

Consolidated Financial Results for the Three Months Ended April 30, 2021 [Japanese GAAP]



June 14, 2021

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 Stock exchange listing: Tokyo Stock Exchange
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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 Three Months Ended April 30, 2021 (February 1, 2021 to April 30, 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	%
Three months ended April 30, 2021	—	—	(1,540)	—	(855)	—	(860)	—
April 30, 2020	—	—	(1,242)	—	(1,505)	—	(1,507)	—

(Note) Comprehensive income: Three months ended April 30, 2021: ¥(1,491) million [—%]

Three months ended April 30, 2020: ¥(1,205) million [—%]

	Net income per share	Diluted net income per share
	Yen	Yen
Three months ended April 30, 2021	(16.61)	—
April 30, 2020	(29.10)	—

(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, 2021	11,520	6,900	57.7	128.33
As of January 31, 2021	13,343	8,349	61.0	157.07

(Reference) Equity: As of April 30, 2021: ¥6,645 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	—				
Fiscal year ending January 31, 2022 (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, 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
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
First half	—	—	(3,492)	—	(3,550)	—	(3,551)	—	(68.57)
Full year	—	—	(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):
 - April 30, 2021: 51,787,073 shares
 - January 31, 2021: 51,785,505 shares
 - 2) Total number of treasury shares at the end of the period:
 - April 30, 2021: 196 shares
 - January 31, 2021: 196 shares
 - 3) Average number of shares during the period
 - Three months ended April 30, 2021: 51,786,683 shares
 - Three months ended April 30, 2020: 51,784,827 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.

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

(1) Explanation of Operating Results

During the three months ended April 30, 2021 (from February 1, 2021 to April 30, 2021), the global economy saw effective vaccines for new coronavirus infection becoming extensively available worldwide. Economic activities are expected to accelerate from now on, following the relaxation of restriction measures concerning public health. Meanwhile, there has been polarization in resumption of economic activities between countries with fast vaccine rollout and countries slow in vaccination. In Japan, especially, due to the third declaration of the state of emergency and its extension primarily in the Greater Tokyo Area, personal consumption, which accounts for more than half of gross domestic product (GDP), remained weak and the economic situation is still unpredictable. According to the preliminary figures for GDP for the January-March quarter of 2021 announced by the Cabinet Office, the economy in Japan contracted for the first time in three quarters by an annualized rate of 5.1%, which is greater than 3.6% in 2008, the year of the global financial crisis, and the largest since the end of the World War II.

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, we established SanBio Asia Pte. Ltd., our first subsidiary in Asia outside Japan, in Singapore on February 1, 2021, with a view to expanding sales channels in the Asian region. The Group (hereinafter referring to three companies; the Company, SanBio, Inc. of Mountain View, California, US, and SanBio Asia Pte. Ltd. of Singapore) pressed ahead with development and commercialization, primarily in Japan and the US, of our unique regenerative cell medicine, SB623, as a new drug candidate for central nervous system diseases.

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. Currently, in Japan, we are actively negotiating with the Pharmaceuticals and Medical Devices Agency (PMDA) within the framework of the SAKIGAKE Designation System, aimed at applying for approval for manufacture and sales of SB623 as a regenerative medical product as early as possible. (For the detailed situation so far, please refer to the Company’s press release dated December 15, 2020 entitled “Notice regarding the status of domestic approval filing for regenerative cell medicine SB623 for treatment of chronic effects associated with traumatic brain injury.”) Under this system, active discussion is being held preferentially in the preliminary evaluation preceding the application for approval for manufacture and sales of the designated products in order to shorten the examination period after the application. We will continue to hold negotiations with the PMDA toward the earliest possible acquisition of the approval for domestic manufacture and sales of SB623, while steadily proceeding with preparations for establishment of a sales system after obtaining the approval. 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 (Note), 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 three months ended April 30, 2021, the Company recorded ¥1,126 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 ¥1,540 million (operating loss of ¥1,242 million for the same period in the previous fiscal year), ordinary loss was ¥855 million (ordinary loss of ¥1,505 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥860 million (net loss attributable to owners of parent of ¥1,507 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.

