Consolidated Financial Results for the Three Months Ended April 30, 2018 [Japanese GAAP]

June 13, 2018

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Stock exchange listing: Tokyo Stock Exchange
Code number: 4592
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Scheduled date of filing quarterly securities report: June 13, 2018
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, 2018 (February 1, 2018 to April 30, 2018)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
April 30, 2018	158	27.9	(1,004)	—	(836)	—	(837)	—
April 30, 2017	123	(80.2)	(1,021)	—	(1,098)	—	(1,097)	—

(Note) Comprehensive income: Three months ended April 30, 2018: ¥(875) million [–%]
Three months ended April 30, 2017: ¥(1,061) million [–%]

	Net income per share	Diluted net income per share
Three months ended	Yen	Yen
April 30, 2018	(18.30)	–
April 30, 2017	(24.24)	–

(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, 2018	8,007	3,486	42.4	72.45
As of January 31, 2018	5,193	853	16.1	18.33

(Reference) Equity: As of April 30, 2018: ¥3,394 million
As of January 31, 2018: ¥833 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended January 31, 2018	–	0.00	–	0.00	0.00
Fiscal year ending January 31, 2019	–				
Fiscal year ending January 31, 2019 (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, 2019 (February 1, 2018 to January 31, 2019)

(% 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	317	(27.0)	(2,305)	—	(2,034)	—	(2,052)	—	(45.00)
Full year	1,025	(109.0)	(3,540)	—	(2,529)	—	(2,564)	—	(56.00)

(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, 2018: 46,850,033 shares
January 31, 2018: 45,492,281 shares

2) Total number of treasury shares at the end of the period:
April 30, 2018: 115 shares
January 31, 2018: 115 shares

3) Average number of shares during the period
Three months ended April 30, 2018: 45,778,038 shares
Three months ended April 30, 2017: 45,273,614 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

The Japanese economy during the three months ended April 30, 2018 (from February 1, 2018 to April 30, 2018) maintained a recovery path due to moderate improvements in personal consumption, as corporate earnings and the employment environment remained robust. The US economy continued to recover, backed by improvements in the employment and income environments, amid growing recovery trend of corporate earnings.

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 medicines 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 medicine 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.

During the three months ended April 30, 2018, patients enrolled in a Phase 2b clinical trial of SB623, which has been conducted in the US, for the treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”), entered a follow-up period of 12 months after the completion of patient enrollment, and the top-line results are scheduled to be announced in the first half of the fiscal year ending January 31, 2020 (February 2019 – July 2019). Regarding this trial, the Group passed the screening in relation to continuation of the trial by an outside Data and Safety Monitoring Board (See Note) when 50% and 75% of the enrollment were completed.

As to the development of SB623 program in Japan, the Group entered into an exclusive licensing agreement concerning development and sales with Teijin Ltd. in 2009; however, both companies agreed to terminate the agreement as of February 14, 2018. As a result, the rights relating to this program in Japan were reverted to the Group, and going forward, the Group will promote the development for the treatment of chronic stroke as an indication in Japan.

Regarding a Phase 2 clinical trial of SB623, which has been conducted in the US and Japan, for the treatment of chronic motor deficit from traumatic brain injury (“development program for treatment of chronic traumatic brain injury”), the first patient (with an objective of 52 participants; double-blind trial) was enrolled in the US in July 2016, and in Japan in October 2016. Although the objective was to enroll 52 patients, the number had in the end risen to 61 patients in April 2018. Going forward, the Group aims to utilize the conditional and time-limited early authorization system in Japan, and is striving for the delivery of a product to the market faster than any other SB623 development programs after a follow-up period of 6 months. Specifically, the Group aims to announce the results during the fiscal year ending January 31, 2019 (from February 1, 2018 to January 31, 2019) and apply for approval in the fiscal year ending January 31, 2020 (from February 1, 2019 to January 31, 2020). Regarding this program, the Group received approval from the US Food and Drug Administration (FDA) and the Pharmaceuticals and Medical Devices Agency (PMDA) to initiate Phase 2 clinical trials without conducting Phase 1 clinical trials, in view of results of the previous Phase 1/2a clinical trials for chronic stroke, which was conducted in the US. Regarding this trial, the Group again passed the screening in relation to continuation of the trial by an outside Data and Safety Monitoring Board (See Note) when 50%, 75% and 100% of the enrollment was completed. As for this program, after the completion of the Phase 2 clinical trial, the Group aims to utilize the conditional and time-limited marketing approval system (early approval system) for regenerative medical products in Japan, which started under the Revised Pharmaceutical Affairs Act, and strives

for the delivery of a product to the market in Japan earlier than in any other region in the world.

As these two clinical trials were progressing steadily, the Group issued the 13th Share Acquisition Rights with an exercise price adjustment clause by third-party allotment in March 2018 (estimated procurement amount of ¥15,290 million, and an exercise period of share acquisition rights until April 2021). The funds procured from the issuance of the share acquisition rights are to be allocated as growth funds for activities such as: (1) the establishment of manufacturing, logistics, and sales systems for SB623 following its launch; (2) development related to programs for the treatment of chronic stroke in Japan, and research and development to expand markets for future SB623 sales; and (3) research and development to expand new adaptations for SB623 and introduce new substances. As well as building capital through the fund procurement, the Group also intends to steadily resolve business-related issues that are important for the medium- and long-term growth of the Group, such as the development of markets and research and development to expand target diseases, and the establishment of manufacturing, logistics and sales systems appropriate for the market by allocating the funds procured as funds for growth investment with the aim of improving corporate value.

