

Consolidated Financial Results for the Nine Months Ended October 31, 2023 [Japanese GAAP]



December 14, 2023

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 Stock exchange listing: Tokyo Stock Exchange
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 Scheduled date of filing quarterly securities report: December 14, 2023
 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, 2023 (February 1, 2023 to October 31, 2023)

(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, 2023	—	—	(3,725)	—	(1,837)	—	(1,883)	—
October 31, 2022	—	—	(6,404)	—	437	—	(1,758)	—

(Note) Comprehensive income: Nine months ended October 31, 2023: ¥(3,502) million [–%]
 Nine months ended October 31, 2022: ¥(8,282) million [–%]

	Net income per share		Diluted net income per share	
	Yen		Yen	
Nine months ended October 31, 2023	(28.99)		—	
October 31, 2022	(31.12)		—	

(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, 2023	4,302		1,877		34.5		22.63	
As of January 31, 2023	7,045		4,428		56.5		62.12	

(Reference) Equity: As of October 31, 2023: ¥1,482 million
 As of January 31, 2023: ¥3,980 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2023	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2024	—	0.00	—		
Fiscal year ending January 31, 2024 (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, 2024 (February 1, 2023 to January 31, 2024)

(% 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	—	—	(4,642)	—	(4,597)	—	(4,598)	—	(72.30)

(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: Yes
 - 2) Changes in accounting policies other than 1) above: No
 - 3) Changes in accounting estimates: No
 - 4) Retrospective restatement: No(Note) For details, please refer to “2. Quarterly Consolidated Financial Statements and Primary Notes, (3) Notes to the Quarterly Consolidated Financial Statements (Changes in accounting policies)” on page 8 of the attachment.
- (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, 2023: 65,508,502 shares
January 31, 2023: 64,076,202 shares
 - 2) Total number of treasury shares at the end of the period:
October 31, 2023: 230 shares
January 31, 2023: 230 shares
 - 3) Average number of shares during the period:
Nine months ended October 31, 2023: 64,949,133 shares
Nine months ended October 31, 2022: 56,482,974 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

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, 17 products were approved for manufacture and marketing as regenerative medicine products by the end of 2022. In addition, in the US, the Regenerative Medicine Advanced Therapy (RMAT) Designation program was established under the 21st Century Cures Act which was passed in December 2016, which enables expedited approval of regenerative medicine products for the purpose of treatment of serious diseases. In 2021, biologics license applications (BLAs) were approved for three products designated as RMAT, including one that received BLA approval as an RMAT-designated product for the first time. No RMAT-designated items received BLA approval in 2022, but 14 items received new RMAT designation. Even going into 2023, the practical application of regenerative medicine continued to make steady progress, with three products having received approval for manufacture and marketing as regenerative medicine products in Japan as well as two products designated as RMAT having received BLA approval in the US, as of the end of October.

In this environment, the Group (hereinafter referring to three companies: the Company, SanBio, Inc. of Mountain View, California, US, and SanBio Asia Pte. Ltd. of Singapore) promoted research and development aiming at the commercialization of its unique regenerative cell medicine, SB623, mainly for central nervous system diseases with high unmet medical needs.

For the SB623 development program for treatment of chronic traumatic brain injury, in the Phase 2 global clinical trial including Japan and involving 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 the primary endpoint was met.” In April 2019, the development program for treatment of chronic traumatic brain injury in Japan was chosen as a designated regenerative medical product by the Ministry of Health, Labour and Welfare under the “SAKIGAKE Designation System.” Since the designation, under the framework of the SAKIGAKE Designation System, the Company has negotiated with the Pharmaceuticals and Medical Devices Agency (PMDA), completed the SAKIGAKE comprehensive evaluation consultation in January 2022, and submitted the application for approval of manufacture and marketing of regenerative medicine products in Japan in March 2022 for the first time. In order to obtain approval, the Company is currently responding to the review by PMDA, as well as steadily proceeding with preparations for establishment of sales structure so that sales can be started promptly after approval is obtained. While the timing for approval is outside of the Company’s control, the Company will aim to obtain the approval in March 2024.

For the SB623 development program for treatment of chronic hemorrhagic stroke that began following the positive results of the program for treatment of chronic traumatic brain injury, the Company is swiftly proceeding with efforts to begin clinical trials in Japan following the approval of the SB623 development program for treatment of chronic traumatic brain injury in Japan.

For the SB623 development program for treatment of chronic ischemic stroke, efforts are being made to swiftly begin clinical trials in Japan following the approval of the SB623 development program for treatment of chronic traumatic brain injury in Japan based on the results of an additional analysis on the Phase 2b clinical trial in 163 patients in the US, which failed to meet its primary endpoint.

Under these circumstances, during the nine months ended October 31, 2023, the Company recorded ¥2,447 million in research and development expenses mainly consisting of manufacturing-related costs incurred to obtain approval with respect to the SB623 development program for treatment of chronic traumatic brain injury. As a result, operating loss was ¥3,725 million (operating loss of ¥6,404 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥1,912 million in foreign exchange gains as non-operating income, owing to the foreign exchange gains resulting from fluctuations in foreign exchange rates. Furthermore, ordinary loss was ¥1,837 million (ordinary income of ¥437 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,883 million (net loss attributable to owners of parent of ¥1,758 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 third quarter of the fiscal year under review was ¥4,190 million, a decrease of ¥2,777 million compared to the end of the previous fiscal year (¥6,967 million), mainly due to a decrease of ¥2,926 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 ¥112 million, an increase of ¥34 million compared to the end of the previous fiscal year (¥77 million), mainly due to an increase of ¥42 million in intangible assets.

(Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥959 million, a decrease of ¥130 million compared to the end of the previous fiscal year (¥1,090 million), mainly due to a decrease of ¥250 million in accounts payable - other, despite an increase of ¥216 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥1,465 million, a decrease of ¥60 million compared to the end of the previous fiscal year (¥1,525 million), mainly due to a decrease of ¥201 million in long-term loans payable, despite an increase of ¥140 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥1,877 million, a decrease of ¥2,551 million compared to the end of the previous fiscal year (¥4,428 million), mainly due to the recording of ¥1,883 million in net loss attributable to owners of parent and a decrease of ¥1,619 million in foreign currency translation adjustment, despite increases of ¥502 million in capital stock and capital surplus respectively resulting from exercise of subscription rights to shares.

(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 16, 2023.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2023	As of October 31, 2023
Assets		
Current assets		
Cash and deposits	6,732,775	3,806,146
Advance payments	46,506	239,343
Other	187,980	144,571
Total current assets	6,967,262	4,190,061
Non-current assets		
Property, plant and equipment	47,863	44,009
Intangible assets	1,292	43,891
Investments and other assets	28,695	24,919
Total non-current assets	77,851	112,820
Total assets	7,045,114	4,302,881
Liabilities		
Current liabilities		
Current portion of long-term loans payable	268,000	268,000
Accounts payable - other	331,073	80,484
Accrued expenses	314,590	530,829
Income taxes payable	605	907
Provision for bonuses	60,875	70,565
Other	115,129	9,213
Total current liabilities	1,090,274	959,999
Non-current liabilities		
Long-term loans payable	665,000	464,000
Deferred tax liabilities	860,930	1,001,040
Total non-current liabilities	1,525,930	1,465,040
Total liabilities	2,616,205	2,425,040
Net assets		
Shareholders' equity		
Capital stock	6,407,189	2,473,793
Capital surplus	10,118,632	6,185,235
Retained earnings	(8,177,057)	(1,188,722)
Treasury shares	(899)	(899)
Total shareholders' equity	8,347,864	7,469,407
Accumulated other comprehensive income		
Foreign currency translation adjustment	(4,367,549)	(5,986,730)
Total accumulated other comprehensive income	(4,367,549)	(5,986,730)
Subscription rights to shares	448,593	395,163
Total net assets	4,428,909	1,877,841
Total liabilities and net assets	7,045,114	4,302,881

(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, 2022	For the nine months ended October 31, 2023
Operating revenue	–	–
Operating expenses		
Research and development expenses	4,981,094	2,447,014
Other selling, general and administrative expenses	1,422,984	1,278,261
Total operating expenses	6,404,079	3,725,275
Operating loss	(6,404,079)	(3,725,275)
Non-operating income		
Interest income	1,443	1,940
Foreign exchange gains	6,885,443	1,912,494
Other	2,629	1,837
Total non-operating income	6,889,516	1,916,272
Non-operating expenses		
Interest expenses	22,121	8,207
Financing expenses	26,228	12,039
Share issuance costs	–	5,471
Other	–	2,424
Total non-operating expenses	48,350	28,142
Ordinary income (loss)	437,086	(1,837,145)
Extraordinary income		
Gain on sale of non-current assets	–	26,853
Gain on reversal of subscription rights to shares	–	71,350
Total extraordinary income	–	98,203
Extraordinary losses		
Loss on retirement of non-current assets	–	3,092
Total extraordinary losses	–	3,092
Net income (loss) before income taxes	437,086	(1,742,034)
Income taxes - current	907	907
Income taxes - deferred	2,194,186	140,109
Total income taxes	2,195,094	141,017
Net loss	(1,758,007)	(1,883,051)
Net loss attributable to owners of parent	(1,758,007)	(1,883,051)

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

(Thousand yen)

	For the nine months ended October 31, 2022	For the nine months ended October 31, 2023
Net loss	(1,758,007)	(1,883,051)
Other comprehensive income		
Foreign currency translation adjustment	(6,524,735)	(1,619,180)
Total other comprehensive income	(6,524,735)	(1,619,180)
Comprehensive income	(8,282,743)	(3,502,232)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(8,282,743)	(3,502,232)
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)

During the nine months ended October 31, 2023, the Company received a payment for the issuance of new shares accompanying the exercise of the 34th Share Acquisition Rights (share acquisition rights with exercise price amendment clause by third-party allotment) issued on November 15, 2022, and capital stock and capital reserves each increased by ¥500,499 thousand. In addition, capital stock and capital reserves each increased by ¥1,797 thousand due to the exercise of share acquisition rights as stock options.

Capital stock and capital surplus each decreased by ¥4,435,693 thousand and retained earnings increased by ¥8,871,387 thousand as a result of covering the loss in retained earnings brought forward as of June 6, 2023 based on the resolution of the 10th Annual General Meeting of Shareholders held on April 26, 2023.

As a result, at the end of the third quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥2,473,793 thousand, ¥6,185,235 thousand and ¥(1,188,722) thousand, respectively.

(Changes in accounting policies)

(Application of the Implementation Guidance on Accounting Standard for Fair Value Measurement)

The Company has applied the "Implementation Guidance on Accounting Standard for Fair Value Measurement" (ASBJ Guidance No. 31, June 17, 2021; hereinafter "Fair Value Measurement Guidance") from the beginning of the first quarter of the fiscal year under review, and will prospectively apply the new accounting policies stipulated by the Fair Value Measurement Guidance in accordance with the transitional treatment provided in Paragraph 27-2 of the Fair Value Measurement Guidance. This has no effect on the quarterly consolidated financial statements.