

Consolidated Financial Results for the Nine Months Ended October 31, 2019 [Japanese GAAP]



December 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: December 13, 2019
 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, 2019 (February 1, 2019 to October 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	%
Nine months ended October 31, 2019	424	(25.4)	(3,628)	—	(3,271)	—	(3,280)	—
October 31, 2018	568	53.2	(2,479)	—	(1,547)	—	(1,549)	—

(Note) Comprehensive income: Nine months ended October 31, 2019: ¥(3,379) million [–%]

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

	Net income per share	Diluted net income per share
	Yen	Yen
Nine months ended October 31, 2019	(64.47)	—
October 31, 2018	(32.19)	—

(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, 2019	17,215	12,693	73.3	243.57
As of January 31, 2019	13,975	8,909	63.5	178.42

(Reference) Equity: As of October 31, 2019: ¥12,613 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	447	(39.7)	(5,088)	—	(4,617)	—	(4,619)	—	(90.77)	

(Note) Revision to the financial results forecast announced most recently: Yes

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, 2019: 51,785,023 shares
January 31, 2019: 49,732,868 shares
 - 2) Total number of treasury shares at the end of the period:
October 31, 2019: 190 shares
January 31, 2019: 190 shares
 - 3) Average number of shares during the period
Nine months ended October 31, 2019: 50,888,090 shares
Nine months ended October 31, 2018: 48,137,734 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

During the nine months ended October 31, 2019 (from February 1, 2019 to October 31, 2019), domestic demand in the US remained robust on the back of favorable employment and income environments. However, conditions remain unpredictable, as there is uncertainty over the course of US-China trade talks. The Japanese economy, supported by positive employment conditions, saw a moderate recovery in personal consumption, and this drove a continued moderate recovery.

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, the Group will apply for approval for manufacture and sales of regenerative medical products. Regarding the scheduled time of the application, the Group reviewed its plan so that it could spend enough time preparing the production of commercial-use products to fulfill its responsibility to ensure a stable supply following their launch. As a result, the Group has decided to make the application during the fiscal year ending January 31, 2021 (from February 2020 to January 2021). In addition, overseas, SB623 was designated as an Advanced Therapy Medicinal Product (ATMP) by the European Medicines Agency (EMA) in Europe in April 2019. In the US, it was announced that SB623 for chronic traumatic brain injury was designated as RMAT by the U.S. Food and Drug Administration (FDA) in September 2019. In particular, since RMAT is FDA’s main system related to regenerative medicine, the RMAT designation will provide strong support and a great potential for the approval of SB623 in the US. 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 are now under consideration, and they will be announced promptly upon being finalized.

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 nine months ended October 31, 2019, operating revenue totaled ¥424 million (operating revenue of ¥568 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 ¥3,628 million (operating loss of ¥2,479 million for the same period in the previous fiscal year), due to the recording of ¥2,862 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 ¥3,271 million (ordinary loss of ¥1,547 million for the same period in the previous fiscal year) mainly due to the recording of ¥489 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 ¥3,280 million (net loss attributable to owners of parent of ¥1,549 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 ¥16,409 million, an increase of ¥3,350 million compared to the end of the previous fiscal year (¥13,058 million), mainly due to an increase of ¥3,091 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 ¥806 million, a decrease of ¥110 million compared to the end of the previous fiscal year (¥917 million), mainly due to a decrease of ¥107 million in investment securities.

(Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥522 million, a decrease of ¥544 million compared to the end of the previous fiscal year (¥1,066 million), mainly due to a decrease of ¥489 million in advance received.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third 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 third quarter of the fiscal year under review were ¥12,693 million, an increase of ¥3,784 million compared to the end of the previous fiscal year (¥8,909 million), mainly due to the recording of ¥3,280 million in net loss attributable to owners of the parent, and increases of ¥3,548 million each in capital stock and capital surplus due to the issue of new shares through overseas subscription.

(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information

The consolidated financial results forecast for the fiscal year ending January 31, 2020 has been revised from the forecast released on March 15, 2019. For details, please refer to the “Notice Concerning Revisions to Consolidated Financial Forecasts for the Fiscal Year Ending January 31, 2020” released today.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2019	As of October 31, 2019
Assets		
Current assets		
Cash and deposits	12,453,031	15,544,366
Supplies	—	204,675
Advance payments	519,009	560,158
Other	86,872	100,182
Total current assets	13,058,913	16,409,383
Non-current assets		
Property, plant and equipment	74,165	67,155
Intangible assets	2,601	631
Investments and other assets		
Investment securities	828,828	721,188
Other	11,467	17,455
Total investments and other assets	840,295	738,643
Total non-current assets	917,061	806,429
Total assets	13,975,975	17,215,813
Liabilities		
Current liabilities		
Current portion of long-term loans payable	33,380	—
Accounts payable - other	315,509	290,009
Advance received	489,282	—
Provision for bonuses	—	80,695
Other	228,682	151,516
Total current liabilities	1,066,854	522,220
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	4,522,220
Net assets		
Shareholders' equity		
Capital stock	9,431,953	8,083,986
Capital surplus	13,143,396	11,795,428
Retained earnings	(13,675,118)	(7,140,773)
Treasury shares	(837)	(837)
Total shareholders' equity	8,899,393	12,737,803
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(171,147)	(278,787)
Foreign currency translation adjustment	145,293	154,002
Total accumulated other comprehensive income	(25,854)	(124,785)
Subscription rights to shares	35,580	80,574
Total net assets	8,909,120	12,693,592
Total liabilities and net assets	13,975,975	17,215,813

(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, 2018	For the nine months ended October 31, 2019
Operating revenue	568,894	424,344
Operating expenses		
Research and development expenses	2,497,194	2,862,278
Other selling, general and administrative expenses	551,057	1,190,888
Total operating expenses	3,048,251	4,053,167
Operating loss	(2,479,357)	(3,628,823)
Non-operating income		
Interest income	11,630	7,716
Dividend income	—	6,458
Foreign exchange gains	325,524	—
Subsidy income	675,374	489,686
Other	6,644	3,266
Total non-operating income	1,019,173	507,128
Non-operating expenses		
Interest expenses	23,848	35,512
Foreign exchange losses	—	81,511
Financing expenses	6,987	7,332
Share issuance expenses	56,652	25,432
Total non-operating expenses	87,488	149,788
Ordinary loss	(1,547,672)	(3,271,483)
Extraordinary income		
Gain on reversal of subscription rights to shares	568	—
Total extraordinary income	568	—
Extraordinary losses		
Loss on retirement of non-current assets	—	7,382
Total extraordinary losses	—	7,382
Loss before income taxes	(1,547,103)	(3,278,865)
Income taxes - current	2,344	2,077
Total income taxes	2,344	2,077
Net loss	(1,549,448)	(3,280,943)
Net loss attributable to owners of parent	(1,549,448)	(3,280,943)

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

(Thousand yen)

	For the nine months ended October 31, 2018	For the nine months ended October 31, 2019
Net loss	(1,549,448)	(3,280,943)
Other comprehensive income		
Valuation difference on available-for-sale securities	(8,611)	(107,640)
Foreign currency translation adjustment	(225,587)	8,708
Total other comprehensive income	(234,198)	(98,931)
Comprehensive income	(1,783,646)	(3,379,874)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,783,646)	(3,379,874)
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 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 ¥10,876 thousand due to the exercise of share acquisition rights as stock options during the nine months ended October 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 third quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥8,083,986 thousand, ¥11,795,428 thousand and ¥(7,140,773) thousand, respectively.