

Consolidated Financial Results for the Three Months Ended April 30, 2022 [Japanese GAAP]



June 14, 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: June 14, 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 Three Months Ended April 30, 2022 (February 1, 2022 to April 30, 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	%
Three months ended April 30, 2022	—	—	(1,844)	—	869	—	(315)	—
April 30, 2021	—	—	(1,540)	—	(855)	—	(860)	—

(Note) Comprehensive income: Three months ended April 30, 2022: ¥(2,945) million [–%]
 Three months ended April 30, 2021: ¥(1,491) million [–%]

	Net income per share	Diluted net income per share
Three months ended April 30, 2022	Yen (5.98)	Yen —
April 30, 2021	(16.61)	—

(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, 2022	8,049	2,445	25.5	37.59
As of January 31, 2022	5,510	2,035	31.0	32.99

(Reference) Equity: As of April 30, 2022: ¥2,056 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	–				
Fiscal year ending January 31, 2023 (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, 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
First half	–	–	(3,067)	–	(3,168)	–	(3,169)	–	(61.19)
Full year	–	–	(5,858)	–	(5,991)	–	(5,997)	–	(115.79)

(Note) Revision to the financial results forecast announced most recently: No

(Note) As of June 14, 2022, the NHI drug price which will be determined after the manufacture and marketing approval of the Company's regenerative medicine product SB623 for the chronic traumatic brain injury in Japan (hereinafter referred to as the "Approval") is not yet determined. For this reason, operating revenue related to SB623 is not reflected in the above financial results forecast. The Company will consider disclosing operating revenue and other data after the date of the drug price is determined. The financial results forecast figures in this document were estimated on the basis of projections until the Approval. The Company plans to revise these forecast figures to reflect its post-approval business plans once being sure that the Approval will be granted.

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):

April 30, 2022: 54,703,402 shares

January 31, 2022: 51,793,402 shares

2) Total number of treasury shares at the end of the period:

April 30, 2022: 196 shares

January 31, 2022: 196 shares

3) Average number of shares during the period

Three months ended April 30, 2022: 52,807,026 shares

Three months ended April 30, 2021: 51,786,683 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.

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review	2
(1) Explanation of Operating Results	2
(2) Explanation of Financial Position	3
(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information	3
2. Quarterly Consolidated Financial Statements and Primary Notes	4
(1) Quarterly Consolidated Balance Sheets	4
(2) Quarterly Consolidated Statements of Income and Comprehensive Income	5
Quarterly Consolidated Statements of Income	
For the Three Months Ended April 30	5
Quarterly Consolidated Statements of Comprehensive Income	
For the Three Months Ended April 30	6
(3) Notes to the Quarterly Consolidated Financial Statements	7
(Notes on going concern assumption)	7
(Notes in the event of significant changes in shareholders' equity).....	7
(Changes in accounting policies)	7

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 April, two 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 (hereinafter referred to as the “application for approval”) 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 three months ended April 30, 2022, the Company recorded ¥1,370 million in research and development expenses mainly consisting of manufacturing-related costs incurred in applying for approval with respect to the SB623 development program for treatment of chronic traumatic brain injury. As a result, operating loss was ¥1,844 million (operating loss of ¥1,540 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥2,729 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 ¥869 million (ordinary loss of ¥855 million for the same period in the previous fiscal year), income taxes - deferred was ¥1,184 million, and net loss attributable to owners of parent was ¥315 million (net loss attributable to owners of parent of ¥860 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 first quarter of the fiscal year under review was ¥7,892 million, an increase of ¥2,541 million compared to the end of the previous fiscal year (¥5,351 million), mainly due to an increase of ¥2,461 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 ¥156 million, a decrease of ¥2 million compared to the end of the previous fiscal year (¥159 million).

