

Consolidated Financial Results
for the Nine Months Ended October 31, 2022
[Japanese GAAP]



December 15, 2022

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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 15, 2022
 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, 2022 (February 1, 2022 to October 31, 2022)

(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, 2022	—	—	(6,404)	—	437	—	(1,758)	—
October 31, 2021	—	—	(4,739)	—	(3,032)	—	(3,115)	—

(Note) Comprehensive income: Nine months ended October 31, 2022: ¥(8,282) million [–%]
 Nine months ended October 31, 2021: ¥(4,534) million [–%]

	Net income per share	Diluted net income per share
	Yen	Yen
Nine months ended October 31, 2022	(31.12)	—
October 31, 2021	(60.16)	—

(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, 2022	5,749	1,668	21.9	21.17
As of January 31, 2022	5,510	2,035	31.0	32.99

(Reference) Equity: As of October 31, 2022: ¥1,261 million
 As of January 31, 2022: ¥1,708 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2022	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2023	—	0.00	—		
Fiscal year ending January 31, 2023 (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, 2023 (February 1, 2022 to January 31, 2023)

(% 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	—	—	(8,131)	—	(4,298)	—	(5,684)	—	(95.36)

(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 7 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, 2022: 59,606,102 shares
 - January 31, 2022: 51,793,402 shares
 - 2) Total number of treasury shares at the end of the period:
 - October 31, 2022: 230 shares
 - January 31, 2022: 196 shares
 - 3) Average number of shares during the period:
 - Nine months ended October 31, 2022: 56,482,974 shares
 - Nine months ended October 31, 2021: 51,787,764 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

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, a record number of five products were approved for manufacture and marketing as regenerative medicine products in 2021. 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. In 2022, as of the end of October, three products were already approved for manufacture and marketing as regenerative medicine products in Japan, and the practical application of regenerative medicine continued to steadily progress.

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. The Company will respond to the review by PMDA in order to obtain approval, and steadily proceed with preparations for establishment of sales structure so that sales can be started promptly after approval is obtained.

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, efforts are being made to begin clinical trials in Japan.

For the SB623 development program for treatment of chronic ischemic stroke, efforts are being made to begin clinical trials 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, 2022, the Company recorded ¥4,981 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 ¥6,404 million (operating loss of ¥4,739 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥6,885 million of foreign exchange gains as non-operating income owing to the foreign exchange gains resulting from fluctuations in foreign exchange rates. Furthermore, ordinary income was ¥437 million (ordinary loss of ¥3,032 million for the same period in the previous fiscal year), income taxes - deferred was ¥2,194 million, and net loss attributable to owners of parent was ¥1,758 million (net loss attributable to owners of parent of ¥3,115 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 ¥5,662 million, an increase of ¥310 million compared to the end of the previous fiscal year (¥5,351 million), mainly due to an increase of ¥848 million in cash and deposits, despite a decrease of ¥467 million in supplies.

(Non-current assets)

The balance of non-current assets at the end of the third quarter of the fiscal year under review was ¥87 million, a decrease of ¥72 million compared to the end of the previous fiscal year (¥159 million), mainly due to a decrease of ¥64 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 ¥1,155 million, a decrease of ¥308 million compared to the end of the previous fiscal year (¥1,463 million), mainly due to decreases of ¥244 million in current portion of long-term loans payable, ¥275 million in accrued expenses, and ¥109 million in income taxes payable, despite increases of ¥114 million in accounts payable - other and ¥201 million in provision for bonuses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥2,926 million, an increase of ¥913 million compared to the end of the previous fiscal year (¥2,012 million), mainly due to an increase of ¥2,194 million in deferred tax liabilities, despite a decrease of ¥1,280 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 ¥1,668 million, a decrease of ¥367 million compared to the end of the previous fiscal year (¥2,035 million), mainly due to increases of ¥3,917 million in capital stock and capital surplus each resulting from exercise of subscription rights to shares, despite the recording of ¥1,758 million in net loss attributable to owners of parent and a decrease of ¥6,524 million in foreign currency translation adjustment.

