Consolidated Financial Results for the Six Months Ended July 31, 2017 [Japanese GAAP]

September 12, 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: September 12, 2017
Scheduled date of commencing dividend payments: —
Availability of supplementary briefing material on quarterly financial results: No
Schedule of quarterly 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, 2017 (February 1, 2017 to July 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	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
July 31, 2017	249	(63.5)	(2,149)	–	(2,282)	–	(2,276)	–
July 31, 2016	684	66.4	(610)	–	(1,228)	–	(1,145)	–

(Note) Comprehensive income: Six months ended July 31, 2017: ¥(2,208) million [–%]
Six months ended July 31, 2016: ¥(1,106) million [–%]

	Net income per share	Diluted net income per share
Six months ended	Yen	Yen
July 31, 2017	(50.25)	–
July 31, 2016	(25.60)	–

(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, 2017	5,386	2,410	44.4	52.82
As of January 31, 2017	6,292	4,594	72.8	101.52

(Reference) Equity: As of July 31, 2017: ¥2,393 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):
July 31, 2017: 45,319,676 shares
January 31, 2017: 45,109,032 shares

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

3) Average number of shares during the period:
Six months ended July 31, 2017: 45,295,918 shares
Six months ended July 31, 2016: 44,733,516 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 six months ended July 31, 2017 (from February 1, 2017 to July 31, 2017) showed a moderate recovery due to improvements in consumer confidence, 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 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.

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 continued during the six months ended July 31, 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 continued 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.

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 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.

Under these circumstances, for the six months ended July 31, 2017, operating revenue totaled ¥249 million (operating revenue of ¥684 million for the same period in the previous fiscal year), reflecting proceeds from the development support fee, etc. received from the joint development and license agreements of SB623 concluded by the Group with Sumitomo Dainippon Pharma Co., Ltd. in North America. Operating loss was ¥2,149 million

(operating loss of ¥610 million for the same period in the previous fiscal year). Ordinary loss was ¥2,282 million (ordinary loss of ¥1,228 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥2,276 million (net loss attributable to owners of parent of ¥1,145 million for the same period in the previous fiscal year), mainly due to the recording of ¥121 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

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 ¥5,249 million, a decrease of ¥874 million compared to the end of the previous fiscal year (¥6,124 million), mainly due to a decrease of ¥890 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the second quarter of the fiscal year under review was ¥136 million, a decrease of ¥31 million compared to the end of the previous fiscal year (¥167 million), mainly due to a decrease of ¥29 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the second quarter of the fiscal year under review was ¥709 million, an increase of ¥161 million compared to the end of the previous fiscal year (¥547 million), mainly due to a decrease of ¥100 million in short-term loans payable and an increase of ¥299 million in accounts payable - other included in other of current liabilities.

(Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was ¥2,266 million, an increase of ¥1,116 million compared to the end of the previous fiscal year (¥1,150 million), due to an increase of ¥1,116 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 ¥2,410 million, a decrease of ¥2,184 million compared to the end of the previous fiscal year (¥4,594 million), mainly due to the recording of ¥2,276 million in net loss attributable to owners of parent.

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 ¥2,183 million, a decrease of ¥2,693 million compared to the end of the previous fiscal year (¥4,876 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, 2017 was ¥1,936 million (compared to outflow of ¥633 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥2,274 million recorded.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2017 was ¥1,868 million (compared

to inflow of ¥455 million for the same period in the previous fiscal year). This was primarily due to payments into time deposits of ¥1,837 million.

(Cash flows from financing activities)

Net cash provided by financing activities for the six months ended July 31, 2017 was ¥1,045 million (compared to outflow of ¥357 million for the same period in the previous fiscal year). This was primarily due to proceeds from long-term loans payable of ¥1,150 million.

(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 Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2017	As of July 31, 2017
Assets		
Current assets		
Cash and deposits	5,561,424	4,670,660
Advance payments	495,531	543,695
Other	67,608	35,545
Total current assets	6,124,564	5,249,901
Non-current assets		
Property, plant and equipment	148,371	118,891
Intangible assets	7,701	6,848
Investments and other assets	11,776	10,938
Total non-current assets	167,849	136,677
Total assets	6,292,414	5,386,579
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	24,892
Other	384,088	617,830
Total current liabilities	547,395	709,363
Non-current liabilities		
Long-term loans payable	1,150,020	2,266,700
Total non-current liabilities	1,150,020	2,266,700
Total liabilities	1,697,415	2,976,063
Net assets		
Shareholders' equity		
Capital stock	3,852,012	3,863,755
Capital surplus	7,563,454	7,575,197
Retained earnings	(6,814,228)	(9,090,251)
Treasury shares	(146)	(180)
Total shareholders' equity	4,601,091	2,348,521
Accumulated other comprehensive income		
Foreign currency translation adjustment	(21,642)	45,462
Total accumulated other comprehensive income	(21,642)	45,462
Subscription rights to shares	15,548	16,531
Total net assets	4,594,998	2,410,515
Total liabilities and net assets	6,292,414	5,386,579

