

**Consolidated Financial Results**  
**for the Nine Months Ended October 31, 2021**  
**[Japanese GAAP]**



December 15, 2021

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: December 15, 2021  
 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, 2021 (February 1, 2021 to October 31, 2021)**

(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, 2021	—	—	(4,739)	—	(3,032)	—	(3,115)	—
October 31, 2020	—	—	(4,188)	—	(4,839)	—	(4,841)	—

(Note) Comprehensive income: Nine months ended October 31, 2021: ¥(4,534) million [-%]

Nine months ended October 31, 2020: ¥(2,517) million [-%]

	Net income per share	Diluted net income per share
	Yen	Yen
Nine months ended October 31, 2021	(60.16)	—
October 31, 2020	(93.49)	—

(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, 2021	8,285	3,897	43.5	69.59
As of January 31, 2021	13,343	8,349	61.0	157.07

(Reference) Equity: As of October 31, 2021: ¥3,604 million

As of January 31, 2021: ¥8,133 million

## 2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2021	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2022	—	0.00	—		
Fiscal year ending January 31, 2022 (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, 2022 (February 1, 2021 to January 31, 2022)

(% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent		Net income per share
Full year	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
	—	—	(5,786)	—	(5,876)	—	(5,877)	—	(113.49)

(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):  
October 31, 2021: 51,793,402 shares  
January 31, 2021: 51,785,505 shares
  - 2) Total number of treasury shares at the end of the period:  
October 31, 2021: 196 shares  
January 31, 2021: 196 shares
  - 3) Average number of shares during the period  
Nine months ended October 31, 2021: 51,787,764 shares  
Nine months ended October 31, 2020: 51,785,033 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 3 of the attachment.

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

### (1) Explanation of Operating Results

During the nine months ended October 31, 2021 (from February 1, 2021 to October 31, 2021), the global economy was exposed to waves of the spread and reduction of the new coronavirus infection. Although many countries tried to recover their economies through promotion of vaccination for the new coronavirus infection and other economic measures, an outlook of the economic recovery was uncertain due to the further spread of the infection even in countries with relatively high vaccination rates. In Japan as well, the preliminary figures for gross domestic product (GDP) for the July-September quarter of 2021 indicated a negative growth for the first time in two quarters, and thus the situation has been unpredictable.

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, the approval for conditional and time-limited sales was granted for the first time in September 2015 under the new program to accelerate the process of drug approval for regenerative medical products developed in Japan. The accelerated delivery of regenerative medical products to the market is rapidly becoming a reality. In addition, the 21st Century Cures Act was passed in the US in December 2016. Under the new legal system, regenerative medical products will be identified as a new category of advanced medical treatment (Regenerative Medicine Advanced Therapy: RMAT) while the establishment of an approval system and approval of new drugs, pertaining to regenerative medicine-related products, are expected to be accelerated.

