Consolidated Financial Results for the Three Months Ended April 30, 2017 [Japanese GAAP]

June 14, 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: June 14, 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 Three Months Ended April 30, 2017 (February 1, 2017 to April 30, 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	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
April 30, 2017	123	(80.2)	(1,021)	–	(1,098)	–	(1,097)	–
April 30, 2016	625	119.7	77	–	(320)	–	(277)	–

(Note) Comprehensive income: Three months ended April 30, 2017: ¥(1,061) million [–%]
Three months ended April 30, 2016: ¥(265) million [–%]

	Net income per share	Diluted net income per share
Three months ended	Yen	Yen
April 30, 2017	(24.24)	–
April 30, 2016	(6.22)	–

(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, 2017	6,400	3,555	55.3	78.10
As of January 31, 2017	6,292	4,594	72.8	101.52

(Reference) Equity: As of April 30, 2017: ¥3,538 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	–				
Fiscal year ending January 31, 2018 (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, 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
First half	328	(52.0)	(1,996)	–	(2,002)	–	(2,015)	–	(44.53)
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):
April 30, 2017: 45,309,258 shares
January 31, 2017: 45,109,032 shares

2) Total number of treasury shares at the end of the period:
April 30, 2017: 115 shares
January 31, 2017: 84 shares

3) Average number of shares during the period:
Three months ended April 30, 2017: 45,273,614 shares
Three months ended April 30, 2016: 44,632,724 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 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 three months ended April 30, 2017 (from February 1, 2017 to April 30, 2017) continued to show a moderate recovery due to robust corporate earnings. However, the recovery remained only moderate as personal consumption remained sluggish. The US economy continued a recovery trend, indicating positive signs for the outlook for corporate activities and the employment environment, backed by improvements in corporate earnings environment as a result of recovering domestic and international demand.

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.

After the first patient (with an objective of 156 participants; double-blind trial) was enrolled 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") in March 2016, subsequent enrollments have ensued during the three months ended April 30, 2017. 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, subsequent enrollments have ensued 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.

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.

Under these circumstances, for the three months ended April 30, 2017, operating revenue totaled ¥123 million (operating revenue of ¥625 million for the same period in the previous fiscal year), reflecting proceeds from the development support fee related to the Phase 2b clinical trial for chronic stroke in the US based on the joint development and license agreements of SB623 concluded with Sumitomo Dainippon Pharma Co., Ltd. in North America. Operating loss was ¥1,021 million (operating income of ¥77 million for the same period in the previous fiscal year), due to the recording of ¥929 million of clinical trial expenses and other expenses related to the two abovementioned development programs as research and development expenses. Ordinary loss was ¥1,098 million (ordinary loss of ¥320 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,097 million (net loss attributable to owners of parent of ¥277 million for the same period in the previous fiscal year), mainly due to the recording of ¥65 million of foreign exchange losses.

(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 ¥6,250 million, an increase of ¥126 million compared to the end of the previous fiscal year (¥6,124 million), mainly due to an increase of ¥174 million in advance payments.

(Non-current assets)

The balance of non-current assets at the end of the first quarter of the fiscal year under review was ¥149 million, a decrease of ¥18 million compared to the end of the previous fiscal year (¥167 million), mainly due to a decrease of ¥16 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 ¥561 million, an increase of ¥14 million compared to the end of the previous fiscal year (¥547 million), mainly due to an increase of ¥148 million in accounts payable - other included in other of current liabilities and decreases of ¥100 million in short-term loans payable and of ¥42 million in accrued expenses included in other of current liabilities.

(Non-current liabilities)

The balance of non-current liabilities at the end of the first quarter of the fiscal year under review was ¥2,283 million, an increase of ¥1,133 million compared to the end of the previous fiscal year (¥1,150 million), due to an increase of ¥1,133 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 ¥3,555 million, a decrease of ¥1,039 million compared to the end of the previous fiscal year (¥4,594 million), mainly due to the recording of ¥1,097 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 first half and the full year of the fiscal year under review, as released on March 17, 2017.

2. Quarterly Consolidated Financial Statements and Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2017	As of April 30, 2017
Assets		
Current assets		
Cash and deposits	5,561,424	5,546,773
Advance payments	495,531	669,984
Other	67,608	33,960
Total current assets	6,124,564	6,250,718
Non-current assets		
Property, plant and equipment	148,371	131,731
Intangible assets	7,701	6,875
Investments and other assets	11,776	11,174
Total non-current assets	167,849	149,780
Total assets	6,292,414	6,400,499
Liabilities		
Current liabilities		
Short-term loans payable	100,000	–
Current portion of long-term loans payable	49,980	66,640
Provision for bonuses	13,327	13,362
Other	384,088	481,661
Total current liabilities	547,395	561,663
Non-current liabilities		
Long-term loans payable	1,150,020	2,283,360
Total non-current liabilities	1,150,020	2,283,360
Total liabilities	1,697,415	2,845,023
Net assets		
Shareholders' equity		
Capital stock	3,852,012	3,862,284
Capital surplus	7,563,454	7,573,726
Retained earnings	(6,814,228)	(7,911,555)
Treasury shares	(146)	(180)
Total shareholders' equity	4,601,091	3,524,274
Accumulated other comprehensive income		
Foreign currency translation adjustment	(21,642)	14,218
Total accumulated other comprehensive income	(21,642)	14,218
Subscription rights to shares	15,548	16,983
Total net assets	4,594,998	3,555,475
Total liabilities and net assets	6,292,414	6,400,499

(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, 2016	For the three months ended April 30, 2017
Operating revenue	625,598	123,870
Operating expenses		
Research and development expenses	366,964	929,145
Other selling, general and administrative expenses	181,414	216,489
Total operating expenses	548,378	1,145,634
Operating income (loss)	77,220	(1,021,764)
Non-operating income		
Interest income	4,109	3,811
Other	124	168
Total non-operating income	4,234	3,979
Non-operating expenses		
Interest expenses	7,143	4,415
Foreign exchange losses	364,427	65,324
Financing expenses	30,000	11,034
Total non-operating expenses	401,570	80,774
Ordinary loss	(320,115)	(1,098,559)
Extraordinary income		
Gain on reversal of subscription rights to shares	–	1,716
Total extraordinary income	–	1,716
Loss before income taxes	(320,115)	(1,096,842)
Income taxes - current	371	485
Income taxes - deferred	(43,084)	–
Total income taxes	(42,713)	485
Net loss	(277,402)	(1,097,327)
Net loss attributable to owners of parent	(277,402)	(1,097,327)

Quarterly Consolidated Statements of Comprehensive Income

For the Three Months Ended April 30

(Thousand yen)

	For the three months ended April 30, 2016	For the three months ended April 30, 2017
Net loss	(277,402)	(1,097,327)
Other comprehensive income		
Foreign currency translation adjustment	12,244	35,860
Total other comprehensive income	12,244	35,860
Comprehensive income	(265,157)	(1,061,467)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(265,157)	(1,061,467)
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 under review, 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).

(Segment information)

<Segment information>

I. For the three months ended April 30, 2016 (from February 1, 2016 to April 30, 2016)

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

II. For the three months ended April 30, 2017 (from February 1, 2017 to April 30, 2017)

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