

Consolidated Financial Results for the Three Months Ended April 30, 2024 [Japanese GAAP]



June 13, 2024

Company name: SanBio Company Limited
 Stock exchange listing: Tokyo Stock Exchange
 Code number: 4592
 URL: <https://www.sanbio.com/>
 Representative: Keita Mori, Representative Director and President
 Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
 Phone: +81-3-6264-3481
 Scheduled date of filing quarterly securities report: June 13, 2024
 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 Three Months Ended April 30, 2024 (February 1, 2024 to April 30, 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	%
Three months ended April 30, 2024	—	—	(666)	—	91	—	(144)	—
April 30, 2023	—	—	(1,461)	—	(937)	—	(626)	—

(Note) Comprehensive income: Three months ended April 30, 2024: ¥(883) million [–%]
 Three months ended April 30, 2023: ¥(1,068) million [–%]

	Net income per share		Diluted net income per share	
	Yen		Yen	
Three months ended April 30, 2024	(2.12)		—	
April 30, 2023	(9.68)		—	

(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 April 30, 2024	4,420		2,399		49.6		31.98	
As of January 31, 2024	5,047		2,792		51.3		38.08	

(Reference) Equity: As of April 30, 2024: ¥2,194 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	—				
Fiscal year ending January 31, 2025 (Forecast)		0.00	—	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
First half	—	—	(1,414)	—	(1,425)	—	(1,425)	—	(20.98)
Full year	—	—	(3,339)	—	(3,359)	—	(3,359)	—	(49.45)

(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: 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):
 - April 30, 2024: 68,630,102 shares
 - January 31, 2024: 67,929,202 shares
 - 2) Total number of treasury shares at the end of the period:
 - April 30, 2024: 368 shares
 - January 31, 2024: 278 shares
 - 3) Average number of shares during the period:
 - Three months ended April 30, 2024: 68,441,619 shares
 - Three months ended April 30, 2023: 64,654,653 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 4 of the attachment.

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review	2
(1) Explanation of Operating Results.....	2
(2) Explanation of Financial Position	4
(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information	4
2. Quarterly Consolidated Financial Statements and Primary Notes	5
(1) Quarterly Consolidated Balance Sheets.....	5
(2) Quarterly Consolidated Statements of Income and Comprehensive Income.....	6
Quarterly Consolidated Statements of Income	
For the Three Months Ended April 30.....	6
Quarterly Consolidated Statements of Comprehensive Income	
For the Three Months Ended April 30.....	7
(3) Notes to the Quarterly Consolidated Financial Statements	8
(Notes on going concern assumption).....	8
(Notes in the event of significant changes in shareholders' equity).....	8

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, 20 products were approved for manufacture and marketing as regenerative medicine products by the end of April 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, two 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) 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 (hereinafter the “Application”) for the first time. The Application / at the Pharmaceutical Affairs and Food Sanitation Council’s Subcommittee on Regenerative Medicine Products (hereinafter the “Subcommittee”) held on March 25, 2024, it concluded to continue the deliberation at a later date and we planned to engage in further consultations with the regulatory authorities and to submit additional information such as additional data addressing quality.

Yesterday, the Ministry of Health, Labour and Welfare announced that the Pharmaceutical Affairs and the Subcommittee will hold a meeting on June 19, and we learned that the Subcommittee will deliberate, among others, on whether to grant marketing approval for the regenerative medicine “AKUUGO suspension for intracranial implantation”, whether to stipulate conditions and a time limit for the approval, and whether to designate a reexamination period. Accordingly, the Subcommittee will determine whether to grant the Company’s development program SB623 marketing approval in the meeting.

After receiving approval for the SB623 development program for treatment of chronic traumatic brain injury, the Company will swiftly proceed with efforts to begin domestic clinical trials for programs for treatment of chronic ischemic stroke and hemorrhagic stroke.

Under these circumstances, during the three months ended April 30, 2024, the Company recorded ¥387 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 ¥666 million (operating loss of ¥1,461 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥767 million in foreign exchange gains as non-operating income, owing to the foreign exchange gains resulting from fluctuations in foreign exchange rates. Furthermore, ordinary income was ¥91 million (ordinary loss of ¥937 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥144 million (net loss attributable to owners of parent of ¥626 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

(Current assets)

The balance of current assets at the end of the first quarter of the fiscal year under review was ¥4,297 million, a decrease of ¥639 million compared to the end of the previous fiscal year (¥4,937 million), mainly due to a decrease of ¥497 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the first quarter of the fiscal year under review was ¥123 million, an increase of ¥13 million compared to the end of the previous fiscal year (¥109 million).

