

**Consolidated Financial Results**  
**for the Six Months Ended July 31, 2023**  
**[Japanese GAAP]**



September 14, 2023

Company name: SanBio Company Limited  
 Stock exchange listing: Tokyo Stock Exchange  
 Code number: 4592  
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 Scheduled date of filing quarterly securities report: September 14, 2023  
 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, 2023 (February 1, 2023 to July 31, 2023)**

(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, 2023	—	—	(3,084)	—	(1,930)	—	(1,787)	—
July 31, 2022	—	—	(4,621)	—	(774)	—	(2,154)	—

(Note) Comprehensive income: Six months ended July 31, 2023: ¥(2,764) million [–%]  
 Six months ended July 31, 2022: ¥(5,991) million [–%]

	Net income per share		Diluted net income per share	
	Yen		Yen	
Six months ended July 31, 2023	(27.59)		—	
July 31, 2022	(39.26)		—	

(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, 2023	4,875		2,229		37.6		28.23	
As of January 31, 2023	7,045		4,428		56.5		62.12	

(Reference) Equity: As of July 31, 2023: ¥1,833 million  
 As of January 31, 2023: ¥3,980 million

## 2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2023	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2024	—	0.00			
Fiscal year ending January 31, 2024 (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, 2024 (February 1, 2023 to January 31, 2024)

(% 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	—	—	(4,642)	—	(4,597)	—	(4,598)	—	(72.30)

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

**Notes:**

- (1) Changes in significant subsidiaries during the period under review (changes in specified subsidiaries resulting in changes in scope of consolidation): 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, (4) Notes to the Quarterly Consolidated Financial Statements (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, 2023: 64,956,902 shares  
January 31, 2023: 64,076,202 shares
  - 2) Total number of treasury shares at the end of the period:  
July 31, 2023: 230 shares  
January 31, 2023: 230 shares
  - 3) Average number of shares during the period:  
Six months ended July 31, 2023: 64,781,562 shares  
Six months ended July 31, 2022: 54,895,835 shares

\*These quarterly financial results are outside the scope of quarterly 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. Qualitative Information on Quarterly Financial Results for the Period under Review, (3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information” on page 5 of the attachment.

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## 1. Qualitative Information on Quarterly Financial Results for the Period under Review

### (1) Explanation of Operating Results

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, 17 products were approved for manufacture and marketing as regenerative medicine products by the end of 2022. 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. No RMAT-designated items received BLA approval in 2022, but 14 items received new RMAT designation. Even going into 2023, the practical application of regenerative medicine continued to make steady progress, with three products having already received approval for manufacture and marketing as regenerative medicine products in Japan as of the end of July.

In this environment, the Group (hereinafter referring to three companies: the Company, SanBio, Inc. of Mountain View, California, US, and SanBio Asia Pte. Ltd. of Singapore) promoted research and development aiming at the commercialization of its unique regenerative cell medicine, SB623, mainly for central nervous system diseases with high unmet medical needs.

For the SB623 development program for treatment of chronic traumatic brain injury, 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 development program for treatment of chronic traumatic brain injury 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 for the first time. In order to obtain approval, the Company is currently responding to the review by PMDA and the yield-related issues (i.e., lower yield compared to the yield level at the time of the application), as well as steadily proceeding with preparations for establishment of sales structure so that sales can be started promptly after approval is obtained. While the timing for approval is outside of the Company’s control, the Company will continue to aim to obtain the approval in the fiscal year ending January 31, 2024.

For the SB623 development program for treatment of chronic hemorrhagic stroke that began following the positive results of the program for treatment of chronic traumatic brain injury, the Company is swiftly proceeding with efforts to begin clinical trials in Japan following the approval of the SB623 development program for treatment of chronic traumatic brain injury in Japan.

For the SB623 development program for treatment of chronic ischemic stroke, efforts are being made to swiftly begin clinical trials in Japan following the approval of the SB623 development program for treatment of chronic traumatic brain injury in Japan based on the results of an additional analysis on the Phase 2b clinical trial in 163 patients in the US, which failed to meet its primary endpoint.

Under these circumstances, during the six months ended July 31, 2023, the Company recorded ¥2,112 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 ¥3,084 million (operating loss of ¥4,621 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥1,172 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 ¥1,930 million (ordinary loss of ¥774 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,787 million (net loss attributable to owners of parent of ¥2,154 million for the same period in the previous fiscal year).

