

# Consolidated Financial Results for the Nine Months Ended October 31, 2020 [Japanese GAAP]



December 15, 2020

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 Stock exchange listing: Tokyo Stock Exchange  
 Code number: 4592  
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 Scheduled date of filing quarterly securities report: December 15, 2020  
 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, 2020 (February 1, 2020 to October 31, 2020)

(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, 2020	—	—	(4,188)	—	(4,839)	—	(4,841)	—
October 31, 2019	424	(25.4)	(3,628)	—	(3,271)	—	(3,280)	—

(Note) Comprehensive income: Nine months ended October 31, 2020: ¥(2,517) million [–%]

Nine months ended October 31, 2019: ¥(3,379) million [–%]

	Net income per share	Diluted net income per share
	Yen	Yen
Nine months ended October 31, 2020	(93.49)	—
October 31, 2019	(64.47)	—

(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, 2020	13,714	8,494	60.6	160.45
As of January 31, 2020	15,605	10,930	69.4	209.05

(Reference) Equity: As of October 31, 2020: ¥8,309 million

As of January 31, 2020: ¥10,825 million

## 2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2020	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2021	—	0.00	—		
Fiscal year ending January 31, 2021 (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, 2021 (February 1, 2020 to January 31, 2021)

(% 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	—	—	(5,453)	—	(5,543)	—	(5,544)	—	(107.06)

(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, 2020: 51,785,505 shares
    - January 31, 2020: 51,785,023 shares
  - 2) Total number of treasury shares at the end of the period:
    - October 31, 2020: 196 shares
    - January 31, 2020: 196 shares
  - 3) Average number of shares during the period
    - Nine months ended October 31, 2020: 51,785,033 shares
    - Nine months ended October 31, 2019: 50,888,090 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, 2020 (from February 1, 2020 to October 31, 2020), the global economy faced an increasingly uncertain outlook due to the further spread of the new coronavirus infection in Europe and the US. In Japan and the US, GDP (Gross Domestic Product) has not reached the levels seen prior to the outbreak of the new coronavirus pandemic, despite the gradual resumption of economic activity. Infections are still spreading once again, and the economies of both countries continue to be unpredictable amid uncertainties over when the pandemic will come to an end.

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, the Group (hereinafter referring to both the Company and its consolidated subsidiary, SanBio, Inc. of Mountain View, California, US) pressed ahead with development and commercialization, both 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, it was chosen as a designated regenerative medical product in Japan 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, and plan to apply for approval for manufacture and sales of SB623 as a regenerative medical product during the fiscal year ending January 31, 2021. However, at this point it is expected that the application during the fiscal year ending January 31, 2021 is likely to be delayed (Note 1). 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 2), 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. Following this result, we started preparing for the commencement of domestic late-phase clinical trials for the SB623 development programs for treatment of ischemic stroke and hemorrhagic stroke. Specific designs of the clinical trials and the contents of the development of both the programs will be announced promptly once they are finalized. To maximize the value of SB623 by selection and concentration of our management resources, the Group has decided to give priority to 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.

Under these circumstances, during the nine months ended October 31, 2020, the Company recorded ¥2,974 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 ¥4,188 million (operating loss of ¥3,628 million for the same period in the previous fiscal year), ordinary loss was ¥4,839 million (ordinary loss of ¥3,271 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥4,841 million

(net loss attributable to owners of parent of ¥3,280 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 1: For details, 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."

Note 2: 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

### 1) Assets, liabilities and net assets

#### (Current assets)

The balance of current assets at the end of the third quarter of the fiscal year under review was ¥10,133 million, a decrease of ¥4,492 million compared to the end of the previous fiscal year (¥14,626 million), mainly due to a decrease of ¥4,248 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 ¥3,581 million, an increase of ¥2,602 million compared to the end of the previous fiscal year (¥979 million), mainly due to an increase of ¥2,544 million in investment securities.

#### (Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥2,595 million, an increase of ¥1,420 million compared to the end of the previous fiscal year (¥1,175 million), mainly due to increases of ¥500 million in short-term loans payable and ¥1,100 million in current portion of long-term loans payable, despite a decrease of ¥163 million in accounts payable - other.

#### (Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥2,625 million, a decrease of ¥874 million compared to the end of the previous fiscal year (¥3,500 million), mainly due to a decrease of ¥1,600 million in long-term loans payable, despite an increase of ¥725 million in deferred tax liabilities.

