

Consolidated Financial Results for the Six Months Ended July 31, 2018 [Japanese GAAP]



September 13, 2018

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 13, 2018

Scheduled date of commencing dividend payments: —

Availability of supplementary briefing material on financial results: No

Schedule of 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, 2018 (February 1, 2018 to July 31, 2018)

(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 July 31, 2018	Million yen 415 66.3	Million yen (1,615) —	Million yen (1,040) —	Million yen (1,041) —
July 31, 2017	249 (63.5)	(2,149) —	(2,282) —	(2,276) —

(Note) Comprehensive income: Six months ended July 31, 2018: ¥(1,150) million [-%]

Six months ended July 31, 2017: ¥(2,208) million [-%]

	Net income per share	Diluted net income per share
Six months ended July 31, 2018	Yen (22.01)	Yen —
July 31, 2017	(50.25)	—

(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
As of July 31, 2018	Million yen 14,791	Million yen 10,808	% 72.8	Yen 216.81
As of January 31, 2018	5,193	853	16.1	18.33

(Reference) Equity: As of July 31, 2018: ¥10,775 million

As of January 31, 2018: ¥833 million

2. Dividends

	Annual dividends				
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total
Fiscal year ended January 31, 2018	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 0.00
Fiscal year ending January 31, 2019	—	0.00	—	—	—
Fiscal year ending January 31, 2019 (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, 2019 (February 1, 2018 to January 31, 2019)

(% indicates changes from the previous corresponding period.)

	Operating revenue	Operating income	Ordinary income	Net income attributable to owners of parent	Net income per share				
Full year	Million yen 1,025	109.0	Million yen (3,540)	—	Million yen (2,529)	—	Yen (2,564)	—	(56.00)

(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, 2018: 49,700,049 shares
 - January 31, 2018: 45,492,281 shares
- 2) Total number of treasury shares at the end of the period:
 - July 31, 2018: 115 shares
 - January 31, 2018: 115 shares
- 3) Average number of shares during the period
 - Six months ended July 31, 2018: 47,338,137 shares
 - Six months ended July 31, 2017: 45,295,918 shares

*These quarterly financial results are outside the scope of quarterly review by a certified public accountant or an audit corporation.

* 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, 2018 (from February 1, 2018 to July 31, 2018) maintained a recovery path as corporate earnings, employment environment, and personal consumption 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 time-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 (RMAT: Regenerative Medicine Advanced Therapy) 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.

During the six months ended July 31, 2018, for the treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”), the Group has been conducting a Phase 2b clinical trial in the US jointly with Sumitomo Dainippon Pharma Co., Ltd. The trial entered a follow-up period of 12 months after the completion of enrollment of all 163 patients in December 2017, and the trial results are scheduled to be announced in the first half of the fiscal year ending January 31, 2020 (from February 2019 to July 2019). Regarding this trial, the Group passed the screening in relation to continuation of the trial by an outside Data and Safety Monitoring Board (See Note) when 50% and 75% of the enrollment was completed.

As to the development of the program in Japan, the Group entered into an exclusive licensing agreement concerning development and sales with Teijin Ltd. in 2009; however, both companies agreed to terminate the agreement as of February 14, 2018. As a result, the rights relating to this program in Japan were reverted to the Group, and the Group is promoting independent development in order to deliver a product for the treatment of chronic stroke to the market earlier than in any other region in the world.

A Phase 2 clinical trial has been conducted for the treatment of chronic motor deficit from traumatic brain injury (“development program for treatment of chronic traumatic brain injury”), which has been conducted independently by the Group in the US and Japan. The trial entered a follow-up period of 6 months after the completion of enrollment of all 61 patients in April 2018, and the trial results are scheduled to be announced in the fiscal year ending January 31, 2019 (from February 2018 to January 2019). In particular, as to the development program for treatment of chronic traumatic brain injury in Japan, the Group aims to apply for approval for manufacture and sales of pharmaceuticals utilizing the conditional and time-limited marketing approval system for regenerative medical products in Japan, and plans to apply for approval during the fiscal year ending January 31, 2020 (from February 2019 to January 2020). Regarding this program, 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. Regarding this trial, the Group again passed the screening in relation to continuation of the trial by an outside Data and Safety Monitoring Board (See Note) when 50%, 75% and 100% of the enrollment was completed.

