January 31, 2026 (February 2025 to April 2025) by confirming its equivalence and homogeneity, one of the conditions for the approval, as the Company swiftly implement manufacturing of commercially available products about two times. Then, 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.

Under these circumstances, during the six months ended July 31, 2024, the Company recorded ¥1,024 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 ¥1,571 million (operating loss of ¥3,084 million for the same period in the previous fiscal

year). On the other hand, the Company recorded ¥397 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 ¥1,186 million (ordinary loss of ¥1,930 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,309 million (net loss attributable to owners of parent of ¥1,787 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. From the six months ended July 31, 2024, the name of the business segment, which was previously “regenerative cell therapy” has been changed to “cell therapeutic agent.” There is no impact on segment information due to the change in the name of said business segment.

## (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 ¥3,438 million, a decrease of ¥1,498 million compared to the end of the previous fiscal year (¥4,937 million), mainly due to a decrease of ¥1,373 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 ¥119 million, an increase of ¥10 million compared to the end of the previous fiscal year (¥109 million).

#### (Current liabilities)

The balance of current liabilities at the end of the semi-annual period of the fiscal year under review was ¥649 million, a decrease of ¥256 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 semi-annual period of the fiscal year under review was ¥1,337 million, a decrease of ¥11 million compared to the end of the previous fiscal year (¥1,349 million), mainly due to a decrease of ¥134 million in long-term loans payable, despite an increase of ¥122 million in deferred tax liabilities.

#### (Net assets)

Total net assets at the end of the semi-annual period of the fiscal year under review were ¥1,572 million, a decrease of ¥1,220 million compared to the end of the previous fiscal year (¥2,792 million), mainly due to the recording of ¥1,309 million in net loss attributable to owners of parent and a decrease of ¥406 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.

### 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 ¥3,014 million, a decrease of ¥1,375 million compared to the end of the previous fiscal year (¥4,389 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, 2024 was ¥1,703 million (an outflow of ¥2,637 million for the same period in the previous fiscal year). This was primarily due to the recording of a loss before income taxes of ¥1,186 million, foreign exchange gains of ¥399 million, and a decrease of ¥388 million in accrued expenses.

#### (Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2024 was ¥3 million (an outflow of ¥8 million for the same period in the previous fiscal year). This was primarily due to an outflow of ¥3 million for purchase of property, plant and equipment.

#### (Cash flows from financing activities)

Net cash provided by financing activities for the six months ended July 31, 2024 was ¥340 million (an inflow of ¥463 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 and ¥480 million in proceeds from issuance of shares 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. Semi-annual Consolidated Financial Statements and Primary Notes

### (1) Semi-annual Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2024	As of July 31, 2024
<b>Assets</b>		
Current assets		
Cash and deposits	4,454,716	3,081,715
Advance payments	358,924	285,712
Other	123,729	71,531
Total current assets	4,937,370	3,438,959
Non-current assets		
Property, plant and equipment	44,320	44,467
Intangible assets	43,891	43,891
Investments and other assets	21,708	31,621
Total non-current assets	109,920	119,981
Total assets	5,047,291	3,558,940
<b>Liabilities</b>		
Current liabilities		
Current portion of long-term loans payable	268,000	268,000
Accounts payable - other	115,347	202,436
Accrued expenses	486,534	114,025
Income taxes payable	18,510	605
Provision for bonuses	8,313	55,032
Other	8,933	9,356
Total current liabilities	905,639	649,456
Non-current liabilities		
Long-term loans payable	397,000	263,000
Deferred tax liabilities	952,253	1,074,483
Total non-current liabilities	1,349,253	1,337,483
Total liabilities	2,254,892	1,986,939
<b>Net assets</b>		
Shareholders' equity		
Capital stock	3,316,504	1,495,595
Capital surplus	7,027,946	5,207,038
Retained earnings	(1,950,003)	874,857
Treasury shares	(933)	(1,081)
Total shareholders' equity	8,393,514	7,576,409
Accumulated other comprehensive income		
Foreign currency translation adjustment	(5,806,567)	(6,213,196)
Total accumulated other comprehensive income	(5,806,567)	(6,213,196)
Subscription rights to shares	205,451	208,787
Total net assets	2,792,398	1,572,000
Total liabilities and net assets	5,047,291	3,558,940

