Consolidated Financial Results for the Six Months Ended July 31, 2016 [Japanese GAAP]

September 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: September 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: 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, 2016 (February 1, 2016 to July 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	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
July 31, 2016	684	66.4	(610)	–	(1,228)	–	(1,145)	–
July 31, 2015	411	–	(555)	–	(532)	–	(440)	–

(Note) Comprehensive income: Six months ended July 31, 2016: ¥(1,106) million [–%]
Six months ended July 31, 2015: ¥(431) million [–%]

	Net income per share	Diluted net income per share
Six months ended	Yen	Yen
July 31, 2016	(25.60)	–
July 31, 2015	(10.32)	–

(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, 2016	6,711	5,336	79.4	118.72
As of January 31, 2016	8,271	6,366	77.0	142.66

(Reference) Equity: As of July 31, 2016: ¥5,331 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	886	(24.6)	(3,814)	–	(3,830)	–	(3,641)	–	(81.62)

(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: 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):
July 31, 2016: 44,907,491 shares
January 31, 2016: 44,621,741 shares

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

3) Average number of shares during the period:
Six months ended July 31, 2016: 44,733,516 shares
Six months ended July 31, 2015: 42,634,016 shares

* Presentation regarding the implementation status of the quarterly review procedures

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," and "(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, 2016 (from February 1, 2016 to July 31, 2016) saw corporate earnings and the employment environment remain robust. On the other hand, uncertainty over the future of business confidence increased due to the recent strong yen and low stock prices. The U.S. economy continued to recover, as the improvement in the employment environment drove expansion of personal consumption.

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, a conditional and term-limited approval for 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, in both Japan and the US, of our unique regenerative cell medicine, SB623.

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 disability resulting 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 disability resulting from traumatic brain injury. Also, in Japan, we submitted a clinical trial notification concerning chronic motor disability resulting from traumatic brain injury to the Pharmaceuticals and Medical Devices Agency (PMDA) in March 2016. Following a 30-day examination period, it became possible to conduct clinical trials of SB623 in Japan. The Group continues to enroll additional patients for our stroke development program in the US and our traumatic brain injury development program in the US and Japan. In June 2016, interim 12-month Phase 1/2a clinical trial results for SB623 in patients with chronic motor deficits 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 in the same month.

In addition, the Group was granted a patent by the United States Patent and Trademark Office (USPTO) covering SB623 for the treatment of retinal degeneration (United States Patent No. 9,326,999 B2).

For the six months ended July 31, 2016, operating revenue totaled ¥684 million (vs. operating revenue of ¥411 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 ¥610 million (vs. operating loss of ¥555 million for the same period in the previous fiscal year). Ordinary loss was ¥1,228 million (vs. ordinary loss of ¥532 million for the same period in the previous fiscal year), and net loss attributable to owners of parent was ¥1,145 million (vs. net loss attributable to owners of parent of ¥440 million for the same period in the previous fiscal year), due to the recording of ¥6 million of interest expenses and ¥583 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 ¥6,623 million, a decrease of ¥1,568 million compared to the end of the previous fiscal year (¥8,191 million), mainly due to a decrease of ¥1,514 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 ¥88 million, an increase of ¥8 million compared to the end of the previous fiscal year (¥79 million), mainly due to an increase of ¥7 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 ¥994 million, a decrease of ¥424 million compared to the end of the previous fiscal year (¥1,419 million), mainly due to a decrease of ¥400 million in the current portion of long-term loans payable.

(Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was ¥379 million, a decrease of ¥105 million compared to the end of the previous fiscal year (¥484 million), mainly due to a decrease of ¥105 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the second quarter of the fiscal year under review were ¥5,336 million, a decrease of ¥1,029 million compared to the end of the previous fiscal year (¥6,366 million), mainly due to the recording of ¥1,145 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 ¥5,905 million, a decrease of ¥982 million compared to the end of the previous fiscal year (¥6,887 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, 2016 was ¥633 million (compared to outflow of ¥705 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥1,228 million recorded and foreign exchange losses of ¥510 million.

(Cash flows from investing activities)

Net cash provided by investing activities for the six months ended July 31, 2016 was ¥455 million (compared to outflow of ¥44 million for the same period in the previous fiscal year). This was primarily due to proceeds from withdrawal of time deposits of ¥483 million and purchase of property, plant, and equipment of ¥30 million.

(Cash flows from financing activities)

Net cash used in financing activities for the six months ended July 31, 2016 was ¥357 million (compared to inflow of ¥7,391 million for the same period in the previous fiscal year). This was primarily due to repayments of long-term loans of ¥400 million and proceeds from issuance of shares resulting from exercise of subscription rights to shares of ¥72 million.

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

No revisions have been made to the consolidated financial results forecasts for the first half and the full year of the fiscal year under review, as released on March 16, 2016.

