

Consolidated Financial Results
for the Six Months Ended July 31, 2019
[Japanese GAAP]



September 13, 2019

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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 13, 2019
 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, 2019 (February 1, 2019 to July 31, 2019)

(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, 2019	427	2.9	(2,385)	—	(2,039)	—	(2,048)	—
July 31, 2018	415	66.3	(1,615)	—	(1,040)	—	(1,041)	—

(Note) Comprehensive income: Six months ended July 31, 2019: ¥(2,162) million [-%]

Six months ended July 31, 2018: ¥(1,150) million [-%]

	Net income per share	Diluted net income per share
Six months ended	Yen	Yen
July 31, 2019	(40.62)	—
July 31, 2018	(22.01)	—

(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, 2019	18,337	13,870	75.3	267.00
As of January 31, 2019	13,975	8,909	63.5	178.42

(Reference) Equity: As of July 31, 2019: ¥13,812 million

As of January 31, 2019: ¥8,873 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2019	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2020	—	0.00			
Fiscal year ending January 31, 2020 (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, 2020 (February 1, 2019 to January 31, 2020)

(% 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	713	(3.7)	(5,887)	—	(5,390)	—	(5,395)	—	(108.48)

(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, 2019: 51,734,223 shares
 - January 31, 2019: 49,732,868 shares
 - 2) Total number of treasury shares at the end of the period:
 - July 31, 2019: 190 shares
 - January 31, 2019: 190 shares
 - 3) Average number of shares during the period
 - Six months ended July 31, 2019: 50,440,452 shares
 - Six months ended July 31, 2018: 47,338,137 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, 2019 (from February 1, 2019 to July 31, 2019), as evidence of a slowdown in the global economy became more apparent, intensifying international trade frictions, originating in the US, resulted in downward pressure on business sentiment within the US itself. The Japanese economy saw positive growth in real GDP for three consecutive quarters since October 2018 as there was a halt in the decline in exports, the most significant factor weighing down the domestic economy. However, conditions remain unpredictable, with a number of lingering concerns including the strong yen caused by trade friction between the US and China and the consumption tax hike scheduled in October.

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 (RMAT: Regenerative Medicine Advanced Therapy) 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. A Phase 2 clinical trial for the treatment of chronic motor deficit from traumatic brain injury (“development program for treatment of chronic traumatic brain injury”), has been conducted independently by the Group 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. This designation allows the program to receive prioritized consultation and review for pharmaceutical approval from the Pharmaceuticals and Medical Devices Agency (PMDA). By utilizing this advantage, as well as the conditional and time-limited marketing approval system for regenerative medical products in Japan, the Group aims to apply for approval for manufacture and sales of regenerative medical products during the fiscal year ending January 31, 2020 (from February 2019 to January 2020). In parallel with this, as an initiative to follow-up on its launch, the Group concluded a basic transaction agreement regarding the commercial distribution of regenerative medicine products with SUZUKEN CO., LTD. in August 2019. In addition, in April 2019, SB623 was designated as an Advanced Therapy Medicinal Product (ATMP) by the European Medicines Agency (EMA), and Phase 3 clinical trials in the development program for treatment of chronic traumatic brain injury is scheduled to commence globally including Europe in addition to the US. Details of the plan is to be featured in the financial results briefing session for institutional investors and analysts on September 19, 2019 (Note).

Meanwhile, as for the Phase 2b clinical trial of SB623 for the treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”), which has been conducted by the Group jointly with Sumitomo Dainippon Pharma Co., Ltd. in the US with 163 patients, the analytic results released in January 2019 indicated that it did not meet the primary endpoint. However, the decision has been made to continue development with the aim of global expansion. The Group will proceed with the analysis of detailed results, determine the design of the next clinical trials reflecting the results of this analysis, and consider implementing a trial from next fiscal year onward.

To advance these businesses, in May 2019, the Group raised ¥7,097 million from the issue of new shares through overseas subscription. These funds were raised in expectation of sales demand for SB623 in Japan, the

US and Europe. The Group plans to use the funds to diversify its contracted manufacturers and secure inventory of SB623, which will initially be sold for the treatment of chronic traumatic brain injury within Japan, in order that the Group may increase the mass-production capability of SB623 and build its stable supply system.