(2) Semi-annual Consolidated Statements of Income and Comprehensive Income  
Semi-annual Consolidated Statements of Income  
For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2023	For the six months ended July 31, 2024
Operating revenue	–	–
Operating expenses		
Research and development expenses	2,112,104	1,024,418
Other selling, general and administrative expenses	972,850	547,505
Total operating expenses	3,084,955	1,571,923
Operating loss	(3,084,955)	(1,571,923)
Non-operating income		
Interest income	1,391	1,036
Foreign exchange gains	1,172,365	397,932
Other	1,806	2,349
Total non-operating income	1,175,563	401,318
Non-operating expenses		
Interest expenses	5,652	4,299
Financing expenses	8,813	6,382
Share issuance costs	3,905	4,821
Other	2,398	–
Total non-operating expenses	20,768	15,502
Ordinary loss	(1,930,159)	(1,186,107)
Extraordinary income		
Gain on reversal of subscription rights to shares	71,350	–
Total extraordinary income	71,350	–
Loss before income taxes	(1,858,809)	(1,186,107)
Income taxes - current	605	788
Income taxes - deferred	(71,889)	122,230
Total income taxes	(71,284)	123,019
Net loss	(1,787,524)	(1,309,126)
Net loss attributable to owners of parent	(1,787,524)	(1,309,126)

Semi-annual Consolidated Statements of Comprehensive Income  
For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2023	For the six months ended July 31, 2024
Net loss	(1,787,524)	(1,309,126)
Other comprehensive income		
Foreign currency translation adjustment	(976,698)	(406,629)
Total other comprehensive income	(976,698)	(406,629)
Comprehensive income	(2,764,222)	(1,715,756)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(2,764,222)	(1,715,756)
Comprehensive income attributable to non-controlling interests	—	—

## (3) Semi-annual Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2023	For the six months ended July 31, 2024
<b>Cash flows from operating activities</b>		
Loss before income taxes	(1,858,809)	(1,186,107)
Depreciation	8,629	4,943
Share based compensation expenses	24,012	9,704
Increase (decrease) in provision for bonuses	6,033	46,719
Interest and dividend income	(1,391)	(1,036)
Foreign exchange losses (gains)	(1,131,451)	(399,123)
Interest expenses	5,652	4,299
Financing expenses	8,813	6,382
Share issuance costs	3,905	4,821
Gain on reversal of subscription rights to shares	(71,350)	–
Decrease (increase) in advance payments	9,396	86,068
Increase (decrease) in accounts payable - other	(123,573)	85,896
Increase (decrease) in accrued expenses	410,127	(388,351)
Other	77,666	36,114
Subtotal	(2,632,341)	(1,689,669)
Interest and dividends received	1,391	1,036
Interest expenses paid	(5,656)	(4,299)
Income taxes paid	(605)	(10,879)
Net cash provided by (used in) operating activities	(2,637,211)	(1,703,812)
<b>Cash flows from investing activities</b>		
Purchase of property, plant and equipment	(8,698)	(3,555)
Payments of leasehold deposits	–	(200)
Net cash provided by (used in) investing activities	(8,698)	(3,755)
<b>Cash flows from financing activities</b>		
Repayments of long-term loans payable	(134,000)	(134,000)
Payments of financing expenses	(6,355)	(6,390)
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	603,929	480,980
Other	–	(147)
Net cash provided by (used in) financing activities	463,573	340,441
Effect of exchange rate change on cash and cash equivalents	69,338	(8,052)
Net increase (decrease) in cash and cash equivalents	(2,112,998)	(1,375,178)
Cash and cash equivalents at beginning of period	6,675,198	4,389,520
Cash and cash equivalents at end of period	4,562,200	3,014,341

(4) Notes to the Semi-annual Consolidated Financial Statements

(Notes on segment information, etc.)

<Segment information>

I For the six months ended July 31, 2023 (from February 1, 2023 to July 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 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.

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

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 under review, capital stock, capital surplus, and retained earnings were ¥1,495,595 thousand, ¥5,207,038 thousand, and ¥874,857 thousand, respectively.

(Notes on going concern assumption)

None