

Consolidated Financial Results for the Six Months Ended July 31, 2021 [Japanese GAAP]



September 14, 2021

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 Stock exchange listing: Tokyo Stock Exchange
 Code number: 4592
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 Scheduled date of filing quarterly securities report: September 14, 2021
 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, 2021 (February 1, 2021 to July 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	%
Six months ended July 31, 2021	—	—	(3,052)	—	(2,146)	—	(2,134)	—
July 31, 2020	—	—	(2,570)	—	(3,205)	—	(3,207)	—

(Note) Comprehensive income: Six months ended July 31, 2021: ¥(2,845) million [–%]

Six months ended July 31, 2020: ¥(1,961) million [–%]

	Net income per share	Diluted net income per share
Six months ended	Yen	Yen
July 31, 2021	(41.21)	—
July 31, 2020	(61.94)	—

(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, 2021	9,709	5,552	54.5	102.18
As of January 31, 2021	13,343	8,349	61.0	157.07

(Reference) Equity: As of July 31, 2021: ¥5,291 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
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
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):
 - July 31, 2021: 51,787,073 shares
 - January 31, 2021: 51,785,505 shares
 - 2) Total number of treasury shares at the end of the period:
 - July 31, 2021: 196 shares
 - January 31, 2021: 196 shares
 - 3) Average number of shares during the period:
 - Six months ended July 31, 2021: 51,786,782 shares
 - Six months ended July 31, 2020: 51,784,931 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 six months ended July 31, 2021 (from February 1, 2021 to July 31, 2021), despite the restraint on economic activities amid the new coronavirus pandemic, the global economy saw a recovery trend mainly in developed countries due to vaccination for the new coronavirus infection and other economic measures. However, the economic recovery has been unpredictable due to the spread of the infection caused by delays in the vaccination as well as the new coronavirus variants. In Japan as well, the preliminary figures for gross domestic product (GDP) for the April-June quarter of 2021 indicated a positive growth for the first time in two quarters, but with a low growth rate.

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. 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 (for details, please refer to the Company’s press release dated September 14, 2020 entitled “Additional analytical results of the US-based Phase 2b clinical trial of regenerative cell medicine SB623 for the treatment of chronic motor deficit from

ischemic stroke, and review of plans to initiate clinical trials for the ischemic stroke and hemorrhagic stroke programs in Japan based on these results.”), 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 six months ended July 31, 2021, the Company recorded ¥2,251 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 ¥3,052 million (operating loss of ¥2,570 million for the same period in the previous fiscal year), ordinary loss was ¥2,146 million (ordinary loss of ¥3,205 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥2,134 million (net loss attributable to owners of parent of ¥3,207 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 ¥9,515 million, a decrease of ¥3,616 million compared to the end of the previous fiscal year (¥13,131 million), mainly due to a decrease of ¥3,685 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 ¥193 million, a decrease of ¥17 million compared to the end of the previous fiscal year (¥211 million), mainly due to a decrease of ¥32 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the second quarter of the fiscal year under review was ¥1,857 million, a decrease of ¥611 million compared to the end of the previous fiscal year (¥2,468 million), mainly due to decreases of ¥300 million in current portion of long-term loans payable, ¥112 million in accounts payable – other, ¥381 million in accrued expenses, and ¥180 million in income taxes payable, despite increases of ¥225 million in short-term loans payable and ¥131 million in provision for bonuses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the second 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 second quarter of the fiscal year under review were ¥5,552 million, a decrease of ¥2,797 million compared to the end of the previous fiscal year (¥8,349 million), mainly due to the

recording of ¥2,134 million in net loss attributable to owners of parent and a decrease of ¥711 million in foreign currency translation adjustment.

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 ¥8,794 million, a decrease of ¥3,685 million compared to the end of the previous fiscal year (¥12,480 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, 2021 was ¥3,475 million (an outflow of ¥2,501 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥2,127 million recorded, an increase of ¥130 million in provision for bonuses, decreases of ¥139 million in accounts payable - other and ¥277 million in accrued expenses, and income taxes paid of ¥164 million.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2021 was ¥27 million (an outflow of ¥88 million for the same period in the previous fiscal year). This was primarily due to an outflow of ¥26 million for purchase of property, plant and equipment.

(Cash flows from financing activities)

Net cash used in financing activities for the six months ended July 31, 2021 was ¥300 million (an outflow of ¥4 million for the same period in the previous fiscal year). This was primarily due to an increase of ¥225 million in short-term loans payable and an outflow of ¥525 million for repayments of long-term loans payable.