#### (Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥8,494 million, a decrease of ¥2,436 million compared to the end of the previous fiscal year (¥10,930 million), mainly due to an increase of ¥2,323 million in accumulated other comprehensive income, despite the recording of ¥4,841 million in net loss attributable to owners of parent.

## (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, 2020.

## 2. Quarterly Consolidated Financial Statements and Primary Notes

### (1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2020	As of October 31, 2020
<b>Assets</b>		
Current assets		
Cash and deposits	13,646,073	9,397,466
Supplies	469,600	444,922
Advance payments	375,790	177,842
Other	134,585	112,957
Total current assets	14,626,050	10,133,188
Non-current assets		
Property, plant and equipment	123,943	159,793
Intangible assets	13,650	36,029
Investments and other assets		
Investment securities	824,522	3,369,132
Other	17,248	16,675
Total investments and other assets	841,770	3,385,807
Total non-current assets	979,364	3,581,630
Total assets	15,605,414	13,714,818
<b>Liabilities</b>		
Current liabilities		
Short-term loans payable	–	500,000
Current portion of long-term loans payable	500,000	1,600,000
Accounts payable - other	296,749	133,428
Accrued expenses	319,205	214,000
Provision for bonuses	20,698	133,014
Other	38,578	14,860
Total current liabilities	1,175,232	2,595,304
Non-current liabilities		
Long-term loans payable	3,500,000	1,900,000
Deferred tax liabilities	–	725,435
Total non-current liabilities	3,500,000	2,625,435
Total liabilities	4,675,232	5,220,740
<b>Net assets</b>		
Shareholders' equity		
Capital stock	8,083,986	5,561,072
Capital surplus	11,795,428	9,272,515
Retained earnings	(9,017,546)	(8,812,246)
Treasury shares	(853)	(853)
Total shareholders' equity	10,861,014	6,020,488
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(175,453)	1,643,720
Foreign currency translation adjustment	140,157	644,893
Total accumulated other comprehensive income	(35,296)	2,288,614
Subscription rights to shares	104,464	184,975
Total net assets	10,930,182	8,494,078
Total liabilities and net assets	15,605,414	13,714,818

(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, 2019	For the nine months ended October 31, 2020
Operating revenue	424,344	—
Operating expenses		
Research and development expenses	2,862,278	2,974,467
Other selling, general and administrative expenses	1,190,888	1,213,903
Total operating expenses	4,053,167	4,188,371
Operating loss	(3,628,823)	(4,188,371)
Non-operating income		
Interest income	7,716	2,012
Dividend income	6,458	6,458
Subsidy income	489,686	—
Other	3,266	237
Total non-operating income	507,128	8,707
Non-operating expenses		
Interest expenses	35,512	36,755
Foreign exchange losses	81,511	615,877
Financing expenses	7,332	7,379
Share issuance expenses	25,432	—
Total non-operating expenses	149,788	660,013
Ordinary loss	(3,271,483)	(4,839,676)
Extraordinary losses		
Loss on retirement of non-current assets	7,382	46
Total extraordinary losses	7,382	46
Loss before income taxes	(3,278,865)	(4,839,723)
Income taxes - current	2,077	1,899
Total income taxes	2,077	1,899
Net loss	(3,280,943)	(4,841,623)
Net loss attributable to owners of parent	(3,280,943)	(4,841,623)



Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2019	For the nine months ended October 31, 2020
Net loss	(3,280,943)	(4,841,623)
Other comprehensive income		
Valuation difference on available-for-sale securities	(107,640)	1,819,173
Foreign currency translation adjustment	8,708	504,736
Total other comprehensive income	(98,931)	2,323,910
Comprehensive income	(3,379,874)	(2,517,713)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(3,379,874)	(2,517,713)
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 ¥2,523,461 thousand and retained earnings increased by ¥5,046,923 thousand as a result of covering the loss in retained earnings brought forward as of June 9, 2020 based on the resolution of the 7th Annual General Meeting of Shareholders held on April 28, 2020. Additionally, capital stock and legal capital surplus each increased by ¥548 thousand due to the exercise of share acquisition rights as stock options during the nine months ended October 31, 2020.

As a result, at the end of the third quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥5,561,072 thousand, ¥9,272,515 thousand and ¥(8,812,246) thousand, respectively.