[Delayed] Consolidated Financial Results for the Six Months Ended July 31, 2015 [Japanese GAAP]



September 14, 2015

Company name: SanBio Company Limited Stock exchange listing: Tokyo Stock Exchange Code number: 4592 URL: http://www.sanbio.jp/ Representative: Keita Mori, Representative Director and President Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration Phone: +81-3-6264-3481 Scheduled date of filing quarterly securities report: September 14, 2015 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, 2015 (February 1, 2015 to July 31, 2015)

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

	Operating reve	enue	Operating inc	ome	Ordinary inco	ome	Net income	
Six months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
July 31, 2015	411	_	(555)	_	(532)	_	(440)	_
July 31, 2014	_	_	_	_	_	_	_	_

(Note) Comprehensive income: Six months ended July 31, 2015: ¥(431) million [-%]

	Six months ended July 31, 2014: \neq – million [–%]				
	Net income per share	Diluted net income per share			
		per share			
Six months ended	Yen	Yen			
July 31, 2015	(10.32)	_			
July 31, 2014					

- (Notes) 1. The Company started to disclose the second quarter financial results from the fiscal year ending January 31, 2016, and thus the figures for the six months ended July 31, 2014 and year-on-year changes are not stated herein.
 - 2. The Company's stock was listed on the TSE Mothers market on April 8, 2015. 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, 2015	8,888	6,904	77.7	155.24
As of January 31, 2015	1,755	(87)	(5.0)	(2.22)
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(Reference) Equity: As of July 31, 2015: ¥6,903 million As of January 31, 2015: ¥(87) 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, 2015	_	0.00	_	0.00	0.00
Fiscal year ending January 31, 2016	_	0.00			
Fiscal year ending January 31, 2016 (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, 2016 (February 1, 2015 to January 31, 2016)

(% indicates changes from the previous corresponding period.)

	Operating revenue	Operating income	Ordinary income	Net income	Net income per share
	Million yen %	Million yen %	Million yen %	Million yen %	Yen
Full year	1,835 (43.2)	(855) –	(838) –	(744) –	(17.47)

(Note) Revision to the financial results forecast announced most recently: Yes For revision to the consolidated financial results forecast, please refer to the "Notification of Differences between Consolidated Financial Results Forecast and Actual Financial Results for the Second Quarter (Six Months) and Revision to Consolidated Financial Results Forecast for the Full Fiscal Year" announced today (September 14, 2015).

* 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, 2015: 44,470,491 shares January 31, 2015: 39,620,484 shares
- 2) Total number of treasury shares at the end of the period: July 31, 2015: 16 shares January 31, 2015: – shares
- 3) Average number of shares during the period: Six months ended July 31, 2015: 42,634,016 shares Six months ended July 31, 2014: 38,773,398 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 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 moment and certain assumptions deemed to be reasonable, and the Company does not assure any achievement of them. 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 in 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, 2015 (from February 1, 2015 to July 31, 2015) continued a moderate recovery trend, with active corporate capital investment, expansion of employment and wage increase, backed by strong corporate earnings. The economy in North America is gaining strength, driven by steady household spending on the back of an improved labor market. Nevertheless, the outlook remained uncertain due to concerns about global economic downturn mainly in Europe and China and the effect of declining crude oil prices.

In the regenerative medicine industry, the environment for supporting creation of medicines and medical equipment originated in Japan is being developed as there are rising expectations for promotion of regenerative medicine industry by the enforcement of the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Act in 2014, and the Japan Agency for Medical Research and Development was established in April 2015 to promote integrated medical research and development from basic research to practical applications.

Under this environment, the Group (hereinafter referring to both the Company and its consolidated subsidiary, SanBio, Inc. (Mountain View, California, U.S.)) listed its stock on the Mothers market of the Tokyo Stock Exchange on April 8, 2015 to make use of the movement to backup the regenerative medicine industry in Japan led by the government for raising capital. In addition, the Group is currently preparing for the commencement of Phase IIb clinical trial for SB623, a cell therapy for chronic stroke with a scale of 150 participants in the U.S., for which the U.S. Food and Drug Administration (FDA) granted an approval in June 2014. While development in the U.S. is underway, we have been studying the feasibility of securing approval for production and sales in Japan for treatment of chronic traumatic brain injury. During the second quarter of the fiscal year under review, we have decided to start a full-scale development program for regenerative therapy of chronic traumatic brain injury using SB623 cells in Japan with the aim of securing approval for production and sales. As to intellectual property rights, the Group acquired the substance patent (see note) related to its regenerative cell medicine SB623 in the U.S. on March 3, 2015. Two patents, including this one, were acquired during the six months ended July 31, 2015.

