

Consolidated Financial Results for the Six Months Ended July 31, 2020 [Japanese GAAP]



September 14, 2020

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 Stock exchange listing: Tokyo Stock Exchange
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 Scheduled date of filing quarterly securities report: September 14, 2020
 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, 2020 (February 1, 2020 to July 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	%
Six months ended July 31, 2020	—	—	(2,570)	—	(3,205)	—	(3,207)	—
July 31, 2019	427	2.9	(2,385)	—	(2,039)	—	(2,048)	—

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

Six months ended July 31, 2019: ¥(2,162) million [–%]

	Net income per share	Diluted net income per share
Six months ended	Yen	Yen
July 31, 2020	(61.94)	—
July 31, 2019	(40.62)	—

(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, 2020	13,796	9,019	64.3	171.20
As of January 31, 2020	15,605	10,930	69.4	209.05

(Reference) Equity: As of July 31, 2020: ¥8,865 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):
 - July 31, 2020: 51,785,389 shares
 - January 31, 2020: 51,785,023 shares
 - 2) Total number of treasury shares at the end of the period:
 - July 31, 2020: 196 shares
 - January 31, 2020: 196 shares
 - 3) Average number of shares during the period:
 - Six months ended July 31, 2020: 51,784,931 shares
 - Six months ended July 31, 2019: 50,440,452 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, 2020 (from February 1, 2020 to July 31, 2020), the global economy deteriorated rapidly due to the spread of the new coronavirus pandemic and sharply declining crude oil prices. In the US, GDP (Gross Domestic Product) for the April-June quarter of 2020 recorded the largest negative drop since the start of the statistics. In Japan, the real GDP growth rate for the April-June quarter of 2020 fell significantly year on year, recording the biggest decline since the end of the World War II. Currently, the economic situation both in Japan and the US is highly unpredictable, faced with the issue of the new coronavirus infection.

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. We are currently receiving continual advice from the Pharmaceuticals and Medical Devices Agency (PMDA), 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 (from February 2020 to January 2021). Also, in parallel with this, we are steadily proceeding with preparations for the follow-up after the launch of SB623 in Japan, and led by the Medical Affairs Division, the development of a system for supporting medical institutions is near completion. 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.” The Group, however, subsequently continued to carry out additional detailed analyses of the trial data. 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. Following this result, the Group started preparing for the commencement of late-phase clinical trials for the next 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 for the application for approval for manufacture and sales of SB623 for treatment

of chronic traumatic brain injury in Japan by the end of this fiscal year. The Group will also defer the global Phase 3 clinical trials in the SB623 development program for treatment of traumatic brain injury, which had been planned to be commenced during this fiscal year, until the next fiscal year or later.

Under these circumstances, during the six months ended July 31, 2020, the Company recorded ¥1,798 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 ¥2,570 million (operating loss of ¥2,385 million for the same period in the previous fiscal year), ordinary loss was ¥3,205 million (ordinary loss of ¥2,039 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥3,207 million (net loss attributable to owners of parent of ¥2,048 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 Additional 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 second quarter of the fiscal year under review was ¥11,728 million, a decrease of ¥2,897 million compared to the end of the previous fiscal year (¥14,626 million), mainly due to a decrease of ¥2,738 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 ¥2,068 million, an increase of ¥1,089 million compared to the end of the previous fiscal year (¥979 million), mainly due to increases of ¥53 million in property, plant and equipment and ¥1,016 million in investment securities.

(Current liabilities)

The balance of current liabilities at the end of the second quarter of the fiscal year under review was ¥2,619 million, an increase of ¥1,444 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 ¥155 million in accounts payable - other.

(Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was ¥2,157 million, a decrease of ¥1,342 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 ¥257 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the second quarter of the fiscal year under review were ¥9,019 million, a decrease of ¥1,910 million compared to the end of the previous fiscal year (¥10,930 million), mainly due to an increase of ¥1,246 million in accumulated other comprehensive income, despite the recording of ¥3,207

million in net loss attributable to owners of parent.

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 ¥10,907 million, a decrease of ¥2,738 million compared to the end of the previous fiscal year (¥13,646 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, 2020 was ¥2,501 million (an outflow of ¥2,788 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥3,205 million recorded, an increase of ¥78 million in provision for bonuses, and decreases of ¥74 million in advance payments and ¥158 million in accounts payable - other.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2020 was ¥88 million (an outflow of ¥12 million for the same period in the previous fiscal year). This was due to outflows of ¥66 million for purchase of property, plant and equipment and ¥21 million for purchase of intangible assets.

(Cash flows from financing activities)

Net cash used in financing activities for the six months ended July 31, 2020 was ¥4 million (an inflow of ¥7,036 million for the same period in the previous fiscal year). This was primarily due to an increase of ¥500 million in short-term loans payable and outflows of ¥500 million for repayments of long-term loans payable and ¥4 million for payments of financing expenses.