Under these circumstances, for the six months ended July 31, 2019, operating revenue totaled ¥427 million (operating revenue of ¥415 million for the same period in the previous fiscal year), reflecting proceeds from the development support fee, etc. received from the joint development and sales license agreements of SB623 concluded by the Group with Sumitomo Dainippon Pharma Co., Ltd. in North America. Operating loss was ¥2,385 million (operating loss of ¥1,615 million for the same period in the previous fiscal year), due to the recording of ¥2,013 million of research and development expenses as clinical trial expenses and other expenses related to the two abovementioned development programs for the treatments of chronic motor deficit from ischemic stroke and chronic motor deficit from traumatic brain injury. Ordinary loss was ¥2,039 million (ordinary loss of ¥1,040 million for the same period in the previous fiscal year) mainly due to the recording of ¥493 million of non-operating income as a grant from the California Institute for Regenerative Medicine (CIRM), while net loss attributable to owners of parent was ¥2,048 million (net loss attributable to owners of parent of ¥1,041 million for the same period of 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: Materials used at the financial results briefing session for institutional investors and analysts on September 19, 2019 are to be posted on the Company's website on the same day.

(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 ¥17,584 million, an increase of ¥4,525 million compared to the end of the previous fiscal year (¥13,058 million), mainly due to an increase of ¥4,279 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 ¥752 million, a decrease of ¥164 million compared to the end of the previous fiscal year (¥917 million), mainly due to a decrease of ¥149 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 ¥466 million, a decrease of ¥600 million compared to the end of the previous fiscal year (¥1,066 million), mainly due to decreases in accounts payable - other and advance received of ¥92 million and ¥489 million, respectively.

(Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was ¥4,000 million, unchanged from the end of the previous fiscal year (¥4,000 million).

(Net assets)

Total net assets at the end of the second quarter of the fiscal year under review were ¥13,870 million, an increase of ¥4,961 million compared to the end of the previous fiscal year (¥8,909 million), mainly due to the recording of ¥2,048 million in net loss attributable to owners of parent, and increases of ¥3,548 million each in capital stock and capital surplus due to the issue of new shares through overseas subscription.

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 ¥16,732 million, an increase of ¥4,279 million compared to the end of the previous fiscal year (¥12,453 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, 2019 was ¥2,788 million (an outflow of ¥2,137 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥2,047 million recorded and subsidy income of ¥493 million.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2019 was ¥12 million (an outflow of ¥3 million for the same period in the previous fiscal year). This was due to outflows of ¥4 million for purchase of property, plant and equipment and ¥7 million for payments of leasehold deposits.

(Cash flows from financing activities)

Net cash provided by financing activities for the six months ended July 31, 2019 was ¥7,036 million (an inflow of ¥11,493 million for the same period in the previous fiscal year). This was primarily due to an outflow of ¥33 million for repayments of long-term loans payable and proceeds from issuance of shares of ¥7,072 million.

(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 15, 2019.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2019	As of July 31, 2019
Assets		
Current assets		
Cash and deposits	12,453,031	16,732,829
Supplies	—	211,392
Advance payments	519,009	553,893
Other	86,872	86,715
Total current assets	13,058,913	17,584,830
Non-current assets		
Property, plant and equipment	74,165	54,629
Intangible assets	2,601	1,234
Investments and other assets		
Investment securities	828,828	679,208
Other	11,467	17,662
Total investments and other assets	840,295	696,870
Total non-current assets	917,061	752,734
Total assets	13,975,975	18,337,564
Liabilities		
Current liabilities		
Current portion of long-term loans payable	33,380	—
Accounts payable - other	315,509	223,143
Advance received	489,282	—
Provision for bonuses	—	47,663
Other	228,682	195,975
Total current liabilities	1,066,854	466,781
Non-current liabilities		
Long-term loans payable	4,000,000	4,000,000
Total non-current liabilities	4,000,000	4,000,000
Total liabilities	5,066,854	4,466,781
Net assets		
Shareholders' equity		
Capital stock	9,431,953	8,075,442
Capital surplus	13,143,396	11,786,884
Retained earnings	(13,675,118)	(5,908,682)
Treasury shares	(837)	(837)
Total shareholders' equity	8,899,393	13,952,807
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(171,147)	(320,767)
Foreign currency translation adjustment	145,293	180,787
Total accumulated other comprehensive income	(25,854)	(139,979)
Subscription rights to shares	35,580	57,955
Total net assets	8,909,120	13,870,783
Total liabilities and net assets	13,975,975	18,337,564

