

# Consolidated Financial Results for the Six Months Ended July 31, 2022 [Japanese GAAP]



September 14, 2022

Company name: SanBio Company Limited  
 Stock exchange listing: Tokyo Stock Exchange  
 Code number: 4592  
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 Scheduled date of filing quarterly securities report: September 14, 2022  
 Scheduled date of commencing dividend payments: —  
 Availability of supplementary briefing material on financial results: No  
 Schedule of financial results briefing session: Yes (for institutional investors and analysts)

(Amounts of less than one million yen are rounded down.)

## 1. Consolidated Financial Results for the Six Months Ended July 31, 2022 (February 1, 2022 to July 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	%
Six months ended July 31, 2022	—	—	(4,621)	—	(774)	—	(2,154)	—
July 31, 2021	—	—	(3,052)	—	(2,146)	—	(2,134)	—

(Note) Comprehensive income: Six months ended July 31, 2022: ¥(5,991) million [–%]

Six months ended July 31, 2021: ¥(2,845) million [–%]

	Net income per share	Diluted net income per share
Six months ended	Yen	Yen
July 31, 2022	(39.26)	—
July 31, 2021	(41.21)	—

(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 July 31, 2022	8,598	3,932	41.3	59.58
As of January 31, 2022	5,510	2,035	31.0	32.99

(Reference) Equity: As of July 31, 2022: ¥3,551 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: 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: 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, (4) Notes to the Quarterly Consolidated Financial Statements (Changes in accounting policies)” on page 9 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):
    - July 31, 2022: 59,604,902 shares
    - January 31, 2022: 51,793,402 shares
  - 2) Total number of treasury shares at the end of the period:
    - July 31, 2022: 230 shares
    - January 31, 2022: 196 shares
  - 3) Average number of shares during the period:
    - Six months ended July 31, 2022: 54,895,835 shares
    - Six months ended July 31, 2021: 51,786,782 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, 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 July, 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 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 six months ended July 31, 2022, the Company recorded ¥3,620 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 ¥4,621 million (operating loss of ¥3,052 million for the same period in the previous fiscal year). On the other hand, the Company recorded ¥3,879 million of foreign exchange gains as non-operating income owing to the foreign exchange gains resulting from fluctuations in foreign exchange rates. Furthermore, ordinary loss was ¥774 million (ordinary loss of ¥2,146 million for the same period in the previous fiscal year), income taxes - deferred was ¥1,379 million, and net loss attributable to owners of parent was ¥2,154 million (net loss attributable to owners of parent of ¥2,134 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

### 1) Assets, liabilities and net assets

#### (Current assets)

The balance of current assets at the end of the second quarter of the fiscal year under review was ¥8,508 million, an increase of ¥3,157 million compared to the end of the previous fiscal year (¥5,351 million), mainly due to an increase of ¥3,778 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 second quarter of the fiscal year under review was ¥89 million, a decrease of ¥69 million compared to the end of the previous fiscal year (¥159 million), mainly due to a decrease of ¥63 million in intangible assets.

#### (Current liabilities)

The balance of current liabilities at the end of the second quarter of the fiscal year under review was ¥1,561 million, an increase of ¥98 million compared to the end of the previous fiscal year (¥1,463 million), mainly due to increases of ¥62 million in current portion of long-term loans payable, ¥104 million in accrued expenses, and ¥117 million in provision for bonuses, despite decreases of ¥140 million in accounts payable - other and ¥96 million in income taxes payable.

#### (Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was ¥3,104 million, an increase of ¥1,092 million compared to the end of the previous fiscal year (¥2,012 million), mainly due to an increase of ¥1,379 million in deferred tax liabilities, despite a decrease of ¥287 million in long-term loans payable.

#### (Net assets)

Total net assets at the end of the second quarter of the fiscal year under review were ¥3,932 million, an increase of ¥1,896 million compared to the end of the previous fiscal year (¥2,035 million), mainly due to increases of ¥3,916 million in capital stock and capital surplus each resulting from exercise of subscription rights to shares, despite the recording of ¥2,154 million in net loss attributable to owners of parent and a decrease of ¥3,836 million in foreign currency translation adjustment.

### 2) Cash flows

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the second quarter of the fiscal year under review were ¥8,335 million, an increase of ¥3,778 million compared to the end of the previous fiscal year (¥4,557 million). Cash flows in each area of activity and their respective contributing factors are as follows.

#### (Cash flows from operating activities)

Net cash used in operating activities for the six months ended July 31, 2022 was ¥3,977 million (an outflow of ¥3,475 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥774 million recorded, an increase of ¥110 million in provision for bonuses, ¥3,882 million in foreign exchange gains, decreases of ¥494 million in supplies, ¥151 million in advance payments, and ¥177 million in accrued expenses, and income taxes paid of ¥88 million.

#### (Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2022 was ¥7 million (an outflow

of ¥27 million for the same period in the previous fiscal year). This was primarily due to outflows of ¥3 million for purchase of property, plant and equipment and ¥3 million for payments of leasehold deposits.

(Cash flows from financing activities)

Net cash used in financing activities for the six months ended July 31, 2022 was ¥7,593 million (an outflow of ¥300 million for the same period in the previous fiscal year). This was primarily due to ¥225 million for repayments of long-term loans payable and ¥7,780 million in proceeds from issuance of shares resulting from exercise of subscription rights to shares.

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

With regard to the consolidated financial results forecast for the fiscal year ending January 31, 2023, the forecast figures announced on March 11, 2022 have been revised. For details, please refer to "Revision of Consolidated Earnings Forecast for the Fiscal Year Ending January 2023" released today.