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

## (2) Explanation of Financial Position

### 1) Assets, liabilities and net assets

#### (Current assets)

The balance of current assets at the end of the second quarter of the fiscal year under review was ¥4,798 million, a decrease of ¥2,168 million compared to the end of the previous fiscal year (¥6,967 million), mainly due to a decrease of ¥2,108 million in cash and deposits.

#### (Non-current assets)

The balance of non-current assets at the end of the second quarter of the fiscal year under review was ¥76 million, a decrease of ¥1 million compared to the end of the previous fiscal year (¥77 million).

#### (Current liabilities)

The balance of current liabilities at the end of the second quarter of the fiscal year under review was ¥1,325 million, an increase of ¥235 million compared to the end of the previous fiscal year (¥1,090 million), mainly due to an increase of ¥443 million in accrued expenses, despite a decrease of ¥115 million in accounts payable - other.

#### (Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was ¥1,320 million, a decrease of ¥205 million compared to the end of the previous fiscal year (¥1,525 million), mainly due to decreases of ¥134 million in long-term loans payable and ¥71 million in deferred tax liabilities.

#### (Net assets)

Total net assets at the end of the second quarter of the fiscal year under review were ¥2,229 million, a decrease of ¥2,199 million compared to the end of the previous fiscal year (¥4,428 million), mainly due to the recording of ¥1,787 million in net loss attributable to owners of parent and a decrease of ¥976 million in foreign currency translation adjustment, despite increases of ¥308 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 second quarter of the fiscal year under review were ¥4,562 million, a decrease of ¥2,112 million compared to the end of the previous fiscal year (¥6,675 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, 2023 was ¥2,637 million (an outflow of ¥3,977 million for the same period in the previous fiscal year). This was primarily due to the recording of a loss before income taxes of ¥1,858 million, foreign exchange gains of ¥1,131 million, a decrease of ¥123 million in accounts payable - other, and an increase of ¥410 million in accrued expenses.

#### (Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2023 was ¥8 million (an outflow of ¥7 million for the same period in the previous fiscal year). This was due to an outflow of ¥8 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, 2023 was ¥463 million (an inflow

of ¥7,593 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 ¥603 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 16, 2023.



## 2. Quarterly Consolidated Financial Statements and Primary Notes

### (1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2023	As of July 31, 2023
<b>Assets</b>		
Current assets		
Cash and deposits	6,732,775	4,624,473
Advance payments	46,506	40,557
Other	187,980	133,645
Total current assets	6,967,262	4,798,675
Non-current assets		
Property, plant and equipment	47,863	49,775
Intangible assets	1,292	465
Investments and other assets	28,695	26,172
Total non-current assets	77,851	76,413
Total assets	7,045,114	4,875,088
<b>Liabilities</b>		
Current liabilities		
Current portion of long-term loans payable	268,000	268,000
Accounts payable - other	331,073	215,786
Accrued expenses	314,590	758,091
Income taxes payable	605	605
Provision for bonuses	60,875	69,937
Other	115,129	13,558
Total current liabilities	1,090,274	1,325,979
Non-current liabilities		
Long-term loans payable	665,000	531,000
Deferred tax liabilities	860,930	789,041
Total non-current liabilities	1,525,930	1,320,041
Total liabilities	2,616,205	2,646,020
<b>Net assets</b>		
Shareholders' equity		
Capital stock	6,407,189	2,280,227
Capital surplus	10,118,632	5,991,670
Retained earnings	(8,177,057)	(1,093,195)
Treasury shares	(899)	(899)
Total shareholders' equity	8,347,864	7,177,803
Accumulated other comprehensive income		
Foreign currency translation adjustment	(4,367,549)	(5,344,247)
Total accumulated other comprehensive income	(4,367,549)	(5,344,247)
Subscription rights to shares	448,593	395,512
Total net assets	4,428,909	2,229,068
Total liabilities and net assets	7,045,114	4,875,088

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

(Thousand yen)