(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 July 31, 2020
Assets		
Current assets		
Cash and deposits	13,646,073	10,907,649
Supplies	469,600	448,776
Advance payments	375,790	289,302
Other	134,585	82,638
Total current assets	14,626,050	11,728,367
Non-current assets		
Property, plant and equipment	123,943	177,457
Intangible assets	13,650	33,464
Investments and other assets		
Investment securities	824,522	1,840,644
Other	17,248	16,884
Total investments and other assets	841,770	1,857,528
Total non-current assets	979,364	2,068,449
Total assets	15,605,414	13,796,816
Liabilities		
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	141,717
Accrued expenses	319,205	243,035
Provision for bonuses	20,698	96,704
Other	38,578	38,044
Total current liabilities	1,175,232	2,619,502
Non-current liabilities		
Long-term loans payable	3,500,000	1,900,000
Deferred tax liabilities	—	257,412
Total non-current liabilities	3,500,000	2,157,412
Total liabilities	4,675,232	4,776,914
Net assets		
Shareholders' equity		
Capital stock	8,083,986	5,560,978
Capital surplus	11,795,428	9,272,421
Retained earnings	(9,017,546)	(7,177,929)
Treasury shares	(853)	(853)
Total shareholders' equity	10,861,014	7,654,617
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(175,453)	583,255
Foreign currency translation adjustment	140,157	627,720
Total accumulated other comprehensive income	(35,296)	1,210,976
Subscription rights to shares	104,464	154,308
Total net assets	10,930,182	9,019,902
Total liabilities and net assets	15,605,414	13,796,816

(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, 2019	For the six months ended July 31, 2020
Operating revenue	427,768	—
Operating expenses		
Research and development expenses	2,013,617	1,798,667
Other selling, general and administrative expenses	799,355	772,331
Total operating expenses	2,812,972	2,570,999
Operating loss	(2,385,204)	(2,570,999)
Non-operating income		
Interest income	5,478	1,556
Dividend income	6,458	6,458
Subsidy income	493,638	—
Other	3,249	237
Total non-operating income	508,825	8,252
Non-operating expenses		
Interest expenses	24,025	23,209
Foreign exchange losses	108,588	614,468
Financing expenses	5,224	5,238
Share issuance expenses	25,432	—
Total non-operating expenses	163,270	642,916
Ordinary loss	(2,039,648)	(3,205,662)
Extraordinary losses		
Loss on retirement of non-current assets	7,442	46
Total extraordinary losses	7,442	46
Loss before income taxes	(2,047,090)	(3,205,709)
Income taxes - current	1,760	1,596
Total income taxes	1,760	1,596
Net loss	(2,048,851)	(3,207,306)
Net loss attributable to owners of parent	(2,048,851)	(3,207,306)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2019	For the six months ended July 31, 2020
Net loss	(2,048,851)	(3,207,306)
Other comprehensive income		
Valuation difference on available-for-sale securities	(149,619)	758,708
Foreign currency translation adjustment	35,493	487,563
Total other comprehensive income	(114,125)	1,246,272
Comprehensive income	(2,162,977)	(1,961,033)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(2,162,977)	(1,961,033)
Comprehensive income attributable to non-controlling interests	—	—

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2019	For the six months ended July 31, 2020
Cash flows from operating activities		
Loss before income taxes	(2,047,090)	(3,205,709)
Depreciation	18,724	17,106
Share based compensation expenses	23,735	50,543
Increase (decrease) in provision for bonuses	48,021	78,176
Interest and dividend income	(11,937)	(8,015)
Foreign exchange losses (gains)	(7,404)	614,763
Subsidy income	(493,638)	—
Interest expenses	24,025	23,209
Share issuance expenses	25,432	—
Financing expenses	5,224	5,238
Loss on retirement of non-current assets	7,442	46
Decrease (increase) in inventories	(211,392)	9,909
Decrease (increase) in advance payments	(36,840)	74,559
Increase (decrease) in accounts payable - other	(93,035)	(158,691)
Increase (decrease) in accrued expenses	(14,458)	(67,071)
Increase (decrease) in income taxes payable - factor based tax	(22,606)	(464)
Decrease (increase) in other current assets	(1,322)	49,958
Increase (decrease) in other current liabilities	7,500	45,359
Other	1,298	(14,093)
Subtotal	(2,778,322)	(2,485,173)
Interest and dividends received	11,937	8,015
Interest expenses paid	(21,660)	(23,459)
Income taxes paid	(928)	(1,031)
Net cash provided by (used in) operating activities	(2,788,974)	(2,501,649)
Cash flows from investing activities		
Purchase of property, plant and equipment	(4,483)	(66,924)
Purchase of intangible assets	—	(21,068)
Payments of leasehold deposits	(7,735)	(100)
Net cash provided by (used in) investing activities	(12,218)	(88,093)
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	—	500,000
Repayments of long-term loans payable	(33,380)	(500,000)
Payments of financing expenses	(5,786)	(4,257)
Proceeds from issuance of shares	7,072,167	—
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	3,305	209
Net cash provided by (used in) financing activities	7,036,306	(4,048)
Effect of exchange rate change on cash and cash equivalents	44,683	(144,633)
Net increase (decrease) in cash and cash equivalents	4,279,797	(2,738,424)
Cash and cash equivalents at beginning of period	12,453,031	13,646,073
Cash and cash equivalents at end of period	16,732,829	10,907,649

(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 ¥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 ¥454 thousand due to the exercise of share acquisition rights as stock options during the six months ended July 31, 2020.

As a result, at the end of the second quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥5,560,978 thousand, ¥9,272,421 thousand and ¥(7,177,929) thousand, respectively.