

Consolidated Financial Results for the Three Months Ended April 30, 2020 [Japanese GAAP]



June 12, 2020

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 Stock exchange listing: Tokyo Stock Exchange
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 Scheduled date of filing quarterly securities report: June 12, 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 Three Months Ended April 30, 2020 (February 1, 2020 to April 30, 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	%
Three months ended April 30, 2020	—	—	(1,242)	—	(1,505)	—	(1,507)	—
April 30, 2019	189	19.5	(1,248)	—	(727)	—	(736)	—

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

Three months ended April 30, 2019: ¥(886) million [—%]

	Net income per share	Diluted net income per share
	Yen	Yen
Three months ended April 30, 2020	(29.10)	—
April 30, 2019	(14.80)	—

(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, 2020	14,197	9,748	67.8	185.77
As of January 31, 2020	15,605	10,930	69.4	209.05

(Reference) Equity: As of April 30, 2020: ¥9,620 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	—				
Fiscal year ending January 31, 2021 (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, 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
First half	—	—	(2,710)	—	(2,759)	—	(2,760)	—	(53.30)
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):
 - April 30, 2020: 51,785,023 shares
 - January 31, 2020: 51,785,023 shares
 - 2) Total number of treasury shares at the end of the period:
 - April 30, 2020: 196 shares
 - January 31, 2020: 196 shares
 - 3) Average number of shares during the period
 - Three months ended April 30, 2020: 51,784,827 shares
 - Three months ended April 30, 2019: 49,732,818 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.

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review	2
(1) Explanation of Operating Results	2
(2) Explanation of Financial Position	3
(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information	3
2. Quarterly Consolidated Financial Statements and Primary Notes	4
(1) Quarterly Consolidated Balance Sheets	4
(2) Quarterly Consolidated Statements of Income and Comprehensive Income	5
Quarterly Consolidated Statements of Income	5
For the Three Months Ended April 30	5
Quarterly Consolidated Statements of Comprehensive Income	6
For the Three Months Ended April 30	6
(3) Notes to the Quarterly Consolidated Financial Statements	7
(Notes on going concern assumption)	7
(Notes in the event of significant changes in shareholders' equity)	7

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

(1) Explanation of Operating Results

During the three months ended April 30, 2020 (from February 1, 2020 to April 30, 2020), the global economy deteriorated rapidly due to the spread of the new coronavirus pandemic and sharply declining crude oil prices.

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 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). In the US, it was designated as RMAT by the U.S. Food and Drug Administration (FDA). Since RMAT is FDA’s system for promoting the practical use of regenerative medicine, the Group will enhance the business strategy so that SB623 will be able to receive early approval in the US in the future. By leveraging these systems, the Group plans to commence Phase 3 clinical trials in the development program for treatment of chronic traumatic brain injury globally including Europe in addition to the US by the end of the fiscal year ending January 31, 2021 (from February 2020 to January 2021). Specific designs of the clinical trials and the contents of the development will be announced promptly upon being finalized. In addition, as for the SB623 for the treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”), the Group has made the decision to continue development with the aim of global expansion, and will furthermore determine the design of the next clinical trials and consider implementing a trial after the fiscal year ending January 31, 2021. Also, to expand into new indications for SB623, we entered into a business alliance with OCUMENSION (HONG KONG) LIMITED of China in March 2020. The two companies plan to jointly develop SB623 and MSC2 cell medicine in the Greater China area (Mainland China, Hong Kong, Macao, and Taiwan) for indications such as retinitis pigmentosa and dry age-related macular degeneration.

Under these circumstances, during the three months ended April 30, 2020, the Company recorded ¥857 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 ¥1,242 million (operating loss of ¥1,248 million for the same period in the previous fiscal year), ordinary loss was ¥1,505 million (ordinary loss of ¥727 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,507 million (net loss attributable to owners of parent of ¥736 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 first quarter of the fiscal year under review was ¥13,096 million, a decrease of ¥1,529 million compared to the end of the previous fiscal year (¥14,626 million), mainly due to a decrease of ¥1,433 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 ¥1,101 million, an increase of ¥122 million compared to the end of the previous fiscal year (¥979 million), mainly due to increases of ¥32 million in property, plant and equipment and ¥78 million in investment securities.

