

# Consolidated Financial Results for the Nine Months Ended October 31, 2018 [Japanese GAAP]



December 14, 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: December 14, 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 Nine Months Ended October 31, 2018 (February 1, 2018 to October 31, 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	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Nine months ended October 31, 2018	568	53.2	(2,479)	—	(1,547)	—	(1,549)	—
October 31, 2017	371	(51.0)	(3,169)	—	(3,164)	—	(3,158)	—

(Note) Comprehensive income: Nine months ended October 31, 2018: ¥(1,783) million [–%]

Nine months ended October 31, 2017: ¥(3,188) million [–%]

	Net income per share	Diluted net income per share
	Yen	Yen
Nine months ended October 31, 2018	(32.19)	—
October 31, 2017	(69.68)	—

(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, 2018	13,943	10,188	72.8	204.26
As of January 31, 2018	5,193	853	16.1	18.33

(Reference) Equity: As of October 31, 2018: ¥10,155 million

As of January 31, 2018: ¥833 million

## 2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2018	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2019	—	0.00	—		
Fiscal year ending January 31, 2019 (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, 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
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):  
October 31, 2018: 49,716,929 shares  
January 31, 2018: 45,492,281 shares
  - 2) Total number of treasury shares at the end of the period:  
October 31, 2018: 115 shares  
January 31, 2018: 115 shares
  - 3) Average number of shares during the period  
Nine months ended October 31, 2018: 48,137,734 shares  
Nine months ended October 31, 2017: 45,337,618 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

Both the Japanese and US economies during the nine months ended October 31, 2018 (from February 1, 2018 to October 31, 2018) entered an adjustment phase as corporate earnings, employment environment, and personal consumption that remained robust in both countries showed some stability.

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. A 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, has been in a follow-up period of 12 months after the completion of enrollment of all 163 patients in December 2017, and the trial results are scheduled to be announced in the first half of the fiscal year ending January 31, 2020 (from February 2019 to July 2019). As to the development of the program in Japan, the Group is currently promoting independent development in order to deliver a product for the treatment of chronic stroke to the market earlier than in any other region in the world. 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”), which has been conducted independently by the Group in the US and Japan, completed enrollment of all 61 patients in April 2018. The Group announced positive results on November 1, 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.” Accordingly, as to the development program for treatment of chronic traumatic brain injury in Japan, the Group aims to apply for approval for manufacture and sales of pharmaceuticals during the fiscal year ending January 31, 2020 (from February 2019 to January 2020) utilizing the conditional and time-limited marketing approval system for regenerative medical products in Japan.

Meanwhile, for the financial requirements to support these studies, the Group issued the 13th Share Acquisition Rights with an exercise price adjustment clause by third-party allotment in March 2018, for a procurement amount of ¥11,058 million. As the funds are procured for building capital as well as for growth investment, the Group intends to allocate the funds for the establishment of manufacturing, logistics, and sales systems designed for distribution of SB623 in Japan, and for the development of markets and research and development to expand target diseases. As a part of the preparation for the establishment of logistics and sales systems, the Group has already decided and initiated an effort to conduct joint research with four companies including CareNet, Inc.

Under these circumstances, for the nine months ended October 31, 2018, operating revenue totaled ¥568 million (operating revenue of ¥371 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 ¥2,479 million (operating loss of ¥3,169 million for the same period in the previous fiscal year), due to the recording of ¥2,497 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 ¥1,547 million (ordinary loss of ¥3,164 million for the same period in the previous fiscal year) mainly due to the recording of ¥675 million of non-operating income as a grant from the California Institute for Regenerative Medicine (CIRM) and ¥325 million of foreign exchange gains, while net loss attributable to owners of parent was ¥1,549 million (net loss attributable to owners of parent of ¥3,158 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.

## (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 ¥12,850 million, an increase of ¥7,773 million compared to the end of the previous fiscal year (¥5,076 million), mainly due to an increase of ¥7,337 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 ¥1,093 million, an increase of ¥977 million compared to the end of the previous fiscal year (¥116 million), mainly due to an increase of ¥991 million in investment securities included in investments and other assets.

#### (Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥1,055 million, a decrease of ¥1,051 million compared to the end of the previous fiscal year (¥2,106 million), mainly due to decreases of ¥643 million in advance received and ¥370 million in accounts payable - other included in other of current liabilities.