As a result, for the six months ended July 31, 2015, operating revenue totaled ¥411 million and operating loss was ¥555 million. Ordinary loss was ¥532 million and net loss was ¥440 million, due to the recording of ¥83 million of foreign exchange gains, ¥32 million of share issuance cost and ¥18 million of listing-related expenses related to IPO, as well as ¥8 million of interest expenses.

The Group consists of a single business segment, the regenerative cell therapy using allogeneic stem cells; therefore, description of business performance by segment is omitted.

Note: There are four types of the pharmaceutical patents; "substance patent," "process patent," "formulation patent," and "utility patent." A substance patent is a patent giving protection to a substance itself. As this is the most important patent among the pharmaceutical patents and the scope of the rights it protects is wide, substantial costs and time are incurred for its acquisition. The acquisition of a substance patent makes it possible to exclusively manufacture and market a newly developed pharmaceutical product.

(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 \$8,823 million, an increase of \$7,565 million compared to the end of the previous fiscal year (\$1,258 million), mainly due to an increase of \$7,228 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 ¥64 million, a decrease of ¥432 million compared to the end of the previous fiscal year (¥497 million), mainly due to a decrease of ¥467 million in investments and other assets.

(Current liabilities)

The balance of current liabilities at the end of the second quarter of the fiscal year under review was \$599 million, an increase of \$218 million compared to the end of the previous fiscal year (\$380 million), mainly due to an increase of \$224 million in accounts payable – other and a decrease of \$13 million in accrued expenses.

(Non-current liabilities)

The balance of non-current liabilities at the end of the second quarter of the fiscal year under review was \$1,384 million, a decrease of \$77 million compared to the end of the previous fiscal year (\$1,461 million), due to a decrease of \$77 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the second quarter of the fiscal year under review were $\pm 6,904$ million (negative ± 87 million at the end of the previous fiscal year). This contributed to an improvement in equity ratio, from negative 5.0% to positive 77.7%.

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 ¥7,961 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, 2015 was ¥705 million. This was primarily due to loss before income taxes and minority interests of ¥532 million recorded and an increase in advance payments of ¥327 million.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2015 was ¥44 million. This was primarily due to purchase of property, plant and equipment of ¥39 million.

(Cash flows from financing activities)

Net cash provided by financing activities for the six months ended July 31, 2015 was ¥7,391 million. This was primarily due to proceeds from issuance of common shares of ¥7,327 million.

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

Phase IIb clinical trials (U.S.) for chronic stroke and Phase II clinical trials (U.S.) for chronic traumatic brain injury, for which SB623 is in the preparatory stage, are planned to start by the end of the fiscal year ending January 31, 2016. In Japan, as announced in the press release entitled "Development program in Japan for regenerative therapy of Traumatic Brain Injury using SB623" dated July 8, 2015, a full-scale development program for treatment of traumatic brain injury has started with the aim of securing approval for production and sales.

With regard to the consolidated financial results forecast, operating revenue is expected to decrease primarily due to review of the timing of the recording of proceeds from development support fee. Expenses associated with Phase IIb clinical trials (U.S.) for stroke and Phase II clinical trials (U.S.) for traumatic brain injury, for which SB623 is in the preparatory stage, had initially been forecasted to be incurred from the six months ended July 31, 2015, however, are instead expected to arise mainly in the third and the fourth quarters of the fiscal year ending January 31, 2016 as well as in the fiscal year ending January 31, 2017 or later, after the commencement of the clinical trials. Furthermore, expenses relating to clinical trials in Japan for traumatic brain injury are expected to be additionally incurred. As a result of the above, the consolidated financial results forecast for the full fiscal year has been revised.

The development programs for stroke and for traumatic brain injury are making progress as scheduled.

2. Matters Concerning Summary Information (Notes)

- Changes in Significant Subsidiaries during the Six Months Ended July 31, 2015 There is no relevant information.
- (2) Accounting Policies Adopted Specially for the Preparation of Quarterly Consolidated Financial Statements There is no relevant information.
- (3) Changes in Accounting Policies, Changes in Accounting Estimates and Retrospective Restatement There is no relevant information.

3. Significant Events Concerning Going Concern Assumption

There is no relevant information.