	For the six months ended July 31, 2022	For the six months ended July 31, 2023
Operating revenue	–	–
Operating expenses		
Research and development expenses	3,620,776	2,112,104
Other selling, general and administrative expenses	1,001,146	972,850
Total operating expenses	4,621,922	3,084,955
Operating loss	(4,621,922)	(3,084,955)
Non-operating income		
Interest income	321	1,391
Foreign exchange gains	3,879,017	1,172,365
Other	1,743	1,806
Total non-operating income	3,881,081	1,175,563
Non-operating expenses		
Interest expenses	14,782	5,652
Financing expenses	18,892	8,813
Share issuance costs	–	3,905
Other	–	2,398
Total non-operating expenses	33,675	20,768
Ordinary loss	(774,516)	(1,930,159)
Extraordinary income		
Gain on reversal of subscription rights to shares	–	71,350
Total extraordinary income	–	71,350
Loss before income taxes	(774,516)	(1,858,809)
Income taxes - current	605	605
Income taxes - deferred	1,379,870	(71,889)
Total income taxes	1,380,475	(71,284)
Net loss	(2,154,992)	(1,787,524)
Net loss attributable to owners of parent	(2,154,992)	(1,787,524)

Quarterly Consolidated Statements of Comprehensive Income  
For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2022	For the six months ended July 31, 2023
Net loss	(2,154,992)	(1,787,524)
Other comprehensive income		
Foreign currency translation adjustment	(3,836,215)	(976,698)
Total other comprehensive income	(3,836,215)	(976,698)
Comprehensive income	(5,991,207)	(2,764,222)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(5,991,207)	(2,764,222)
Comprehensive income attributable to non-controlling interests	—	—

## (3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2022	For the six months ended July 31, 2023
<b>Cash flows from operating activities</b>		
Loss before income taxes	(774,516)	(1,858,809)
Depreciation	12,824	8,629
Share based compensation expenses	57,086	24,012
Increase (decrease) in provision for bonuses	110,099	6,033
Interest and dividend income	(321)	(1,391)
Foreign exchange losses (gains)	(3,882,029)	(1,131,451)
Interest expenses	14,782	5,652
Financing expenses	18,892	8,813
Share issuance costs	–	3,905
Gain on reversal of subscription rights to shares	–	(71,350)
Decrease (increase) in supplies	494,993	–
Decrease (increase) in advance payments	151,266	9,396
Increase (decrease) in accounts payable - other	(177,095)	(123,573)
Increase (decrease) in accrued expenses	35,116	410,127
Other	64,865	77,666
Subtotal	(3,874,035)	(2,632,341)
Interest and dividends received	321	1,391
Interest expenses paid	(14,969)	(5,656)
Income taxes paid	(88,627)	(605)
Net cash provided by (used in) operating activities	(3,977,310)	(2,637,211)
<b>Cash flows from investing activities</b>		
Purchase of property, plant and equipment	(3,768)	(8,698)
Purchase of intangible assets	(95)	–
Payments of leasehold deposits	(3,530)	–
Net cash provided by (used in) investing activities	(7,394)	(8,698)
<b>Cash flows from financing activities</b>		
Repayments of long-term loans payable	(225,000)	(134,000)
Payments of financing expenses	(12,633)	(6,355)
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	7,780,101	603,929
Proceeds from issuance of share acquisition rights	51,000	–
Other	(46)	–
Net cash provided by (used in) financing activities	7,593,421	463,573
Effect of exchange rate change on cash and cash equivalents	169,766	69,338
Net increase (decrease) in cash and cash equivalents	3,778,483	(2,112,998)
Cash and cash equivalents at beginning of period	4,557,006	6,675,198
Cash and cash equivalents at end of period	8,335,489	4,562,200

(4) Notes to the Quarterly Consolidated Financial Statements  
(Notes on going concern assumption)

None

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

During the six months ended July 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 ¥308,192 thousand. In addition, capital stock and capital reserves each increased by ¥539 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 loss 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 second quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥2,280,227 thousand, ¥5,991,670 thousand and ¥(1,093,195) thousand, respectively.

(Changes in accounting policies)

(Application of the Implementation Guidance on Accounting Standard for Fair Value Measurement)

The Company has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, June 17, 2021; hereinafter "Fair Value Measurement Guidance") from the beginning of the first quarter of the fiscal year under review, and will prospectively apply the new accounting policies stipulated by the Fair Value Measurement Guidance in accordance with the transitional treatment provided in Paragraph 27-2 of the Fair Value Measurement Guidance. This has no effect on the quarterly consolidated financial statements.