#### (Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥2,700 million, an increase of ¥466 million compared to the end of the previous fiscal year (¥2,233 million), due to an increase of ¥466 million in long-term loans payable.

#### (Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥10,188 million, an increase of ¥9,334 million compared to the end of the previous fiscal year (¥853 million). This was primarily due to increases of ¥5,552 million each in capital stock and capital surplus due to the exercise of share acquisition rights with an exercise price adjustment clause, despite the listing of ¥1,549 million in net loss attributable to owners of the 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 13, 2018.

## 2. Quarterly Consolidated Financial Statements and Primary Notes

### (1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2018	As of October 31, 2018
<b>Assets</b>		
Current assets		
Cash and deposits	4,654,820	11,992,017
Advance payments	372,901	799,558
Other	49,103	58,454
Total current assets	5,076,825	12,850,031
Non-current assets		
Property, plant and equipment	100,906	85,528
Intangible assets	5,351	3,412
Investments and other assets	10,470	1,004,833
Total non-current assets	116,728	1,093,774
Total assets	5,193,554	13,943,805
<b>Liabilities</b>		
Current liabilities		
Current portion of long-term loans payable	66,640	50,040
Advance received	1,292,269	648,837
Provision for bonuses	–	52,826
Other	748,014	304,002
Total current liabilities	2,106,923	1,055,706
Non-current liabilities		
Long-term loans payable	2,233,380	2,700,000
Total non-current liabilities	2,233,380	2,700,000
Total liabilities	4,340,303	3,755,706
<b>Net assets</b>		
Shareholders' equity		
Capital stock	3,875,072	9,427,528
Capital surplus	7,586,514	13,138,971
Retained earnings	(10,754,555)	(12,304,003)
Treasury shares	(180)	(180)
Total shareholders' equity	706,851	10,262,316
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	–	(8,611)
Foreign currency translation adjustment	126,936	(98,651)
Total accumulated other comprehensive income	126,936	(107,262)
Subscription rights to shares	19,463	33,044
Total net assets	853,251	10,188,098
<b>Total liabilities and net assets</b>	<b>5,193,554</b>	<b>13,943,805</b>

(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, 2017	For the nine months ended October 31, 2018
Operating revenue	371,294	568,894
Operating expenses		
Research and development expenses	2,999,653	2,497,194
Other selling, general and administrative expenses	540,968	551,057
Total operating expenses	3,540,622	3,048,251
Operating loss	(3,169,327)	(2,479,357)
Non-operating income		
Interest income	17,865	11,630
Foreign exchange gains	69,172	325,524
Subsidy income	—	675,374
Other	767	6,644
Total non-operating income	87,805	1,019,173
Non-operating expenses		
Interest expenses	18,087	23,848
Financing expenses	65,112	6,987
Share issuance expenses	—	56,652
Total non-operating expenses	83,200	87,488
Ordinary loss	(3,164,722)	(1,547,672)
Extraordinary income		
Gain on reversal of subscription rights to shares	7,768	568
Total extraordinary income	7,768	568
Loss before income taxes	(3,156,954)	(1,547,103)
Income taxes - current	2,017	2,344
Total income taxes	2,017	2,344
Net loss	(3,158,971)	(1,549,448)
Net loss attributable to owners of parent	(3,158,971)	(1,549,448)



Quarterly Consolidated Statements of Comprehensive Income  
For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2017	For the nine months ended October 31, 2018
Net loss	(3,158,971)	(1,549,448)
Other comprehensive income		
Valuation difference on available-for-sale securities	—	(8,611)
Foreign currency translation adjustment	(29,073)	(225,587)
Total other comprehensive income	(29,073)	(234,198)
Comprehensive income	(3,188,044)	(1,783,646)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(3,188,044)	(1,783,646)
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 ¥5,529,000 thousand. Additionally, capital stock and legal capital surplus each increased by ¥23,456 thousand due to the exercise of share acquisition rights as stock options during the nine months ended October 31, 2018.

As a result, at the end of the third quarter of the fiscal year under review, capital stock was ¥9,427,528 thousand and capital surplus was ¥13,138,971 thousand.