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥949 million, a decrease of ¥226 million compared to the end of the previous fiscal year (¥1,175 million), mainly due to decreases of ¥129 million in accounts payable - other and ¥156 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥3,500 million, unchanged from the end of the previous fiscal year (¥3,500 million).

(Net assets)

Total net assets at the end of the first quarter of the fiscal year under review were ¥9,748 million, a decrease of ¥1,181 million compared to the end of the previous fiscal year (¥10,930 million), mainly due to an increase of ¥301 million in accumulated other comprehensive income, despite the recording of ¥1,507 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 first half and 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 April 30, 2020
Assets		
Current assets		
Cash and deposits	13,646,073	12,212,733
Supplies	469,600	457,854
Advance payments	375,790	349,973
Other	134,585	75,500
Total current assets	14,626,050	13,096,062
Non-current assets		
Property, plant and equipment	123,943	156,905
Intangible assets	13,650	24,489
Investments and other assets		
Investment securities	824,522	903,099
Other	17,248	17,116
Total investments and other assets	841,770	920,216
Total non-current assets	979,364	1,101,611
Total assets	15,605,414	14,197,674
Liabilities		
Current liabilities		
Current portion of long-term loans payable	500,000	500,000
Accounts payable - other	296,749	167,402
Accrued expenses	319,205	162,970
Provision for bonuses	20,698	57,471
Other	38,578	61,162
Total current liabilities	1,175,232	949,007
Non-current liabilities		
Long-term loans payable	3,500,000	3,500,000
Total non-current liabilities	3,500,000	3,500,000
Total liabilities	4,675,232	4,449,007
Net assets		
Shareholders' equity		
Capital stock	8,083,986	8,083,986
Capital surplus	11,795,428	11,795,428
Retained earnings	(9,017,546)	(10,524,614)
Treasury shares	(853)	(853)
Total shareholders' equity	10,861,014	9,353,947
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(175,453)	(96,876)
Foreign currency translation adjustment	140,157	363,232
Total accumulated other comprehensive income	(35,296)	266,356
Subscription rights to shares	104,464	128,363
Total net assets	10,930,182	9,748,666
Total liabilities and net assets	15,605,414	14,197,674

(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, 2019	For the three months ended April 30, 2020
Operating revenue	189,395	—
Operating expenses		
Research and development expenses	1,095,647	857,217
Other selling, general and administrative expenses	342,594	385,033
Total operating expenses	1,438,242	1,242,251
Operating loss	(1,248,846)	(1,242,251)
Non-operating income		
Interest income	2,270	742
Dividend income	6,458	6,458
Foreign exchange gains	237,655	—
Subsidy income	290,018	—
Other	41	237
Total non-operating income	536,443	7,438
Non-operating expenses		
Interest expenses	11,658	11,604
Foreign exchange losses	—	256,212
Financing expenses	3,105	3,095
Total non-operating expenses	14,763	270,913
Ordinary loss	(727,166)	(1,505,726)
Extraordinary losses		
Loss on retirement of non-current assets	7,522	47
Total extraordinary losses	7,522	47
Loss before income taxes	(734,688)	(1,505,773)
Income taxes - current	1,458	1,294
Total income taxes	1,458	1,294
Net loss	(736,147)	(1,507,067)
Net loss attributable to owners of parent	(736,147)	(1,507,067)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2019	For the three months ended April 30, 2020
Net loss	(736,147)	(1,507,067)
Other comprehensive income		
Valuation difference on available-for-sale securities	29,062	78,577
Foreign currency translation adjustment	(179,672)	223,075
Total other comprehensive income	(150,609)	301,652
Comprehensive income	(886,756)	(1,205,415)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(886,756)	(1,205,415)
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