Under these circumstances, for the three months ended April 30, 2018, operating revenue totaled ¥158 million (operating revenue of ¥123 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 ¥1,004 million (operating loss of ¥1,021 million for the same period in the previous fiscal year), due to the recording of ¥972 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 ¥836 million (ordinary loss of ¥1,098 million for the same period in the previous fiscal year) mainly due to the recording of ¥135 million of non-operating income as a grant from the CIRM and ¥47 million of foreign exchange gains, and net loss attributable to owners of parent was ¥837 million (net loss attributable to owners of parent of ¥1,097 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) Data and Safety Monitoring Board is an organization to be established to monitor adverse events, modification and termination of trials, and information which may affect the participant's willingness to continue trials, evaluate progress of clinical trials and safety data as well as recommend continuation, modification or termination of trials.

(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 ¥7,897 million, an increase of ¥2,820 million compared to the end of the previous fiscal year (¥5,076 million), mainly due to an increase of ¥2,572 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 ¥110 million, a decrease of ¥6 million compared to the end of the previous fiscal year (¥116 million), mainly due to a decrease of ¥5 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥1,803 million, a decrease of ¥302 million compared to the end of the previous fiscal year (¥2,106 million), mainly due to decreases of ¥131 million in advance received and ¥122 million in accrued expenses included in other of current liabilities.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥2,716 million, an increase of ¥483 million compared to the end of the previous fiscal year (¥2,233 million), due to an increase of ¥483 million in long-term loans payable.

(Net assets)

Total net assets at the end of the first quarter of the fiscal year under review were ¥3,486 million, an increase of ¥2,633 million compared to the end of the previous fiscal year (¥853 million), mainly due to increases of ¥1,717 million each in capital stock and capital surplus due to the exercise of share acquisition rights with an exercise price adjustment clause, despite the recording of ¥837 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 13, 2018.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2018	As of April 30, 2018
Assets		
Current assets		
Cash and deposits	4,654,820	7,226,881
Advance payments	372,901	623,007
Other	49,103	47,483
Total current assets	5,076,825	7,897,372
Non-current assets		
Property, plant and equipment	100,906	95,204
Intangible assets	5,351	4,675
Investments and other assets	10,470	10,253
Total non-current assets	116,728	110,133
Total assets	5,193,554	8,007,506
Liabilities		
Current liabilities		
Current portion of long-term loans payable	66,640	66,640
Advance received	1,292,269	1,160,496
Provision for bonuses	—	15,644
Other	748,014	561,146
Total current liabilities	2,106,923	1,803,926
Non-current liabilities		
Long-term loans payable	2,233,380	2,716,720
Total non-current liabilities	2,233,380	2,716,720
Total liabilities	4,340,303	4,520,646
Net assets		
Shareholders' equity		
Capital stock	3,875,072	5,593,055
Capital surplus	7,586,514	9,304,498
Retained earnings	(10,754,555)	(11,592,081)
Treasury shares	(180)	(180)
Total shareholders' equity	706,851	3,305,292
Accumulated other comprehensive income		
Foreign currency translation adjustment	126,936	88,816
Total accumulated other comprehensive income	126,936	88,816
Subscription rights to shares	19,463	92,750
Total net assets	853,251	3,486,859
Total liabilities and net assets	5,193,554	8,007,506

(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, 2017	For the three months ended April 30, 2018
Operating revenue	123,870	158,452
Operating expenses		
Research and development expenses	929,145	972,478
Other selling, general and administrative expenses	216,489	190,288
Total operating expenses	1,145,634	1,162,767
Operating loss	(1,021,764)	(1,004,315)
Non-operating income		
Interest income	3,811	7,058
Foreign exchange gains	–	47,524
Subsidy income	–	135,640
Other	168	35
Total non-operating income	3,979	190,258
Non-operating expenses		
Interest expenses	4,415	7,834
Foreign exchange losses	65,324	–
Financing expenses	11,034	2,954
Share issuance expenses	–	11,631
Total non-operating expenses	80,774	22,420
Ordinary loss	(1,098,559)	(836,478)
Extraordinary income		
Gain on reversal of subscription rights to shares	1,716	67
Total extraordinary income	1,716	67
Loss before income taxes	(1,096,842)	(836,410)
Income taxes - current	485	1,114
Total income taxes	485	1,114
Net loss	(1,097,327)	(837,525)
Net loss attributable to owners of parent	(1,097,327)	(837,525)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2017	For the three months ended April 30, 2018
Net loss	(1,097,327)	(837,525)
Other comprehensive income		
Foreign currency translation adjustment	35,860	(38,119)
Total other comprehensive income	35,860	(38,119)
Comprehensive income	(1,061,467)	(875,645)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,061,467)	(875,645)
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)

The Company received payment due to the issue of shares in accordance with the partial exercise of the 13th Share Acquisition Rights (share acquisition rights with an exercise price adjustment clause by third-party allotment) issued on April 6, 2018. As a result, capital stock and legal capital surplus each increased by ¥1,710,100 thousand. Additionally, capital stock and legal capital surplus each increased by ¥7,883 thousand due to the exercise of share acquisition rights as stock options during the three months ended April 30, 2018.

As a result, at the end of the first quarter of the fiscal year under review, capital stock was ¥5,593,055 thousand and capital surplus was ¥9,304,498 thousand.