In this environment, while aiming at commercialization of its unique regenerative cell medicine, SB623, as a new drug candidate for central nervous system diseases, the Company established SanBio Asia Pte. Ltd., its first subsidiary in Asia outside Japan, in Singapore on February 1, 2021, with a view to expanding sales channels in the Asian region. Regarding the development status of the Group (hereinafter referring to three companies; the Company, SanBio, Inc. of Mountain View, California, US, and SanBio Asia Pte. Ltd. of Singapore), in the Phase 2 clinical trial involving the SB623 development program for treatment of chronic traumatic brain injury and conducted in the US and Japan with 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 primary endpoint was met.” In April 2019, the domestic development program for treatment of chronic traumatic brain injury was chosen as a designated regenerative medical product by the Ministry of Health, Labour and Welfare under the SAKIGAKE Designation System. This system aims to shorten the examination after submitting the application for approval for manufacture and sales (hereinafter referred to as the “application for approval”) and to reduce the period from the application for approval to the approval to six months. Therefore, as for the products subject to the SAKIGAKE designation, face-to-face advice and prior interviews should be completed before the application for approval, and then the SAKIGAKE comprehensive evaluation consultation should be conducted. After obtaining permission of the application for approval in the process, the application for approval must be submitted. The SB623 development program for treatment of chronic traumatic brain injury is currently in the phase of the SAKIGAKE comprehensive evaluation consultation. This consultation consists of five parts: clinical, non-clinical, quality, reliability, and GCTP, and each part requires permission for the application. In addition, as for the SB623 development program for treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”), the Group conducted a Phase 2b clinical trial (STR-02 trial) in the US with 163 patients demonstrating motor deficits associated with chronic ischemic stroke, and announced in January 2019 that “no statistically significant difference was found in the proportion of patients whose Fugl-Meyer Motor Scale (FMMS) score improved by 10 or more points over the baseline at six months after treatment (the primary endpoint) between the SB623 treatment group and the control group, and thus the trial did not meet the primary endpoint.” However, in September 2020, as an additional analysis of STR-02 trial, the Group evaluated the efficacy of SB623 in 77 patients whose infarct area was smaller than a certain size (47% of the patients examined in STR-02 trial) at six months after the SB623 treatment by using the composite FMMS endpoint, and obtained a statistically significant result (P-value=0.02), indicating that 49% of the SB623 treatment group consisting of 51 patients showed improvement compared to 19% of the sham surgery group consisting of 26 patients. To maximize the value of SB623 by selection and concentration of our management resources, the Group has decided to give priority to the preparation for the development of the SB623 programs for treatment of ischemic stroke and hemorrhagic stroke in Japan, in parallel with preparing to apply for approval for manufacture and sales of SB623 for treatment of chronic traumatic brain injury in Japan as early as possible. Specific designs of the clinical trials and the contents of the development of both the programs will be announced promptly once they are finalized.

Under these circumstances, during the nine months ended October 31, 2021, the Company recorded ¥3,546 million in research and development expenses mainly consisting of manufacturing-related costs incurred in applying for approval with respect to the SB623 development program for treatment of chronic traumatic brain injury. As a result, operating loss was ¥4,739 million (operating loss of ¥4,188 million for the same period in the previous fiscal year), ordinary loss was ¥3,032 million (ordinary loss of ¥4,839 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥3,115 million (net loss attributable to owners of parent of ¥4,841 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 third quarter of the fiscal year under review was ¥8,118 million, a decrease of ¥5,013 million compared to the end of the previous fiscal year (¥13,131 million), mainly due to a decrease of ¥5,110 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 ¥166 million, a decrease of ¥45 million compared to the end of the previous fiscal year (¥211 million), mainly due to a decrease of ¥61 million in property, plant and equipment.

### (Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥2,087 million, a decrease of ¥381 million compared to the end of the previous fiscal year (¥2,468 million), mainly due to decreases of ¥525 million in current portion of long-term loans payable, ¥435 million in accrued expenses, and ¥109 million in income taxes payable, despite increases of ¥450 million in short-term loans payable and ¥205 million in provision for bonuses.

### (Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥2,300 million, a decrease of ¥225 million compared to the end of the previous fiscal year (¥2,525 million), due to a decrease of ¥225 million in long-term loans payable.

### (Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥3,897 million, a decrease of ¥4,452 million compared to the end of the previous fiscal year (¥8,349 million), mainly due to the recording of ¥3,115 million in net loss attributable to owners of parent and a decrease of ¥1,419 million in foreign currency translation adjustment.

