

Consolidated Financial Results
for the Three Months Ended April 30, 2019
[Japanese GAAP]



June 14, 2019

Company name: SanBio Company Limited
 Stock exchange listing: Tokyo Stock Exchange
 Code number: 4592
 URL: <http://www.sanbio.jp/>
 Representative: Keita Mori, Representative Director and President
 Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
 Phone: +81-3-6264-3481
 Scheduled date of filing quarterly securities report: June 14, 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 Three Months Ended April 30, 2019 (February 1, 2019 to April 30, 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	%
Three months ended April 30, 2019	189	19.5	(1,248)	—	(727)	—	(736)	—
April 30, 2018	158	27.9	(1,004)	—	(836)	—	(837)	—

(Note) Comprehensive income: Three months ended April 30, 2019: ¥(886) million [–%]

Three months ended April 30, 2018: ¥(875) million [–%]

	Net income per share	Diluted net income per share
	Yen	Yen
Three months ended April 30, 2019	(14.80)	—
April 30, 2018	(18.30)	—

(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, 2019	12,889	8,028	62.0	160.60
As of January 31, 2019	13,975	8,909	63.5	178.42

(Reference) Equity: As of April 30, 2019: ¥7,986 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	—				
Fiscal year ending January 31, 2020 (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, 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
First half	284	(31.4)	(3,445)	—	(3,196)	—	(3,197)	—	(64.29)
Full year	713	(3.7)	(5,887)	—	(5,390)	—	(5,395)	—	(108.48)

(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: 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):
April 30, 2019: 49,733,223 shares
January 31, 2019: 49,732,868 shares
 - 2) Total number of treasury shares at the end of the period:
April 30, 2019: 190 shares
January 31, 2019: 190 shares
 - 3) Average number of shares during the period
Three months ended April 30, 2019: 49,732,818 shares
Three months ended April 30, 2018: 45,778,038 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 three months ended April 30, 2019 (from February 1, 2019 to April 30, 2019), as evidence of a slowdown in the global economy became more apparent, intensifying international trade frictions, originating in the US, resulted in downward pressure on business sentiment within the US itself. Economic conditions in Japan also remain unpredictable, with risks including a slowdown in exports, US sanctions against China and an increase in the consumption tax rate, despite positive growth in real GDP for two consecutive quarters since October, 2018.

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, as well as the conditional and time-limited marketing approval system for regenerative medical products in Japan, the Group aims to apply for approval for manufacture and sales of regenerative medical products during the fiscal year ending January 31, 2020 (from February 2019 to January 2020).

In addition, also in April 2019, the regenerative cell medicine SB623 was designated as an Advanced Therapy Medicinal Product (ATMP) by the European Medicines Agency (EMA). This represents the first step in global expansion, and the Group plans to commence Phase 3 clinical trials in the development program for treatment of chronic traumatic brain injury in Europe by the end of the fiscal year ending January 31, 2020.

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 three months ended April 30, 2019, operating revenue totaled ¥189

million (operating revenue of ¥158 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 ¥1,248 million (operating loss of ¥1,004 million for the same period in the previous fiscal year), due to the recording of ¥1,095 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 ¥727 million (ordinary loss of ¥836 million for the same period in the previous fiscal year) mainly due to the recording of ¥290 million of non-operating income as a grant from the California Institute for Regenerative Medicine (CIRM) and ¥237 million of foreign exchange gains, while net loss attributable to owners of parent was ¥736 million (net loss attributable to owners of parent of ¥837 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

(Current assets)

The balance of current assets at the end of the first quarter of the fiscal year under review was ¥11,957 million, a decrease of ¥1,101 million compared to the end of the previous fiscal year (¥13,058 million), mainly due to a decrease of ¥1,235 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 ¥931 million, an increase of ¥14 million compared to the end of the previous fiscal year (¥917 million), mainly due to an increase of ¥29 million in investment securities, despite a decrease of ¥12 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the first quarter of the fiscal year under review was ¥860 million, a decrease of ¥206 million compared to the end of the previous fiscal year (¥1,066 million), mainly due to a decrease of ¥278 million in advance received.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first 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 first quarter of the fiscal year under review were ¥8,028 million, a decrease of ¥880 million compared to the end of the previous fiscal year (¥8,909 million), mainly due to the recording of ¥736 million in net loss attributable to owners of parent, and a decrease of ¥179 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 15, 2019.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2019	As of April 30, 2019
Assets		
Current assets		
Cash and deposits	12,453,031	11,217,682
Advance payments	519,009	685,359
Other	86,872	54,477
Total current assets	13,058,913	11,957,520
Non-current assets		
Property, plant and equipment	74,165	61,902
Intangible assets	2,601	1,970
Investments and other assets		
Investment securities	828,828	857,890
Other	11,467	10,125
Total investments and other assets	840,295	868,016
Total non-current assets	917,061	931,889
Total assets	13,975,975	12,889,409
Liabilities		
Current liabilities		
Current portion of long-term loans payable	33,380	16,720
Accounts payable - other	315,509	501,713
Advance received	489,282	210,310
Provision for bonuses	—	22,316
Other	228,682	109,535
Total current liabilities	1,066,854	860,595
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	4,860,595
Net assets		
Shareholders' equity		
Capital stock	9,431,953	9,432,048
Capital surplus	13,143,396	13,143,490
Retained earnings	(13,675,118)	(14,411,266)
Treasury shares	(837)	(837)
Total shareholders' equity	8,899,393	8,163,436
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	(171,147)	(142,084)
Foreign currency translation adjustment	145,293	(34,378)
Total accumulated other comprehensive income	(25,854)	(176,463)
Subscription rights to shares	35,580	41,841
Total net assets	8,909,120	8,028,814
Total liabilities and net assets	13,975,975	12,889,409

(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, 2018	For the three months ended April 30, 2019
Operating revenue	158,452	189,395
Operating expenses		
Research and development expenses	972,478	1,095,647
Other selling, general and administrative expenses	190,288	342,594
Total operating expenses	1,162,767	1,438,242
Operating loss	(1,004,315)	(1,248,846)
Non-operating income		
Interest income	7,058	2,270
Dividend income	—	6,458
Foreign exchange gains	47,524	237,655
Subsidy income	135,640	290,018
Other	35	41
Total non-operating income	190,258	536,443
Non-operating expenses		
Interest expenses	7,834	11,658
Financing expenses	2,954	3,105
Share issuance expenses	11,631	—
Total non-operating expenses	22,420	14,763
Ordinary loss	(836,478)	(727,166)
Extraordinary income		
Gain on reversal of subscription rights to shares	67	—
Total extraordinary income	67	—
Extraordinary losses		
Loss on retirement of non-current assets	—	7,522
Total extraordinary losses	—	7,522
Loss before income taxes	(836,410)	(734,688)
Income taxes - current	1,114	1,458
Total income taxes	1,114	1,458
Net loss	(837,525)	(736,147)
Net loss attributable to owners of parent	(837,525)	(736,147)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2018	For the three months ended April 30, 2019
Net loss	(837,525)	(736,147)
Other comprehensive income		
Valuation difference on available-for-sale securities	–	29,062
Foreign currency translation adjustment	(38,119)	(179,672)
Total other comprehensive income	(38,119)	(150,609)
Comprehensive income	(875,645)	(886,756)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(875,645)	(886,756)
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)

None