(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 September 14, 2022. Although the Company recorded ¥6,885 million of foreign exchange gains as non-operating income during the nine months ended October 31, 2022, the full-year forecasts for ordinary income and net income will remain unchanged as it is unclear how foreign exchange rates will move.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2022	As of October 31, 2022
Assets		
Current assets		
Cash and deposits	4,557,006	5,405,659
Supplies	467,846	–
Advance payments	182,565	52,566
Other	144,091	204,158
Total current assets	5,351,509	5,662,384
Non-current assets		
Property, plant and equipment	58,748	53,506
Intangible assets	66,283	2,032
Investments and other assets	34,360	31,564
Total non-current assets	159,392	87,104
Total assets	5,510,901	5,749,488
Liabilities		
Current liabilities		
Current portion of long-term loans payable	512,500	268,000
Accounts payable - other	340,149	454,706
Accrued expenses	451,898	176,578
Income taxes payable	122,494	12,833
Provision for bonuses	21,658	222,812
Other	14,565	20,299
Total current liabilities	1,463,266	1,155,230
Non-current liabilities		
Long-term loans payable	2,012,500	732,000
Deferred tax liabilities	–	2,194,186
Total non-current liabilities	2,012,500	2,926,186
Total liabilities	3,475,766	4,081,416
Net assets		
Shareholders' equity		
Capital stock	4,075,135	4,773,073
Capital surplus	7,786,578	8,484,515
Retained earnings	(9,057,369)	(4,375,480)
Treasury shares	(853)	(899)
Total shareholders' equity	2,803,491	8,881,208
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,094,792)	(7,619,528)
Total accumulated other comprehensive income	(1,094,792)	(7,619,528)
Subscription rights to shares	326,436	406,392
Total net assets	2,035,135	1,668,072
Total liabilities and net assets	5,510,901	5,749,488

(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, 2021	For the nine months ended October 31, 2022
Operating revenue	–	–
Operating expenses		
Research and development expenses	3,546,083	4,981,094
Other selling, general and administrative expenses	1,193,736	1,422,984
Total operating expenses	4,739,819	6,404,079
Operating loss	(4,739,819)	(6,404,079)
Non-operating income		
Interest income	1,796	1,443
Dividend income	3,172	–
Foreign exchange gains	1,615,382	6,885,443
Gain on forgiveness of debts	127,023	–
Other	36	2,629
Total non-operating income	1,747,411	6,889,516
Non-operating expenses		
Interest expenses	35,189	22,121
Financing expenses	5,102	26,228
Total non-operating expenses	40,292	48,350
Ordinary profit (loss)	(3,032,700)	437,086
Extraordinary income		
Gain on reversal of subscription rights to shares	29,487	–
Total extraordinary income	29,487	–
Extraordinary losses		
Loss on retirement of non-current assets	10,106	–
Total extraordinary losses	10,106	–
Profit (loss) before income taxes	(3,013,319)	437,086
Income taxes - current	102,168	907
Income taxes - deferred	–	2,194,186
Total income taxes	102,168	2,195,094
Net loss	(3,115,488)	(1,758,007)
Net loss attributable to owners of parent	(3,115,488)	(1,758,007)

Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2021	For the nine months ended October 31, 2022
Net loss	(3,115,488)	(1,758,007)
Other comprehensive income		
Foreign currency translation adjustment	(1,419,066)	(6,524,735)
Total other comprehensive income	(1,419,066)	(6,524,735)
Comprehensive income	(4,534,554)	(8,282,743)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(4,534,554)	(8,282,743)
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 a payment for the issuance of new shares accompanying the exercise of the 32nd Share Acquisition Rights (share acquisition rights with exercise price amendment clause by third-party allotment) issued on March 4, 2022, and capital stock and capital reserves each increased by ¥3,874,550 thousand. In addition, capital stock and capital reserves each increased by ¥43,335 thousand due to the exercise of share acquisition rights as stock options during the nine months ended October 31, 2022.

Capital stock and capital surplus each decreased by ¥3,219,947 thousand and retained earnings increased by ¥6,439,895 thousand as a result of covering the loss in retained earnings brought forward as of June 6, 2022 based on the resolution of the 9th Annual General Meeting of Shareholders held on April 27, 2022.

As a result, at the end of the third quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥4,773,073 thousand, ¥8,484,515 thousand and ¥(4,375,480) thousand, respectively.

(Changes in accounting policies)

(Application of the Accounting Standard for Revenue Recognition, etc.)

The Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020; hereinafter referred to as the "Revenue Recognition Accounting Standard") and other standards from the beginning of the first quarter of the fiscal year under review. The Company recognizes revenue when control of a promised good or service is transferred to a customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods and services.

The application of the Revenue Recognition Accounting Standard has no effect on the quarterly consolidated financial statements.

(Application of the Accounting Standard for Fair Value Measurement, etc.)

The Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019; hereinafter referred to as the "Fair Value Measurement Accounting Standard") and other standards 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 Accounting Standard, etc. in accordance with the transitional treatment provided in Paragraph 19 of the Fair Value Measurement Accounting Standard and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019). This has no effect on the quarterly consolidated financial statements.