Consolidated Financial Results for the Nine Months Ended October 31, 2017 [Japanese GAAP]

December 13, 2017

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: December 13, 2017
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly 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, 2017 (February 1, 2017 to October 31, 2017)

(1) Consolidated Operating Results (% indicates changes from the previous corresponding period.)

	Operating revenue		Operating income		Ordinary income		Net income attributable to owners of parent	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
October 31, 2017	371	(51.0)	(3,169)	–	(3,164)	–	(3,158)	–
October 31, 2016	758	(31.1)	(1,214)	–	(1,813)	–	(1,691)	–

(Note) Comprehensive income: Nine months ended October 31, 2017: ¥(3,188) million [–%]
Nine months ended October 31, 2016: ¥(1,650) million [–%]

	Net income per share	Diluted net income per share
Nine months ended	Yen	Yen
October 31, 2017	(69.68)	–
October 31, 2016	(37.74)	–

(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, 2017	4,895	1,442	29.1	31.35
As of January 31, 2017	6,292	4,594	72.8	101.52

(Reference) Equity: As of October 31, 2017: ¥1,424 million
As of January 31, 2017: ¥4,579 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended January 31, 2017	–	0.00	–	0.00	0.00
Fiscal year ending January 31, 2018	–	0.00	–		
Fiscal year ending January 31, 2018 (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, 2018 (February 1, 2017 to January 31, 2018)

(% 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	662	(30.2)	(3,945)	–	(3,957)	–	(3,982)	–	(87.82)

(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):
October 31, 2017: 45,440,739 shares
January 31, 2017: 45,109,032 shares

2) Total number of treasury shares at the end of the period:
October 31, 2017: 115 shares
January 31, 2017: 84 shares

3) Average number of shares during the period:
Nine months ended October 31, 2017: 45,337,618 shares
Nine months ended October 31, 2016: 44,827,271 shares

* These quarterly financial results are outside the scope of quarterly review.

* 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

The Japanese economy during the nine months ended October 31, 2017 (from February 1, 2017 to October 31, 2017) maintained a recovery path due to moderate improvements in personal consumption, as corporate earnings and the employment environment remained robust. The US economy continued to recover, backed by improvements in the employment and income environments, amid growing recovery trend of corporate earnings.

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 term-limited sales was granted for the first time in September 2015 under the new program to accelerate the process of drug approval for regenerative medicines 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 medicine 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.

Enrollment of patients (with an objective of 156 participants; double-blind trial) has progressed smoothly in a Phase 2b clinical trial of SB623, which has been conducted in the US, for the treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”) during the nine months ended October 31, 2017. Out of 156 scheduled participants, over 85% of the enrollment has been completed to date. Regarding this trial, the Group passed the screening in relation to continuation of the trial by an outside Data and Safety Monitoring Board (See Note) when 75% of the enrollment was completed and is continuing the enrollment aiming for its completion by the end of March, 2018. Regarding the Phase 2 clinical trial of SB623 for the treatment of chronic motor deficit from traumatic brain injury (“development program for treatment of chronic traumatic brain injury”), which has been conducted in Japan and the US, the subsequent enrollment of patients has progressed smoothly in the period under review after the first patient (with an objective of 52 participants; double-blind trial) was enrolled in the US in July 2016, and in Japan in October 2016. Regarding the development program for treatment of chronic traumatic brain injury, the Group received approval from the US Food and Drug Administration (FDA) and the Pharmaceuticals and Medical Devices Agency (PMDA) to initiate Phase 2 clinical trials without conducting Phase 1 clinical trials, in view of results of the previous Phase 1/2a clinical trials for chronic stroke, which was conducted in the US. As for this program, the Group aims to utilize the conditional and term-limited marketing approval system (early approval system) for regenerative medical products, which started under the Revised Pharmaceutical Affairs Act of Japan, and is focusing on delivery of a product to the market in Japan earlier than in any other region in the world.

Along with the progress of these clinical trials, in June 2016, interim 12-month Phase 1/2a clinical trial results for SB623 in patients with chronic motor deficit from ischemic stroke were published in *Stroke*, a leading professional journal published by the American Heart Association. This article received the third-place prize of the 2016 Innovation Award from the Association in February 2017, garnering the attention of many medical professionals and the media. In June 2017, the Group obtained a grant of US$20 million in total from the California Institute for Regenerative Medicine (CIRM) for Phase 2b clinical trial of SB623 in patients with chronic motor deficit from ischemic stroke. The Institute is a public institution established aimed at promoting research and development of regenerative medicine, particularly stem cell treatment, through a highly competitive grant program. The acquisition of the grant by the Group not only suggests that the potentials of SB623 were highly evaluated by the screening conducted by an expert team of the Institute but also significantly

contributes to financial soundness of the Group. This grant is received in installments based on preset development milestones. Out of US$20 million, the Group has received a total of US$9.4 million so far, of which US$4.5 million was granted for the conclusion of a contract with CIRM pertaining to the grant and US$4.9 million was granted for 65% achievement of the enrollment of patients. A portion of US$4.5 million was recorded as ¥513 million in advance received in current liabilities.