Note: For details, please refer to the Company’s press release dated September 14, 2020 entitled “SanBio Announces Results of New Analyses on the Phase 2b Clinical Trial in the U.S. Evaluating SB623, a Regenerative Cell Medicine for Treatment of Patients with Chronic Stroke, and Consideration of Commencement of Clinical Trials in Japan for the SB623 Development Programs for Treatment of Ischemic Stroke and Hemorrhagic Stroke based on the Results.”

(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 ¥11,333 million, a decrease of ¥1,798 million compared to the end of the previous fiscal year (¥13,131 million), mainly due to a decrease of ¥1,798 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 ¥187 million, a decrease of ¥24 million compared to the end of the previous fiscal year (¥211 million), mainly due to a decrease of ¥24 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥2,320 million, a decrease of ¥148 million compared to the end of the previous fiscal year (¥2,468 million), mainly due to decreases of ¥289 million in accrued expenses and ¥191 million in income taxes payable, despite increases of ¥225 million in current portion of long-term loans payable and ¥74 million in provision for bonuses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first 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), mainly due to a decrease of ¥225 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 ¥6,900 million, a decrease of ¥1,449 million compared to the end of the previous fiscal year (¥8,349 million), mainly due to the recording of ¥860 million in net loss attributable to owners of parent and a decrease of ¥631 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 first half and 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 April 30, 2021
Assets		
Current assets		
Cash and deposits	12,480,165	10,681,876
Supplies	444,519	452,255
Advance payments	107,657	132,196
Other	99,583	66,682
Total current assets	13,131,925	11,333,010
Non-current assets		
Property, plant and equipment	141,784	117,231
Intangible assets	53,650	54,195
Investments and other assets	16,464	16,300
Total non-current assets	211,900	187,727
Total assets	13,343,826	11,520,738
Liabilities		
Current liabilities		
Short-term loans payable	500,000	500,000
Current portion of long-term loans payable	975,000	1,200,000
Accounts payable - other	221,983	252,716
Accrued expenses	555,582	266,247
Income taxes payable	202,685	10,993
Provision for bonuses	6,345	80,949
Other	7,303	9,556
Total current liabilities	2,468,900	2,320,463
Non-current liabilities		
Long-term loans payable	2,525,000	2,300,000
Total non-current liabilities	2,525,000	2,300,000
Total liabilities	4,993,900	4,620,463
Net assets		
Shareholders' equity		
Capital stock	5,561,072	5,562,676
Capital surplus	9,272,515	9,274,118
Retained earnings	(7,356,499)	(8,216,565)
Treasury shares	(853)	(853)
Total shareholders' equity	7,476,235	6,619,375
Accumulated other comprehensive income		
Foreign currency translation adjustment	657,644	26,361
Total accumulated other comprehensive income	657,644	26,361
Subscription rights to shares	216,044	254,537
Total net assets	8,349,925	6,900,274
Total liabilities and net assets	13,343,826	11,520,738

(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, 2020	For the three months ended April 30, 2021
Operating revenue	–	–
Operating expenses		
Research and development expenses	857,217	1,126,499
Other selling, general and administrative expenses	385,033	413,753
Total operating expenses	1,242,251	1,540,253
Operating loss	(1,242,251)	(1,540,253)
Non-operating income		
Interest income	742	219
Dividend income	6,458	3,172
Foreign exchange gains	–	695,283
Other	237	36
Total non-operating income	7,438	698,711
Non-operating expenses		
Interest expenses	11,604	11,845
Foreign exchange losses	256,212	–
Financing expenses	3,095	1,694
Total non-operating expenses	270,913	13,540
Ordinary loss	(1,505,726)	(855,081)
Extraordinary income		
Gain on reversal of subscription rights to shares	–	1,423
Total extraordinary income	–	1,423
Extraordinary losses		
Loss on retirement of non-current assets	47	–
Total extraordinary losses	47	–
Loss before income taxes	(1,505,773)	(853,657)
Income taxes - current	1,294	6,408
Total income taxes	1,294	6,408
Net loss	(1,507,067)	(860,066)
Net loss attributable to owners of parent	(1,507,067)	(860,066)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2020	For the three months ended April 30, 2021
Net loss	(1,507,067)	(860,066)
Other comprehensive income		
Valuation difference on available-for-sale securities	78,577	—
Foreign currency translation adjustment	223,075	(631,283)
Total other comprehensive income	301,652	(631,283)
Comprehensive income	(1,205,415)	(1,491,349)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,205,415)	(1,491,349)
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)

None