## 2. Quarterly Consolidated Financial Statements and Primary Notes

### (1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2022	As of July 31, 2022
<b>Assets</b>		
Current assets		
Cash and deposits	4,557,006	8,335,489
Supplies	467,846	–
Advance payments	182,565	51,969
Other	144,091	121,407
Total current assets	5,351,509	8,508,867
Non-current assets		
Property, plant and equipment	58,748	55,314
Intangible assets	66,283	2,357
Investments and other assets	34,360	32,097
Total non-current assets	159,392	89,768
Total assets	5,510,901	8,598,636
<b>Liabilities</b>		
Current liabilities		
Current portion of long-term loans payable	512,500	575,000
Accounts payable - other	340,149	199,152
Accrued expenses	451,898	556,395
Income taxes payable	122,494	25,651
Provision for bonuses	21,658	139,241
Other	14,565	66,254
Total current liabilities	1,463,266	1,561,696
Non-current liabilities		
Long-term loans payable	2,012,500	1,725,000
Deferred tax liabilities	–	1,379,870
Total non-current liabilities	2,012,500	3,104,870
Total liabilities	3,475,766	4,666,566
<b>Net assets</b>		
Shareholders' equity		
Capital stock	4,075,135	4,772,098
Capital surplus	7,786,578	8,483,541
Retained earnings	(9,057,369)	(4,772,465)
Treasury shares	(853)	(899)
Total shareholders' equity	2,803,491	8,482,274
Accumulated other comprehensive income		
Foreign currency translation adjustment	(1,094,792)	(4,931,007)
Total accumulated other comprehensive income	(1,094,792)	(4,931,007)
Subscription rights to shares	326,436	380,802
Total net assets	2,035,135	3,932,069
Total liabilities and net assets	5,510,901	8,598,636



## (2) Quarterly Consolidated Statements of Income and Comprehensive Income

## Quarterly Consolidated Statements of Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2021	For the six months ended July 31, 2022
Operating revenue	–	–
Operating expenses		
Research and development expenses	2,251,264	3,620,776
Other selling, general and administrative expenses	801,535	1,001,146
Total operating expenses	3,052,800	4,621,922
Operating loss	(3,052,800)	(4,621,922)
Non-operating income		
Interest income	1,110	321
Dividend income	3,172	–
Foreign exchange gains	802,876	3,879,017
Gain on forgiveness of debts	126,153	–
Other	36	1,743
Total non-operating income	933,349	3,881,081
Non-operating expenses		
Interest expenses	23,813	14,782
Financing expenses	3,427	18,892
Total non-operating expenses	27,241	33,675
Ordinary loss	(2,146,691)	(774,516)
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	10,105	–
Total extraordinary losses	10,105	–
Loss before income taxes	(2,127,309)	(774,516)
Income taxes - current	6,711	605
Income taxes - deferred	–	1,379,870
Total income taxes	6,711	1,380,475
Net loss	(2,134,021)	(2,154,992)
Net loss attributable to owners of parent	(2,134,021)	(2,154,992)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2021	For the six months ended July 31, 2022
Net loss	(2,134,021)	(2,154,992)
Other comprehensive income		
Foreign currency translation adjustment	(711,243)	(3,836,215)
Total other comprehensive income	(711,243)	(3,836,215)
Comprehensive income	(2,845,265)	(5,991,207)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(2,845,265)	(5,991,207)
Comprehensive income attributable to non-controlling interests	—	—

## (3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2021	For the six months ended July 31, 2022
Cash flows from operating activities		
Loss before income taxes	(2,127,309)	(774,516)
Depreciation	74,107	12,824
Share based compensation expenses	75,026	57,086
Increase (decrease) in provision for bonuses	130,943	110,099
Interest and dividend income	(4,283)	(321)
Foreign exchange losses (gains)	(804,077)	(3,882,029)
Gain on forgiveness of debts	(126,153)	–
Interest expenses	23,813	14,782
Financing expenses	3,427	18,892
Gain on reversal of subscription rights to shares	(29,487)	–
Loss on retirement of non-current assets	10,105	–
Decrease (increase) in inventories	3,264	494,993
Decrease (increase) in advance payments	(64,382)	151,266
Increase (decrease) in accounts payable - other	(139,694)	(177,095)
Increase (decrease) in accrued expenses	(277,410)	35,116
Other	(38,374)	64,865
Subtotal	(3,290,485)	(3,874,035)
Interest and dividends received	4,283	321
Interest expenses paid	(24,151)	(14,969)
Income taxes paid	(164,852)	(88,627)
Net cash provided by (used in) operating activities	(3,475,205)	(3,977,310)
Cash flows from investing activities		
Purchase of property, plant and equipment	(26,528)	(3,768)
Purchase of intangible assets	(1,241)	(95)
Payments of leasehold deposits	–	(3,530)
Net cash provided by (used in) investing activities	(27,769)	(7,394)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	225,000	–
Repayments of long-term loans payable	(525,000)	(225,000)
Payments of financing expenses	(2,236)	(12,633)
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	1,851	7,780,101
Proceeds from issuance of share acquisition rights	–	51,000
Other	–	(46)
Net cash provided by (used in) financing activities	(300,385)	7,593,421
Effect of exchange rate change on cash and cash equivalents	117,453	169,766
Net increase (decrease) in cash and cash equivalents	(3,685,907)	3,778,483
Cash and cash equivalents at beginning of period	12,480,165	4,557,006
Cash and cash equivalents at end of period	8,794,258	8,335,489

#### (4) 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 32<sup>nd</sup> 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 ¥42,361 thousand due to the exercise of share acquisition rights as stock options during the second quarter of the fiscal year under review.

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 second quarter of the fiscal year under review, capital stock, capital surplus and retained earnings were ¥4,772,098 thousand, ¥8,483,541 thousand and ¥(4,772,465) 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.