Under these circumstances, for the nine months ended October 31, 2017, operating revenue totaled ¥371 million (operating revenue of ¥758 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 ¥3,169 million (operating loss of ¥1,214 million for the same period in the previous fiscal year). Ordinary loss was ¥3,164 million (ordinary loss of ¥1,813 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥3,158 million (net loss attributable to owners of parent of ¥1,691 million for the same period in the previous fiscal year), mainly due to the recording of ¥69 million of foreign exchange gains.

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.

(Note) Data and Safety Monitoring Board is an organization to be established to monitor adverse events, modification and termination of trials, and information which may affect the participant's willingness to continue trials, evaluate progress of clinical trials and safety data as well as recommend continuation, modification or termination of trials.

(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 ¥4,762 million, a decrease of ¥1,362 million compared to the end of the previous fiscal year (¥6,124 million), mainly due to a decrease of ¥1,191 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 ¥133 million, a decrease of ¥34 million compared to the end of the previous fiscal year (¥167 million), mainly due to a decrease of ¥32 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the third quarter of the fiscal year under review was ¥1,203 million, an increase of ¥655 million compared to the end of the previous fiscal year (¥547 million), mainly due to an increase of ¥513 million in advance received.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥2,250 million, an increase of ¥1,100 million compared to the end of the previous fiscal year (¥1,150 million), due to an increase of ¥1,100 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 ¥1,442 million, a decrease of ¥3,152 million compared to the end of the previous fiscal year (¥4,594 million), mainly due to the recording of ¥3,158 million in net loss attributable to owners of parent.

(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 17, 2017.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2017	As of October 31, 2017
Assets		
Current assets		
Cash and deposits	5,561,424	4,369,499
Advance payments	495,531	348,566
Other	67,608	44,290
Total current assets	6,124,564	4,762,356
Non-current assets		
Property, plant and equipment	148,371	116,205
Intangible assets	7,701	6,294
Investments and other assets	11,776	10,741
Total non-current assets	167,849	133,241
Total assets	6,292,414	4,895,597
Liabilities		
Current liabilities		
Short-term loans payable	100,000	–
Current portion of long-term loans payable	49,980	66,640
Advance received	–	513,746
Provision for bonuses	13,327	33,882
Other	384,088	588,745
Total current liabilities	547,395	1,203,013
Non-current liabilities		
Long-term loans payable	1,150,020	2,250,040
Total non-current liabilities	1,150,020	2,250,040
Total liabilities	1,697,415	3,453,053
Net assets		
Shareholders' equity		
Capital stock	3,852,012	3,868,646
Capital surplus	7,563,454	7,580,088
Retained earnings	(6,814,228)	(9,973,200)
Treasury shares	(146)	(180)
Total shareholders' equity	4,601,091	1,475,354
Accumulated other comprehensive income		
Foreign currency translation adjustment	(21,642)	(50,715)
Total accumulated other comprehensive income	(21,642)	(50,715)
Subscription rights to shares	15,548	17,904
Total net assets	4,594,998	1,442,543
Total liabilities and net assets	6,292,414	4,895,597

(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, 2016	For the nine months ended October 31, 2017
Operating revenue	758,007	371,294
Operating expenses		
Research and development expenses	1,416,408	2,999,653
Other selling, general and administrative expenses	556,405	540,968
Total operating expenses	1,972,813	3,540,622
Operating loss	(1,214,805)	(3,169,327)
Non-operating income		
Interest income	6,259	17,865
Foreign exchange gains	–	69,172
Other	168	767
Total non-operating income	6,427	87,805
Non-operating expenses		
Interest expenses	8,951	18,087
Foreign exchange losses	565,363	–
Financing expenses	30,464	65,112
Total non-operating expenses	604,779	83,200
Ordinary loss	(1,813,157)	(3,164,722)
Extraordinary income		
Gain on reversal of subscription rights to shares	–	7,768
Total extraordinary income	–	7,768
Loss before income taxes	(1,813,157)	(3,156,954)
Income taxes - current	1,483	2,017
Income taxes - deferred	(122,862)	–
Total income taxes	(121,379)	2,017
Net loss	(1,691,778)	(3,158,971)
Net loss attributable to owners of parent	(1,691,778)	(3,158,971)

Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2016	For the nine months ended October 31, 2017
Net loss	(1,691,778)	(3,158,971)
Other comprehensive income		
Foreign currency translation adjustment	40,897	(29,073)
Total other comprehensive income	40,897	(29,073)
Comprehensive income	(1,650,880)	(3,188,044)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,650,880)	(3,188,044)
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

(Additional information)

(Adoption of the implementation guidance on recoverability of deferred tax assets)

Effective from the first quarter of the fiscal year, the Company has adopted the "Revised Implementation Guidance on Recoverability of Deferred Tax Assets" (Accounting Standards Board of Japan ("ASBJ") Guidance No. 26, March 28, 2016).