2. Matters Concerning Summary Information (Notes)

(1) Changes in Significant Subsidiaries during the Six Months Ended July 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 six 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 July 31, 2016
Assets		
Current assets		
Cash and deposits	7,733,892	6,219,398
Other	457,599	403,741
Total current assets	8,191,492	6,623,140
Non-current assets		
Property, plant and equipment	67,974	75,880
Intangible assets	207	142
Investments and other assets	11,342	12,133
Total non-current assets	79,524	88,156
Total assets	8,271,017	6,711,296
Liabilities		
Current liabilities		
Short-term loans payable	100,000	100,000
Current portion of long-term loans payable	800,000	400,000
Provision for bonuses	20,994	40,875
Deferred tax liabilities	184,931	159,762
Other	313,651	294,241
Total current liabilities	1,419,577	994,879
Non-current liabilities		
Long-term loans payable	300,000	300,000
Deferred tax liabilities	184,931	79,881
Total non-current liabilities	484,931	379,881
Total liabilities	1,904,508	1,374,760
Net assets		
Shareholders' equity		
Capital stock	3,806,973	3,843,310
Capital surplus	7,518,415	7,554,753
Retained earnings	(4,978,932)	(6,124,308)
Treasury shares	(28)	(146)
Total shareholders' equity	6,346,428	5,273,608
Accumulated other comprehensive income		
Foreign currency translation adjustment	19,362	57,990
Total accumulated other comprehensive income	19,362	57,990
Subscription rights to shares	718	4,937
Total net assets	6,366,509	5,336,535
Total liabilities and net assets	8,271,017	6,711,296

(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, 2015	For the six months ended July 31, 2016
Operating revenue	411,253	684,336
Operating expenses		
Research and development expenses	685,162	944,956
Other selling, general and administrative expenses	281,768	349,784
Total operating expenses	966,931	1,294,740
Operating loss	(555,677)	(610,404)
Non-operating income		
Interest income	241	1,920
Foreign exchange gains	83,156	—
Other	27	142
Total non-operating income	83,425	2,063
Non-operating expenses		
Interest expenses	8,960	6,691
Foreign exchange losses	—	583,251
Share issuance cost	32,446	—
Listing-related expenses	18,356	—
Financing expenses	—	30,000
Total non-operating expenses	59,762	619,942
Ordinary loss	(532,015)	(1,228,283)
Extraordinary losses		
Loss on retirement of non-current assets	1	—
Total extraordinary losses	1	—
Loss before income taxes	(532,016)	(1,228,283)
Income taxes - current	580	798
Income taxes - deferred	(92,595)	(83,706)
Total income taxes	(92,014)	(82,907)
Net loss	(440,002)	(1,145,376)
Net loss attributable to owners of parent	(440,002)	(1,145,376)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2015	For the six months ended July 31, 2016
Net loss	(440,002)	(1,145,376)
Other comprehensive income		
Foreign currency translation adjustment	8,222	38,628
Total other comprehensive income	8,222	38,628
Comprehensive income	(431,779)	(1,106,747)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(431,779)	(1,106,747)
Comprehensive income attributable to non-controlling interests	—	—

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2015	For the six months ended July 31, 2016
Cash flows from operating activities:		
Loss before income taxes	(532,016)	(1,228,283)
Depreciation	5,853	9,427
Share-based compensation expenses	—	4,410
Increase (decrease) in provision for bonuses	(8,278)	23,188
Interest income	(241)	(1,920)
Interest expenses	8,960	6,691
Foreign exchange losses (gains)	(84,384)	510,598
Share issuance cost	32,446	—
Financing expenses	—	30,000
Loss on retirement of non-current assets	1	—
Decrease (increase) in inventories	—	(2,977)
Decrease (increase) in advance payments	(327,677)	17,719
Increase (decrease) in accounts payable - other	218,271	(68,003)
Increase (decrease) in accrued expenses	(16,578)	74,095
Increase (decrease) in advances received	—	9,998
Increase (decrease) in income taxes payable - factor based tax	7,960	(5,898)
Decrease (increase) in other current assets	(176)	(15,815)
Increase (decrease) in other current liabilities	(370)	8,114
Other	—	440
Subtotal	(696,230)	(628,214)
Interest income received	115	2,005
Interest expenses paid	(8,981)	(6,077)
Income taxes paid	(265)	(1,403)
Net cash provided by (used in) operating activities	(705,361)	(633,690)
Cash flows from investing activities		
Payments into time deposits	—	(690)
Proceeds from withdrawal of time deposits	—	483,480
Purchase of property, plant and equipment	(39,072)	(30,355)
Proceeds from sales of property, plant and equipment	—	2,735
Purchase of intangible assets	(258)	—
Payments for lease deposits	(5,587)	—
Net cash provided by (used in) investing activities	(44,918)	455,169
Cash flows from financing activities		
Repayments of long-term loans payable	—	(400,000)
Payments of financing expenses	—	(30,000)
Proceeds from issuance of common shares	7,327,553	—
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	63,527	72,482
Purchase of treasury shares	(28)	(118)
Net cash provided by (used in) financing activities	7,391,053	(357,636)
Effect of exchange rate change on cash and cash equivalents	91,749	(446,177)
Net increase (decrease) in cash and cash equivalents	6,732,522	(982,334)
Cash and cash equivalents at beginning of period	1,228,551	6,887,802
Cash and cash equivalents at end of period	7,961,074	5,905,468

(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

(Segment information)

<Segment information>

I. For the six months ended July 31, 2015 (from February 1, 2015 to July 31, 2015)

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

II. For the six months ended July 31, 2016 (from February 1, 2016 to July 31, 2016)

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