Consolidated Financial Results for the Nine Months Ended October 31, 2015 [Japanese GAAP]

December 14, 2015

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, 2015
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, 2015 (February 1, 2015 to October 31, 2015)

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

	Operating revenue		Operating income		Ordinary income		Net income	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
October 31, 2015	1,099	(64.8)	(566)	–	(608)	–	(470)	–
October 31, 2014	3,120	–	2,411	–	2,403	–	1,913	–

(Note) Comprehensive income: Nine months ended October 31, 2015: ¥(463) million [–%]
Nine months ended October 31, 2014: ¥1,930 million [–%]

	Net income per share	Diluted net income per share
Nine months ended	Yen	Yen
October 31, 2015	(10.88)	–
October 31, 2014	49.03	–

(Note) 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 October 31, 2015	8,782	6,876	78.3	154.26
As of January 31, 2015	1,755	(87)	(5.0)	(2.22)

(Reference) Equity: As of October 31, 2015: ¥6,875 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: 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):
October 31, 2015: 44,570,491 shares
January 31, 2015: 39,620,484 shares

2) Total number of treasury shares at the end of the period:
October 31, 2015: 16 shares
January 31, 2015: – shares

3) Average number of shares during the period:
Nine months ended October 31, 2015: 43,264,984 shares
Nine months ended October 31, 2014: 39,038,355 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 3 in the attachment.

Table of Contents

1. Qualitative Information on Quarterly Financial Results for the Period under Review 2
(1) Explanation of Operating Results 2
(2) Explanation of Financial Position 3
(3) Explanation of Consolidated Financial Results Forecast and Other Forward-looking Information 3

2. Matters Concerning Summary Information (Notes) 4
(1) Changes in Significant Subsidiaries during the Nine Months Ended October 31, 2015 4
(2) Accounting Policies Adopted Specially for the Preparation of Quarterly Consolidated Financial Statements 4
(3) Changes in Accounting Policies, Changes in Accounting Estimates and Retrospective Restatement 4

3. Significant Events Concerning Going Concern Assumption 4

4. Quarterly Consolidated Financial Statements 5
(1) Quarterly Consolidated Balance Sheets 5
(2) Quarterly Consolidated Statements of Income and Comprehensive Income 6
Quarterly Consolidated Statements of Income
For the Nine Months Ended October 31 6
Quarterly Consolidated Statements of Comprehensive Income
For the Nine Months Ended October 31 7
(3) Notes to the Quarterly Consolidated Financial Statements 8
(Notes on going concern assumption) 8
(Notes in the case of significant changes in shareholders' equity) 8
(Segment information) 8

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, 2015 (from February 1, 2015 to October 31, 2015) performed well due to a moderate increase in personal consumption supported by improvements in employment levels and income conditions. Similarly, the U.S. economy remained robust, driven by steady household spending.

In the regenerative medicine industry, amid ongoing promotion of the regenerative medicine industry by the enforcement of the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Act in 2014, 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, and the environment for supporting creation of medicines and medical equipment originated in Japan is being developed. As a result, a conditional and term-limited approval for sales was granted for regenerative medicine for the first time in September 2015, and the industrialization of regenerative medicine products is gradually becoming a reality.

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 the U.S., 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 addition, with regard to treatment of chronic traumatic brain injury using SB623, we began recruiting participants for the Phase II clinical trial in October 2015.

In Japan, we have been studying the feasibility of securing approval for production and sales for treatment of chronic traumatic brain injury using SB623. In July 2015, we decided to start a full-scale development program for treatment of chronic traumatic brain injury using SB623, and are currently in consultation with the authorities for commencement of clinical trials.

As to intellectual property rights, the substance patent (see note) was issued related to its regenerative cell medicine SB623 in the U.S. on March 3, 2015. Two patents, including the aforementioned one, were issued during the nine months ended October 31, 2015. With regard to our unique cell medicine SB623 and subsequent pipeline products, we have already obtained not only the substance patent but also the patents related to production and utility, and strive to secure intellectual property rights which create a competitive advantage.

As a result, for the nine months ended October 31, 2015, operating revenue totaled ¥1,099 million (down 64.8% compared to the same period of the previous fiscal year), primarily reflecting milestone revenue of US$5 million and proceeds from development support fee related to the joint development and license agreements concluded on SB623 with Sumitomo Dainippon Pharma Co., Ltd. in North America, and operating loss was ¥566 million (operating income of ¥2,411 million for the same period of the previous fiscal year). Ordinary loss was ¥608 million (ordinary income of ¥2,403 million for the same period of the previous fiscal year), and net loss was ¥470 million (net income of ¥1,913 million for the same period of the previous fiscal year), due to ¥32 million of share issuance cost and ¥18 million of listing-related expenses in line with the IPO, as well as ¥13 million of interest expenses, despite the recording of ¥20 million of foreign exchange gains as non-operating income.

