Consolidated Financial Results for the Nine Months Ended October 31, 2016 [Japanese GAAP]

December 14, 2016

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 14, 2016
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, 2016 (February 1, 2016 to October 31, 2016)

(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, 2016	758	(31.1)	(1,214)	–	(1,813)	–	(1,691)	–
October 31, 2015	1,099	(64.8)	(566)	–	(608)	–	(470)	–

(Note) Comprehensive income: Nine months ended October 31, 2016: ¥(1,650) million [–%]
Nine months ended October 31, 2015: ¥(463) million [–%]

	Net income per share	Diluted net income per share
Nine months ended	Yen	Yen
October 31, 2016	(37.74)	–
October 31, 2015	(10.88)	–

(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, 2016	6,826	4,812	70.4	106.56
As of January 31, 2016	8,271	6,366	77.0	142.66

(Reference) Equity: As of October 31, 2016: ¥4,802 million
As of January 31, 2016: ¥6,365 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, 2016	–	0.00	–	0.00	0.00
Fiscal year ending January 31, 2017	–	0.00	–		
Fiscal year ending January 31, 2017 (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, 2017 (February 1, 2016 to January 31, 2017)

(% 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	947	(24.6)	(1,804)	–	(2,301)	–	(2,136)	–	(47.65)

(Note) Revision to the financial results forecast announced most recently: Yes
For revision to the consolidated financial results forecast, please refer to the "Notice Regarding Revision to Financial Forecasts and Posting of Non-Operating Expenses (Foreign Exchange Losses)" announced today (December 14, 2016).

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

(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, 2016: 45,067,365 shares
January 31, 2016: 44,621,741 shares

2) Total number of treasury shares at the end of the period:
October 31, 2016: 84 shares
January 31, 2016: 16 shares

3) Average number of shares during the period:
Nine months ended October 31, 2016: 44,827,271 shares
Nine months ended October 31, 2015: 43,264,984 shares

<u>* Presentation regarding the implementation status of the quarterly review procedures</u>

These quarterly financial results are outside the scope of quarterly review procedures under the Financial Instruments and Exchange Act. However, at the time of disclosure of these quarterly financial results, review procedures for the quarterly financial statements under the Financial Instruments and Exchange Act have been completed.

* 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

The Japanese economy during the nine months ended October 31, 2016 (from February 1, 2016 to October 31, 2016) saw corporate earnings and the employment environment remain robust, but business confidence trended flat with personal consumption limited to a moderate increase due to ongoing uncertainty over the economic outlook. The US economy continued to recover, backed by the improvement in the employment and income environment.

In the regenerative medicine industry, amid ongoing promotion of the industry in Japan 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 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.

In March 2016, the first patient (with an objective of 156 participants) in the US was enrolled in a Phase 2b clinical trial of SB623 for the treatment of chronic motor deficit from ischemic stroke. In July 2016 the first patient (with an objective of 52 participants) in the US was enrolled in a Phase 2 clinical trial of SB623 for the treatment of chronic motor deficit from traumatic brain injury. In Japan, we submitted a clinical trial notification concerning chronic motor deficit from traumatic brain injury to the Pharmaceuticals and Medical Devices Agency (PMDA) on March 7, 2016. Following a 30-day examination period, it became possible to conduct clinical trials of SB623 in Japan. We enrolled the first patient in Japan in October 2016 for the development program for treatment of chronic traumatic brain injury currently implemented as a global clinical trial in the US and Japan (with a total of 52 participants in the US and Japan).

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. The results were also presented in the annual meeting of the International Society for Stem Cell Research (ISSCR), held in San Francisco.

For the nine months ended October 31, 2016, operating revenue totaled ¥758 million (operating revenue of ¥1,099 million for the same period in the previous fiscal year), primarily reflecting milestone revenue of US$5 million received upon the first enrollment of patients in the Phase 2b clinical trial for chronic stroke in the US, and proceeds from the development support fee related to the joint development and license agreements concluded with Sumitomo Dainippon Pharma Co., Ltd. in North America. Operating loss was ¥1,214 million (operating loss of ¥566 million for the same period in the previous fiscal year). Ordinary loss was ¥1,813 million (ordinary loss of ¥608 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,691 million (net loss attributable to owners of parent of ¥470 million for the same period in the previous fiscal year), due to the recording of ¥8 million of interest expenses and ¥565 million of foreign exchange losses.

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 ¥6,713 million, a decrease of ¥1,478 million compared to the end of the previous fiscal year (¥8,191 million), mainly due to a decrease of ¥1,471 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 ¥112 million, an increase of ¥33 million compared to the end of the previous fiscal year (¥79 million), mainly due to an increase of ¥31 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 ¥807 million, a decrease of ¥612 million compared to the end of the previous fiscal year (¥1,419 million), mainly due to a decrease of ¥566 million in the current portion of long-term loans payable.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥1,206 million, an increase of ¥721 million compared to the end of the previous fiscal year (¥484 million), mainly due to an increase of ¥866 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 ¥4,812 million, a decrease of ¥1,554 million compared to the end of the previous fiscal year (¥6,366 million), mainly due to the recording of ¥1,691 million in net loss attributable to owners of parent.

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

With regard to the financial results forecast for the fiscal year under review, we expect operating revenue to be more or less in line with the plans, owing to milestone revenue and proceeds from the development support fee based on the agreement with alliance partner Sumitomo Dainippon Pharma Co., Ltd.

On the other hand, in term of expenses, we will revise forecasts for losses to lower than the plans, as some initially planned expenses such as clinical trial expenses are expected to remain unused. This is because the expense plans which included clinical trial expenses had many uncertainties, and their expected maximum amounts incorporated during planning were too conservative.