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥2,550 million, an increase of ¥1,087 million compared to the end of the previous fiscal year (¥1,463 million), mainly due to an increase of ¥1,400 million in short-term loans payable, despite decreases of ¥100 million in accounts payable - other and ¥115 million in income taxes payable.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥3,053 million, an increase of ¥1,041 million compared to the end of the previous fiscal year (¥2,012 million), mainly due to an increase of ¥1,184 million in deferred tax liabilities, despite a decrease of ¥143 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 ¥2,445 million, an increase of ¥410 million compared to the end of the previous fiscal year (¥2,035 million), mainly due to increases of ¥1,646 million in capital stock and capital surplus each resulting from exercise of subscription rights to shares, despite the recording of ¥315 million in net loss attributable to owners of parent and a decrease of ¥2,629 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 first half and the full year of the fiscal year under review, as released on March 11, 2022.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2022	As of April 30, 2022
Assets		
Current assets		
Cash and deposits	4,557,006	7,018,103
Supplies	467,846	495,712
Advance payments	182,565	261,927
Other	144,091	117,084
Total current assets	5,351,509	7,892,826
Non-current assets		
Property, plant and equipment	58,748	55,678
Intangible assets	66,283	66,130
Investments and other assets	34,360	34,934
Total non-current assets	159,392	156,743
Total assets	5,510,901	8,049,569
Liabilities		
Current liabilities		
Short-term loans payable	–	1,400,000
Current portion of long-term loans payable	512,500	431,250
Accounts payable - other	340,149	239,272
Accrued expenses	451,898	362,854
Income taxes payable	122,494	6,866
Provision for bonuses	21,658	94,389
Other	14,565	16,095
Total current liabilities	1,463,266	2,550,729
Non-current liabilities		
Long-term loans payable	2,012,500	1,868,750
Deferred tax liabilities	–	1,184,939
Total non-current liabilities	2,012,500	3,053,689
Total liabilities	3,475,766	5,604,419
Net assets		
Shareholders' equity		
Capital stock	4,075,135	5,721,741
Capital surplus	7,786,578	9,433,183
Retained earnings	(9,057,369)	(9,373,143)
Treasury shares	(853)	(853)
Total shareholders' equity	2,803,491	5,780,928
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,094,792)	(3,724,416)
Total accumulated other comprehensive income	(1,094,792)	(3,724,416)
Subscription rights to shares	326,436	388,638
Total net assets	2,035,135	2,445,150
Total liabilities and net assets	5,510,901	8,049,569

(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, 2021	For the three months ended April 30, 2022
Operating revenue	–	–
Operating expenses		
Research and development expenses	1,126,499	1,370,355
Other selling, general and administrative expenses	413,753	474,039
Total operating expenses	1,540,253	1,844,394
Operating loss	(1,540,253)	(1,844,394)
Non-operating income		
Interest income	219	142
Dividend income	3,172	–
Foreign exchange gains	695,283	2,729,832
Other	36	898
Total non-operating income	698,711	2,730,874
Non-operating expenses		
Interest expenses	11,845	7,477
Financing expenses	1,694	9,532
Total non-operating expenses	13,540	17,010
Ordinary profit (loss)	(855,081)	869,469
Extraordinary income		
Gain on reversal of subscription rights to shares	1,423	–
Total extraordinary income	1,423	–
Profit (loss) before income taxes	(853,657)	869,469
Income taxes - current	6,408	302
Income taxes - deferred	–	1,184,939
Total income taxes	6,408	1,185,242
Net loss	(860,066)	(315,773)
Net loss attributable to owners of parent	(860,066)	(315,773)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2021	For the three months ended April 30, 2022
Net loss	(860,066)	(315,773)
Other comprehensive income		
Foreign currency translation adjustment	(631,283)	(2,629,624)
Total other comprehensive income	(631,283)	(2,629,624)
Comprehensive income	(1,491,349)	(2,945,397)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,491,349)	(2,945,397)
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 ¥1,630,045 thousand. In addition, capital stock and capital reserves each increased by ¥16,560 thousand due to the exercise of share acquisition rights as stock options during the first quarter of the fiscal year under review.

As a result, at the end of the first quarter of the fiscal year under review, capital stock was ¥5,721,741 thousand and capital surplus was ¥9,433,183 thousand.

(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.