(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, 2016	For the six months ended July 31, 2017
Operating revenue	684,336	249,924
Operating expenses		
Research and development expenses	944,956	2,001,011
Other selling, general and administrative expenses	349,784	398,021
Total operating expenses	1,294,740	2,399,033
Operating loss	(610,404)	(2,149,109)
Non-operating income		
Interest income	1,920	10,018
Other	142	410
Total non-operating income	2,063	10,429
Non-operating expenses		
Interest expenses	6,691	11,211
Foreign exchange losses	583,251	121,294
Financing expenses	30,000	11,034
Total non-operating expenses	619,942	143,540
Ordinary loss	(1,228,283)	(2,282,220)
Extraordinary income		
Gain on reversal of subscription rights to shares	–	7,453
Total extraordinary income	–	7,453
Loss before income taxes	(1,228,283)	(2,274,766)
Income taxes - current	798	1,255
Income taxes - deferred	(83,706)	–
Total income taxes	(82,907)	1,255
Net loss	(1,145,376)	(2,276,022)
Net loss attributable to owners of parent	(1,145,376)	(2,276,022)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2016	For the six months ended July 31, 2017
Net loss	(1,145,376)	(2,276,022)
Other comprehensive income		
Foreign currency translation adjustment	38,628	67,104
Total other comprehensive income	38,628	67,104
Comprehensive income	(1,106,747)	(2,208,918)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(1,106,747)	(2,208,918)
Comprehensive income attributable to non-controlling interests	–	–

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2016	For the six months ended July 31, 2017
Cash flows from operating activities:		
Loss before income taxes	(1,228,283)	(2,274,766)
Depreciation	9,427	26,891
Share-based compensation expenses	4,410	8,446
Increase (decrease) in provision for bonuses	23,188	12,110
Interest income	(1,920)	(10,018)
Interest expenses	6,691	11,211
Foreign exchange losses (gains)	510,598	39,418
Financing expenses	30,000	11,034
Gain on reversal of subscription rights to shares	–	(7,453)
Decrease (increase) in inventories	(2,977)	–
Decrease (increase) in notes and accounts receivable - trade	–	17,350
Decrease (increase) in advance payments	17,719	(64,052)
Increase (decrease) in accounts payable - other	(68,003)	330,956
Increase (decrease) in accrued expenses	74,095	(57,261)
Increase (decrease) in advances received	9,998	–
Increase (decrease) in income taxes payable – factor based tax	(5,898)	1,970
Decrease (increase) in other current assets	(15,815)	16,751
Increase (decrease) in other current liabilities	8,114	(2,920)
Other	440	7,980
Subtotal	(628,214)	(1,932,350)
Interest income received	2,005	6,714
Interest expenses paid	(6,077)	(9,886)
Income taxes paid	(1,403)	(1,080)
Net cash provided by (used in) operating activities	(633,690)	(1,936,603)
Cash flows from investing activities		
Payments into time deposits	(690)	(1,837,345)
Proceeds from withdrawal of time deposits	483,480	–
Purchase of property, plant and equipment	(30,355)	(24,164)
Proceeds from sales of property, plant and equipment	2,735	–
Purchase of intangible assets	–	(7,012)
Other	–	354
Net cash provided by (used in) investing activities	455,169	(1,868,167)
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	–	(100,000)
Proceeds from long-term loans payable	–	1,150,000
Repayments of long-term loans payable	(400,000)	(16,660)
Payments of financing expenses	(30,000)	(11,180)
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	72,482	23,476
Purchase of treasury shares	(118)	(33)
Net cash provided by (used in) financing activities	(357,636)	1,045,602
Effect of exchange rate change on cash and cash equivalents	(446,177)	65,906
Net increase (decrease) in cash and cash equivalents	(982,334)	(2,693,262)
Cash and cash equivalents at beginning of period	6,887,802	4,876,574
Cash and cash equivalents at end of period	5,905,468	2,183,311

(4) 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).