<u>4. Quarterly Consolidated Financial Statements</u> (1) Quarterly Consolidated Balance Sheets

	As of January 31, 2015	As of July 31, 2015
Assets		
Current assets		
Cash and deposits	1,228,551	8,457,234
Other	29,464	366,579
Total current assets	1,258,016	8,823,814
Non-current assets		
Property, plant and equipment	18,279	53,064
Investments and other assets	478,761	11,543
Total non-current assets	497,041	64,607
Total assets	1,755,057	8,888,421
Liabilities		
Current liabilities		
Short-term loans payable	100,000	100,000
Provision for bonuses	10,253	1,990
Other	270,252	497,333
Total current liabilities	380,506	599,324
Non-current liabilities		
Long-term loans payable	1,100,000	1,100,000
Other	361,845	284,671
Total non-current liabilities	1,461,845	1,384,671
Total liabilities	1,842,351	1,983,995
Net assets		
Shareholders' equity		
Capital stock	89,573	3,801,388
Capital surplus	3,801,016	7,512,830
Retained earnings	(3,990,534)	(4,430,536)
Treasury shares		(28)
Total shareholders' equity	(99,944)	6,883,653
Accumulated other comprehensive income		
Foreign currency translation adjustment	11,830	20,052
Total accumulated other comprehensive income	11,830	20,052
Subscription rights to shares	819	718
Total net assets	(87,294)	6,904,425
Total liabilities and net assets	1,755,057	8,888,421

(Thousand yen)

(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
Operating revenue	411,253
Operating expenses	
Research and development expenses	685,162
Other selling, general and administrative expenses	281,768
Total operating expenses	966,931
Operating loss	(555,677)
Non-operating income	,,,,,
Interest income	241
Foreign exchange gains	83,156
Other	27
Total non-operating income	83,425
Non-operating expenses	
Interest expenses	8,960
Share issuance cost	32,446
Listing-related expenses	18,356
Total non-operating expenses	59,762
Ordinary loss	(532,015)
Extraordinary losses	
Loss on retirement of non-current assets	1
Total extraordinary losses	1
Loss before income taxes and minority interests	(532,016)
Income taxes - current	580
Income taxes - deferred	(92,595)
Total income taxes	(92,014)
Loss before minority interests	(440,002)
Net loss	(440,002)
	(110,002)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

	(Thousand yen)
	For the six months ended July 31, 2015
Loss before minority interests	(440,002)
Other comprehensive income	
Foreign currency translation adjustment	8,222
Total other comprehensive income	8,222
Comprehensive income	(431,779)
Comprehensive income attributable to	· · · · · ·
Comprehensive income attributable to owners of parent	(431,779)
Comprehensive income attributable to minority interests	_

(3) Quarterly Consolidated Statements of Cash Flows

	For the six months ended July 31, 2015
Cash flows from operating activities:	
Loss before income taxes and minority interests	(532,016)
Depreciation	5,853
Increase (decrease) in provision for bonuses	(8,278)
Interest income	(241)
Interest expenses	8,960
Foreign exchange losses (gains)	(84,384)
Share issuance cost	32,446
Loss on retirement of non-current assets	1
Decrease (increase) in advance payments	(327,677)
Increase (decrease) in accounts payable - other	218,271
Increase (decrease) in accrued expenses	(16,578)
Increase (decrease) in income taxes payable - factor based tax	7,960
Decrease (increase) in other current assets	(176)
Increase (decrease) in other current liabilities	(370)
Subtotal	(696,230)
Interest income received	115
Interest expenses paid	(8,981)
Income taxes paid	(265)
Net cash provided by (used in) operating activities	(705,361)
Cash flows from investing activities	
Purchase of property, plant and equipment	(39,072)
Purchase of intangible assets	(258)
Payments for lease deposits	(5,587)
Net cash provided by (used in) investing activities	(44,918)
Cash flows from financing activities	
Proceeds from issuance of common shares	7,327,553
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	63,527
Purchase of treasury shares	(28)
Net cash provided by (used in) financing activities	7,391,053
Effect of exchange rate change on cash and cash equivalents	91,749
Net increase (decrease) in cash and cash equivalents	6,732,522
Cash and cash equivalents at beginning of period	1,228,551
Cash and cash equivalents at end of period	7,961,074

(4) Notes to the Quarterly Consolidated Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Notes in the case of significant changes in shareholders' equity)

Capital stock and capital surplus of the Company increased by ¥3,680,000 thousand respectively as a result of the issuance of 4,000,000 new shares (issue price: ¥2,000; subscription price: ¥1,840; and capitalization: ¥920) through public offering (offering by the book building method) with payment due date set on April 7, 2015.

In addition, during the six months ended July 31, 2015, capital stock and legal capital surplus increased by ¥31,814 thousand respectively due to the exercise of subscription rights to shares as stock options.

As a result, capital stock and capital surplus were ¥3,801,388 thousand and ¥7,512,830 thousand respectively at the end of the second quarter of the fiscal year under review.

(Segment information)

<Segment information>

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, the regenerative cell therapy using allogeneic stem cells.