(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, 2018	For the six months ended July 31, 2019
Operating revenue	415,597	427,768
Operating expenses		
Research and development expenses	1,669,146	2,013,617
Other selling, general and administrative expenses	362,304	799,355
Total operating expenses	2,031,451	2,812,972
Operating loss	(1,615,853)	(2,385,204)
Non-operating income		
Interest income	9,500	5,478
Dividend income	—	6,458
Foreign exchange gains	165,198	—
Subsidy income	472,185	493,638
Other	6,413	3,249
Total non-operating income	653,296	508,825
Non-operating expenses		
Interest expenses	15,868	24,025
Foreign exchange losses	—	108,588
Financing expenses	4,971	5,224
Share issuance expenses	56,652	25,432
Total non-operating expenses	77,492	163,270
Ordinary loss	(1,040,048)	(2,039,648)
Extraordinary income		
Gain on reversal of subscription rights to shares	279	—
Total extraordinary income	279	—
Extraordinary losses		
Loss on retirement of non-current assets	—	7,442
Total extraordinary losses	—	7,442
Loss before income taxes	(1,039,769)	(2,047,090)
Income taxes - current	1,993	1,760
Total income taxes	1,993	1,760
Net loss	(1,041,762)	(2,048,851)
Net loss attributable to owners of parent	(1,041,762)	(2,048,851)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2018	For the six months ended July 31, 2019
Net loss	(1,041,762)	(2,048,851)
Other comprehensive income		
Valuation difference on available-for-sale securities	—	(149,619)
Foreign currency translation adjustment	(108,783)	35,493
Total other comprehensive income	(108,783)	(114,125)
Comprehensive income	(1,150,546)	(2,162,977)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,150,546)	(2,162,977)
Comprehensive income attributable to non-controlling interests	—	—

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2018	For the six months ended July 31, 2019
Cash flows from operating activities		
Loss before income taxes	(1,039,769)	(2,047,090)
Depreciation	17,791	18,724
Share based compensation expenses	17,291	23,735
Increase (decrease) in provision for bonuses	32,156	48,021
Interest and dividend income	(9,500)	(11,937)
Foreign exchange losses (gains)	(21,546)	(7,404)
Subsidy income	(472,185)	(493,638)
Interest expenses	15,868	24,025
Share issuance expenses	56,652	25,432
Financing expenses	4,971	5,224
Gain on reversal of subscription rights to shares	(279)	—
Loss on retirement of non-current assets	—	7,442
Decrease (increase) in inventories	—	(211,392)
Decrease (increase) in advance payments	(307,350)	(36,840)
Increase (decrease) in accounts payable - other	(284,204)	(93,035)
Increase (decrease) in accrued expenses	(143,376)	(14,458)
Increase (decrease) in income taxes payable - factor based tax	21,199	(22,606)
Decrease (increase) in other current assets	(11,649)	(1,322)
Increase (decrease) in other current liabilities	(6,246)	7,500
Other	(4,383)	1,298
Subtotal	(2,134,560)	(2,778,322)
Interest and dividends received	12,700	11,937
Interest expenses paid	(15,879)	(21,660)
Income taxes paid	(2,598)	(2,365)
Income taxes refund	2,602	1,437
Net cash provided by (used in) operating activities	(2,137,734)	(2,788,974)
Cash flows from investing activities		
Purchase of property, plant and equipment	(3,009)	(4,483)
Payments of leasehold deposits	(747)	(7,735)
Net cash provided by (used in) investing activities	(3,756)	(12,218)
Cash flows from financing activities		
Proceeds from long-term loans payable	500,000	—
Repayments of long-term loans payable	(33,320)	(33,380)
Payments of financing expenses	(5,036)	(5,786)
Proceeds from issuance of shares	—	7,072,167
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	10,932,043	3,305
Proceeds from issuance of subscription rights to shares	100,000	—
Net cash provided by (used in) financing activities	11,493,686	7,036,306
Effect of exchange rate change on cash and cash equivalents	(74,879)	44,683
Net increase (decrease) in cash and cash equivalents	9,277,314	4,279,797
Cash and cash equivalents at beginning of period	4,654,820	12,453,031
Cash and cash equivalents at end of period	13,932,135	16,732,829

(4) Notes to the Quarterly Consolidated Financial Statements

(Notes on going concern assumption)

None

(Notes in the event of significant changes in shareholders' equity)

The Company issued new shares through overseas subscription with a payment date of May 29, 2019. As a result, capital stock and legal capital surplus each increased by ¥3,548,800 thousand. Additionally, capital stock and legal capital surplus each increased by ¥2,332 thousand due to the exercise of share acquisition rights as stock options during the six months ended July 31, 2019.

Capital stock and capital surplus each decreased by ¥4,907,644 thousand and retained earnings increased by ¥9,815,288 thousand as a result of covering the loss in retained earnings brought forward as of June 11, 2019 based on the resolution of the 6th Annual General Meeting of Shareholders held on April 26, 2019.

As a result, at the end of the second quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥8,075,442 thousand, ¥11,786,884 thousand and ¥(5,908,682) thousand, respectively.