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

(Current assets)

The balance of current assets at the end of the third quarter of the fiscal year under review was ¥8,714 million, an increase of ¥7,456 million compared to the end of the previous fiscal year (¥1,258 million), mainly due to an increase of ¥7,018 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 ¥68 million, a decrease of ¥428 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 third quarter of the fiscal year under review was ¥575 million, an increase of ¥194 million compared to the end of the previous fiscal year (¥380 million), mainly due to an increase of ¥182 million in accounts payable – other.

(Non-current liabilities)

The balance of non-current liabilities at the end of the third quarter of the fiscal year under review was ¥1,331 million, a decrease of ¥130 million compared to the end of the previous fiscal year (¥1,461 million), mainly due to a decrease of ¥130 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the third quarter of the fiscal year under review were ¥6,876 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 78.3%.

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

No revisions have been made so far to the consolidated financial results forecasts for the full year of the fiscal year under review announced in the “Notification of Differences between Consolidated Financial Results Forecast and Actual Financial Results for the Second Quarter (Six Months) and Revision of Consolidated Financial Results Forecast for the Full Fiscal Year ending January 31, 2016” on September 14, 2015.

2. Matters Concerning Summary Information (Notes)

(1) Changes in Significant Subsidiaries during the Nine Months Ended October 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.

4. Quarterly Consolidated Financial Statements

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2015	As of October 31, 2015
Assets		
Current assets		
Cash and deposits	1,228,551	8,247,160
Other	29,464	466,945
Total current assets	1,258,016	8,714,106
Non-current assets		
Property, plant and equipment	18,279	56,977
Investments and other assets	478,761	11,691
Total non-current assets	497,041	68,668
Total assets	1,755,057	8,782,774
Liabilities		
Current liabilities		
Short-term loans payable	100,000	100,000
Provision for bonuses	10,253	20,976
Other	270,252	454,217
Total current liabilities	380,506	575,193
Non-current liabilities		
Long-term loans payable	1,100,000	1,100,000
Other	361,845	231,221
Total non-current liabilities	1,461,845	1,331,221
Total liabilities	1,842,351	1,906,415
Net assets		
Shareholders' equity		
Capital stock	89,573	3,803,338
Capital surplus	3,801,016	7,514,780
Retained earnings	(3,990,534)	(4,461,337)
Treasury shares	—	(28)
Total shareholders' equity	(99,944)	6,856,753
Accumulated other comprehensive income		
Foreign currency translation adjustment	11,830	18,887
Total accumulated other comprehensive income	11,830	18,887
Subscription rights to shares	819	718
Total net assets	(87,294)	6,876,359
Total liabilities and net assets	1,755,057	8,782,774

(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, 2014	For the nine months ended October 31, 2015
Operating revenue	3,120,093	1,099,484
Operating expenses		
Research and development expenses	460,194	1,227,894
Other selling, general and administrative expenses	247,919	437,948
Total operating expenses	708,114	1,665,843
Operating income (loss)	2,411,979	(566,358)
Non-operating income		
Interest income	79	948
Foreign exchange gains	—	20,839
Other	9	64
Total non-operating income	88	21,852
Non-operating expenses		
Interest expenses	1,742	13,549
Foreign exchange losses	6,342	—
Share issuance cost	744	32,446
Listing-related expenses	—	18,356
Total non-operating expenses	8,828	64,351
Ordinary income (loss)	2,403,239	(608,857)
Extraordinary losses		
Loss on retirement of non-current assets	—	1
Total extraordinary losses	—	1
Income (loss) before income taxes and minority interests	2,403,239	(608,858)
Income taxes - current	217	883
Income taxes - deferred	489,084	(138,939)
Total income taxes	489,302	(138,055)
Income (loss) before minority interests	1,913,936	(470,802)
Net income (loss)	1,913,936	(470,802)

Quarterly Consolidated Statements of Comprehensive Income

For the Nine Months Ended October 31

(Thousand yen)

	For the nine months ended October 31, 2014	For the nine months ended October 31, 2015
Income (loss) before minority interests	1,913,936	(470,802)
Other comprehensive income		
Foreign currency translation adjustment	16,734	7,057
Total other comprehensive income	16,734	7,057
Comprehensive income	1,930,670	(463,745)
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	1,930,670	(463,745)
Comprehensive income attributable to minority interests	—	—

(3) 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 legal 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 nine months ended October 31, 2015, capital stock and legal capital surplus increased by ¥33,764 thousand respectively due to the exercise of subscription rights to shares as stock options.

As a result, capital stock and capital surplus were ¥3,803,338 thousand and ¥7,514,780 thousand respectively at the end of the third quarter of the fiscal year under review.

(Segment information)

<Segment information>

I. Nine months ended October 31, 2014 (from February 1, 2014 to October 31, 2014)

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

II. 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, the regenerative cell therapy using allogeneic stem cells.