(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 July 31, 2021
Assets		
Current assets		
Cash and deposits	12,480,165	8,794,258
Supplies	444,519	453,514
Advance payments	107,657	177,616
Other	99,583	90,069
Total current assets	13,131,925	9,515,458
Non-current assets		
Property, plant and equipment	141,784	108,830
Intangible assets	53,650	53,799
Investments and other assets	16,464	31,292
Total non-current assets	211,900	193,922
Total assets	13,343,826	9,709,380
Liabilities		
Current liabilities		
Short-term loans payable	500,000	725,000
Current portion of long-term loans payable	975,000	675,000
Accounts payable - other	221,983	109,073
Accrued expenses	555,582	174,418
Income taxes payable	202,685	21,987
Provision for bonuses	6,345	137,953
Other	7,303	13,897
Total current liabilities	2,468,900	1,857,329
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	4,157,329
Net assets		
Shareholders' equity		
Capital stock	5,561,072	4,074,182
Capital surplus	9,272,515	7,785,625
Retained earnings	(7,356,499)	(6,513,534)
Treasury shares	(853)	(853)
Total shareholders' equity	7,476,235	5,345,421
Accumulated other comprehensive income		
Foreign currency translation adjustment	657,644	(53,599)
Total accumulated other comprehensive income	657,644	(53,599)
Subscription rights to shares	216,044	260,228
Total net assets	8,349,925	5,552,050
Total liabilities and net assets	13,343,826	9,709,380

(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, 2020	For the six months ended July 31, 2021
Operating revenue	–	–
Operating expenses		
Research and development expenses	1,798,667	2,251,264
Other selling, general and administrative expenses	772,331	801,535
Total operating expenses	2,570,999	3,052,800
Operating loss	(2,570,999)	(3,052,800)
Non-operating income		
Interest income	1,556	1,110
Dividend income	6,458	3,172
Foreign exchange gains	–	802,876
Gain on forgiveness of debts	–	126,153
Other	237	36
Total non-operating income	8,252	933,349
Non-operating expenses		
Interest expenses	23,209	23,813
Foreign exchange losses	614,468	–
Financing expenses	5,238	3,427
Total non-operating expenses	642,916	27,241
Ordinary loss	(3,205,662)	(2,146,691)
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	10,105
Total extraordinary losses	46	10,105
Loss before income taxes	(3,205,709)	(2,127,309)
Income taxes - current	1,596	6,711
Total income taxes	1,596	6,711
Net loss	(3,207,306)	(2,134,021)
Net loss attributable to owners of parent	(3,207,306)	(2,134,021)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2020	For the six months ended July 31, 2021
Net loss	(3,207,306)	(2,134,021)
Other comprehensive income		
Valuation difference on available-for-sale securities	758,708	–
Foreign currency translation adjustment	487,563	(711,243)
Total other comprehensive income	1,246,272	(711,243)
Comprehensive income	(1,961,033)	(2,845,265)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,961,033)	(2,845,265)
Comprehensive income attributable to non-controlling interests	–	–

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2020	For the six months ended July 31, 2021
Cash flows from operating activities		
Loss before income taxes	(3,205,709)	(2,127,309)
Depreciation	17,106	74,107
Share based compensation expenses	50,543	75,026
Increase (decrease) in provision for bonuses	78,176	130,943
Interest and dividend income	(8,015)	(4,283)
Foreign exchange losses (gains)	614,763	(804,077)
Gain on forgiveness of debts	–	(126,153)
Interest expenses	23,209	23,813
Financing expenses	5,238	3,427
Gain on reversal of subscription rights to shares	–	(29,487)
Loss on retirement of non-current assets	46	10,105
Decrease (increase) in inventories	9,909	3,264
Decrease (increase) in advance payments	74,559	(64,382)
Increase (decrease) in accounts payable - other	(158,691)	(139,694)
Increase (decrease) in accrued expenses	(67,071)	(277,410)
Other	80,760	(38,374)
Subtotal	(2,485,173)	(3,290,485)
Interest and dividends received	8,015	4,283
Interest expenses paid	(23,459)	(24,151)
Income taxes paid	(1,031)	(164,852)
Net cash provided by (used in) operating activities	(2,501,649)	(3,475,205)
Cash flows from investing activities		
Purchase of property, plant and equipment	(66,924)	(26,528)
Purchase of intangible assets	(21,068)	(1,241)
Payments of leasehold deposits	(100)	–
Net cash provided by (used in) investing activities	(88,093)	(27,769)
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	500,000	225,000
Repayments of long-term loans payable	(500,000)	(525,000)
Payments of financing expenses	(4,257)	(2,236)
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	209	1,851
Net cash provided by (used in) financing activities	(4,048)	(300,385)
Effect of exchange rate change on cash and cash equivalents	(144,633)	117,453
Net increase (decrease) in cash and cash equivalents	(2,738,424)	(3,685,907)
Cash and cash equivalents at beginning of period	13,646,073	12,480,165
Cash and cash equivalents at end of period	10,907,649	8,794,258

(4) 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 ¥1,603 thousand due to the exercise of share acquisition rights as stock options during the six months ended July 31, 2021.

As a result, at the end of the second quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥4,074,182 thousand, ¥7,785,625 thousand and ¥(6,513,534) thousand, respectively.