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥503 million, a decrease of ¥402 million compared to the end of the previous fiscal year (¥905 million), mainly due to a decrease of ¥429 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥1,518 million, an increase of ¥168 million compared to the end of the previous fiscal year (¥1,349 million), mainly due to an increase of ¥235 million in deferred tax liabilities, despite a decrease of ¥67 million in long-term loans payable.

(Net assets)

Total net assets at the end of the first quarter of the fiscal year under review were ¥2,399 million, a decrease of ¥392 million compared to the end of the previous fiscal year (¥2,792 million), mainly due to the recording of ¥144 million in net loss attributable to owners of parent and a decrease of ¥738 million in foreign currency translation adjustment, despite increases of ¥245 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 first half and 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 April 30, 2024
Assets		
Current assets		
Cash and deposits	4,454,716	3,957,530
Advance payments	358,924	279,271
Other	123,729	60,819
Total current assets	4,937,370	4,297,621
Non-current assets		
Property, plant and equipment	44,320	45,694
Intangible assets	43,891	43,891
Investments and other assets	21,708	33,530
Total non-current assets	109,920	123,116
Total assets	5,047,291	4,420,738
Liabilities		
Current liabilities		
Current portion of long-term loans payable	268,000	268,000
Accounts payable - other	115,347	137,079
Accrued expenses	486,534	57,335
Income taxes payable	18,510	302
Provision for bonuses	8,313	31,290
Other	8,933	9,024
Total current liabilities	905,639	503,032
Non-current liabilities		
Long-term loans payable	397,000	330,000
Deferred tax liabilities	952,253	1,188,033
Total non-current liabilities	1,349,253	1,518,033
Total liabilities	2,254,892	2,021,065
Net assets		
Shareholders' equity		
Capital stock	3,316,504	3,562,037
Capital surplus	7,027,946	7,273,479
Retained earnings	(1,950,003)	(2,094,853)
Treasury shares	(933)	(969)
Total shareholders' equity	8,393,514	8,739,694
Accumulated other comprehensive income		
Foreign currency translation adjustment	(5,806,567)	(6,545,122)
Total accumulated other comprehensive income	(5,806,567)	(6,545,122)
Subscription rights to shares	205,451	205,100
Total net assets	2,792,398	2,399,672
Total liabilities and net assets	5,047,291	4,420,738

(2) Quarterly Consolidated Statements of Income and Comprehensive Income
Quarterly Consolidated Statements of Income
For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2023	For the three months ended April 30, 2024
Operating revenue	–	–
Operating expenses		
Research and development expenses	1,048,774	387,101
Other selling, general and administrative expenses	413,046	279,482
Total operating expenses	1,461,820	666,583
Operating loss	(1,461,820)	(666,583)
Non-operating income		
Interest income	960	532
Foreign exchange gains	534,554	767,299
Other	1,830	47
Total non-operating income	537,345	767,880
Non-operating expenses		
Interest expenses	2,882	2,096
Financing expenses	4,584	3,156
Share issuance costs	3,634	4,821
Other	2,073	–
Total non-operating expenses	13,174	10,074
Ordinary profit (loss)	(937,649)	91,222
Extraordinary income		
Gain on reversal of subscription rights to shares	71,350	–
Total extraordinary income	71,350	–
Profit (loss) before income taxes	(866,298)	91,222
Income taxes - current	302	292
Income taxes - deferred	(240,439)	235,780
Total income taxes	(240,137)	236,072
Net loss	(626,161)	(144,850)
Net loss attributable to owners of parent	(626,161)	(144,850)

Quarterly Consolidated Statements of Comprehensive Income
For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2023	For the three months ended April 30, 2024
Net loss	(626,161)	(144,850)
Other comprehensive income		
Foreign currency translation adjustment	(442,266)	(738,554)
Total other comprehensive income	(442,266)	(738,554)
Comprehensive income	(1,068,427)	(883,405)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,068,427)	(883,405)
Comprehensive income attributable to non-controlling interests	—	—

(3) 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 three months ended April 30, 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 ¥777 thousand due to the exercise of share acquisition rights as stock options.

As a result, at the end of the first quarter of the fiscal year under review, capital stock and capital surplus were ¥3,562,037 thousand and ¥7,273,479 thousand, respectively.