Under a joint development agreement with Sumitomo Dainippon Pharma Co., Ltd. carried out in the US, the Group is currently conducting a Phase 2b clinical trial on our unique regenerative cell medicine SB623 for patients with chronic motor deficit from ischemic stroke, involving a scale of 156 participants. The first patients were enrolled for the trial in March 2016, with successive enrollments ensuing thereafter.

In addition, we are independently conducting a global study between Japan and the US of a Phase 2 clinical trial for patients with chronic motor deficit from traumatic brain injury (with a total scale of 52 participants in the US and Japan), which is an expanded indication for the drug. The first patients were enrolled in the US in July 2016, and in Japan in October 2016, with subsequent enrollments.

The financial results forecast for the next fiscal year (from February 1, 2017 to January 31, 2018) will be announced in mid-March 2017 reflecting the above.

The exchange rate as of the end of November and the average exchange rate for the nine months ended October 31, 2016 were adopted for the revisions to the financial results forecast for the fiscal year under review.

2. Matters Concerning Summary Information (Notes)

(1) Changes in Significant Subsidiaries during the Nine Months Ended October 31, 2016

None

(2) Accounting Policies Adopted Specially for the Preparation of Quarterly Consolidated Financial Statements

None

(3) Changes in Accounting Policies, Changes in Accounting Estimates and Retrospective Restatement

(Adoption of accounting standards for business combinations)

Effective from the first quarter of the fiscal year under review, the Company has adopted the "Revised Accounting Standard for Business Combinations" (Accounting Standards Board of Japan ("ASBJ") Statement No. 21, September 13, 2013), "Revised Accounting Standard for Consolidated Financial Statements" (ASBJ Statement No. 22, September 13, 2013) and "Revised Accounting Standard for Business Divestitures" (ASBJ Statement No. 7, September 13, 2013). Consequently, the Company has changed the presentation of net income and other items, and minority interests have been changed to non-controlling interests. To reflect the changes in presentation, quarterly consolidated financial statements for the first nine months of the previous fiscal year and consolidated financial statements for the previous fiscal year have been reclassified.

3. Significant Events Concerning Going Concern Assumption

None

4. Quarterly Consolidated Financial Statements

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2016	As of October 31, 2016
Assets		
Current assets		
Cash and deposits	7,733,892	6,262,403
Other	457,599	451,024
Total current assets	8,191,492	6,713,428
Non-current assets		
Property, plant and equipment	67,974	99,498
Intangible assets	207	1,380
Investments and other assets	11,342	11,911
Total non-current assets	79,524	112,791
Total assets	8,271,017	6,826,219
Liabilities		
Current liabilities		
Short-term loans payable	100,000	100,000
Current portion of long-term loans payable	800,000	233,320
Provision for bonuses	20,994	61,192
Deferred tax liabilities	184,931	160,435
Other	313,651	252,458
Total current liabilities	1,419,577	807,406
Non-current liabilities		
Long-term loans payable	300,000	1,166,680
Deferred tax liabilities	184,931	40,108
Total non-current liabilities	484,931	1,206,788
Total liabilities	1,904,508	2,014,195
Net assets		
Shareholders' equity		
Capital stock	3,806,973	3,850,755
Capital surplus	7,518,415	7,562,198
Retained earnings	(4,978,932)	(6,670,710)
Treasury shares	(28)	(146)
Total shareholders' equity	6,346,428	4,742,096
Accumulated other comprehensive income		
Foreign currency translation adjustment	19,362	60,259
Total accumulated other comprehensive income	19,362	60,259
Subscription rights to shares	718	9,667
Total net assets	6,366,509	4,812,023
Total liabilities and net assets	8,271,017	6,826,219

(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, 2015	For the nine months ended October 31, 2016
Operating revenue	1,099,484	758,007
Operating expenses		
Research and development expenses	1,227,894	1,416,408
Other selling, general and administrative expenses	437,948	556,405
Total operating expenses	1,665,843	1,972,813
Operating loss	(566,358)	(1,214,805)
Non-operating income		
Interest income	948	6,259
Foreign exchange gains	20,839	–
Other	64	168
Total non-operating income	21,852	6,427
Non-operating expenses		
Interest expenses	13,549	8,951
Foreign exchange losses	–	565,363
Share issuance cost	32,446	–
Listing-related expenses	18,356	–
Financing expenses	–	30,464
Total non-operating expenses	64,351	604,779
Ordinary loss	(608,857)	(1,813,157)
Extraordinary losses		
Loss on retirement of non-current assets	1	–
Total extraordinary losses	1	–
Loss before income taxes	(608,858)	(1,813,157)
Income taxes - current	883	1,483
Income taxes - deferred	(138,939)	(122,862)
Total income taxes	(138,055)	(121,379)
Net loss	(470,802)	(1,691,778)
Net loss attributable to owners of parent	(470,802)	(1,691,778)

Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2015	For the nine months ended October 31, 2016
Net loss	(470,802)	(1,691,778)
Other comprehensive income		
Foreign currency translation adjustment	7,057	40,897
Total other comprehensive income	7,057	40,897
Comprehensive income	(463,745)	(1,650,880)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(463,745)	(1,650,880)
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

(Segment information)

<Segment information>

I. For the nine months ended October 31, 2015 (from February 1, 2015 to October 31, 2015)

Segment information is omitted as the Group consists of a single business segment, regenerative cell therapy using modified allogeneic stem cells.

II. For the nine months ended October 31, 2016 (from February 1, 2016 to October 31, 2016)

Segment information is omitted as the Group consists of a single business segment, regenerative cell therapy using modified allogeneic stem cells.