## (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 17, 2021.

## 2. Quarterly Consolidated Financial Statements and Primary Notes

### (1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2021	As of October 31, 2021
<b>Assets</b>		
Current assets		
Cash and deposits	12,480,165	7,369,470
Supplies	444,519	463,627
Advance payments	107,657	185,000
Other	99,583	100,599
<b>Total current assets</b>	<b>13,131,925</b>	<b>8,118,698</b>
Non-current assets		
Property, plant and equipment	141,784	80,143
Intangible assets	53,650	55,710
Investments and other assets	16,464	30,524
<b>Total non-current assets</b>	<b>211,900</b>	<b>166,378</b>
<b>Total assets</b>	<b>13,343,826</b>	<b>8,285,077</b>
<b>Liabilities</b>		
Current liabilities		
Short-term loans payable	500,000	950,000
Current portion of long-term loans payable	975,000	450,000
Accounts payable - other	221,983	248,991
Accrued expenses	555,582	120,314
Income taxes payable	202,685	93,222
Provision for bonuses	6,345	211,993
Other	7,303	12,701
<b>Total current liabilities</b>	<b>2,468,900</b>	<b>2,087,223</b>
Non-current liabilities		
Long-term loans payable	2,525,000	2,300,000
<b>Total non-current liabilities</b>	<b>2,525,000</b>	<b>2,300,000</b>
<b>Total liabilities</b>	<b>4,993,900</b>	<b>4,387,223</b>
<b>Net assets</b>		
Shareholders' equity		
Capital stock	5,561,072	4,075,135
Capital surplus	9,272,515	7,786,578
Retained earnings	(7,356,499)	(7,495,000)
Treasury shares	(853)	(853)
<b>Total shareholders' equity</b>	<b>7,476,235</b>	<b>4,365,859</b>
Accumulated other comprehensive income		
Foreign currency translation adjustment	657,644	(761,421)
<b>Total accumulated other comprehensive income</b>	<b>657,644</b>	<b>(761,421)</b>
Subscription rights to shares	216,044	293,415
<b>Total net assets</b>	<b>8,349,925</b>	<b>3,897,853</b>
<b>Total liabilities and net assets</b>	<b>13,343,826</b>	<b>8,285,077</b>

(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 October 31, 2020	For the nine months ended October 31, 2021
Operating revenue	–	–
Operating expenses		
Research and development expenses	2,974,467	3,546,083
Other selling, general and administrative expenses	1,213,903	1,193,736
Total operating expenses	4,188,371	4,739,819
Operating loss	(4,188,371)	(4,739,819)
Non-operating income		
Interest income	2,012	1,796
Dividend income	6,458	3,172
Foreign exchange gains	–	1,615,382
Gain on forgiveness of debts	–	127,023
Other	237	36
Total non-operating income	8,707	1,747,411
Non-operating expenses		
Interest expenses	36,755	35,189
Foreign exchange losses	615,877	–
Financing expenses	7,379	5,102
Total non-operating expenses	660,013	40,292
Ordinary loss	(4,839,676)	(3,032,700)
Extraordinary income		
Gain on reversal of subscription rights to shares	–	29,487
Total extraordinary income	–	29,487
Extraordinary losses		
Loss on retirement of non-current assets	46	10,106
Total extraordinary losses	46	10,106
Loss before income taxes	(4,839,723)	(3,013,319)
Income taxes - current	1,899	102,168
Total income taxes	1,899	102,168
Net loss	(4,841,623)	(3,115,488)
Net loss attributable to owners of parent	(4,841,623)	(3,115,488)



Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2020	For the nine months ended October 31, 2021
Net loss	(4,841,623)	(3,115,488)
Other comprehensive income		
Valuation difference on available-for-sale securities	1,819,173	–
Foreign currency translation adjustment	504,736	(1,419,066)
Total other comprehensive income	2,323,910	(1,419,066)
Comprehensive income	(2,517,713)	(4,534,554)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(2,517,713)	(4,534,554)
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)

Capital stock and capital surplus each decreased by ¥1,488,493 thousand and retained earnings increased by ¥2,976,986 thousand as a result of covering the loss in retained earnings brought forward as of June 9, 2021 based on the resolution of the 8th Annual General Meeting of Shareholders held on April 28, 2021. Additionally, capital stock and legal capital surplus each increased by ¥2,556 thousand due to the exercise of share acquisition rights as stock options during the nine months ended October 31, 2021.

As a result, at the end of the third quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥4,075,135 thousand, ¥7,786,578 thousand and ¥(7,495,000) thousand, respectively.

(Significant subsequent events)

(Conclusion of commitment line agreement)

The Company has entered into the following commitment line agreement with Resona Bank, Limited as funds for the establishment of post-launch manufacture, distribution, and marketing infrastructure for SB623.

- |                      |  |
|----------------------|--|
| 1. Loan limit        | ¥1,000,000 thousand  |
| 2. Date of agreement | December 15, 2021  |
| 3. Commitment period | January 14, 2022 - June 30, 2023   |
| 4. Repayment method  | Repayment within the commitment period   |
| 5. Main conditions   | During the terms of the agreement, the Company must maintain net assets and after-tax income above their corresponding amounts indicated in the business plan the Company submitted. |