As these two clinical trials were progressing steadily, the Group issued the 13th Share Acquisition Rights with an exercise price adjustment clause by third-party allotment in March 2018, with all of those rights exercised in June of that year for a procurement amount of ¥11,058 million. The procured funds are scheduled to be allocated as growth funds for activities such as: (1) establishment of manufacturing, logistics, and sales systems for SB623 following its launch; (2) development related to programs for the treatment of chronic stroke in Japan, and research and development to expand markets for future SB623 sales; and (3) research and development to expand new adaptations for SB623 and introduce new substances. As well as building capital through the fund procurement, the Group also intends to steadily resolve business-related issues that are important for the medium- and long-term growth of the Group, such as the development of markets and research and development to expand target diseases, and the establishment of manufacturing, logistics and

sales systems appropriate for the market by allocating the funds procured as funds for growth investment with the aim of improving corporate value.

Under these circumstances, for the six months ended July 31, 2018, operating revenue totaled ¥415 million (operating revenue of ¥249 million for the same period in the previous fiscal year), reflecting proceeds from the development support fee, etc. received from the joint development and sales license agreements of SB623 concluded by the Group with Sumitomo Dainippon Pharma Co., Ltd. in North America. Operating loss was ¥1,615 million (operating loss of ¥2,149 million for the same period in the previous fiscal year), due to the recording of ¥1,669 million of research and development expenses as clinical trial expenses and other expenses related to the two abovementioned development programs for the treatments of chronic motor deficit from ischemic stroke and chronic motor deficit from traumatic brain injury. Ordinary loss was ¥1,040 million (ordinary loss of ¥ 2,282 million for the same period in the previous fiscal year) mainly due to the recording of ¥472 million of non-operating income as a grant from the California Institute for Regenerative Medicine (CIRM) and ¥165 million of foreign exchange gains, while net loss attributable to owners of parent was ¥1,041 million (net loss attributable to owners of parent of ¥2,276 million for the same period of the previous fiscal year).

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.

(Note) Data and Safety Monitoring Board is an organization to be established to monitor adverse events, modification and termination of trials, and information which may affect the participant's willingness to continue trials, evaluate progress of clinical trials and safety data as well as recommend continuation, modification or termination of trials.

(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 ¥14,681 million, an increase of ¥9,604 million compared to the end of the previous fiscal year (¥5,076 million), mainly due to an increase of ¥9,277 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 ¥109 million, a decrease of ¥7 million compared to the end of the previous fiscal year (¥116 million), mainly due to a decrease of ¥10 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 ¥1,282 million, a decrease of ¥824 million compared to the end of the previous fiscal year (¥2,106 million), mainly due to decreases of ¥455 million in advance received and ¥279 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 ¥2,700 million, an increase of ¥466 million compared to the end of the previous fiscal year (¥2,233 million), due to an increase of ¥466 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 ¥10,808 million, an increase of ¥9,955 million compared to the end of the previous fiscal year (¥853 million). This was primarily due to increases of ¥5,546 million each in capital stock and capital surplus due to the exercise of share acquisition rights with an exercise price adjustment clause, despite the listing of ¥1,041 million in net loss attributable to owners of the 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 ¥13,932 million, an increase of ¥9,277 million compared to the end of the previous fiscal year (¥4,654 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, 2018 was ¥2,137 million (compared to an outflow of ¥1,936 million for the same period in the previous fiscal year). This was primarily due to a loss before income taxes of ¥1,039 recorded.

(Cash flows from investing activities)

Net cash used in investing activities for the six months ended July 31, 2018 was ¥3 million (compared to outflow of ¥1,868 million for the same period in the previous fiscal year). This was primarily due to an outflow of ¥3 million for purchase of property, plant and equipment.

(Cash flows from financing activities)

Net cash provided by financing activities for the six months ended July 31, 2018 was ¥11,493 million (compared to outflow of ¥1,045 million for the same period in the previous fiscal year). This was primarily due to proceeds from issuance of shares resulting from exercise of subscription rights to shares of ¥10,932 million and proceeds from long-term loans payable of ¥500 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 13, 2018.

2. Quarterly Consolidated Financial Statements and Primary Notes

(1) Quarterly Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2018	As of July 31, 2018
Assets		
Current assets		
Cash and deposits	4,654,820	13,932,135
Advance payments	372,901	694,191
Other	49,103	55,216
Total current assets	<u>5,076,825</u>	<u>14,681,543</u>
Non-current assets		
Property, plant and equipment	100,906	90,211
Intangible assets	5,351	4,038
Investments and other assets	10,470	15,384
Total non-current assets	<u>116,728</u>	<u>109,635</u>
Total assets	<u>5,193,554</u>	<u>14,791,178</u>
Liabilities		
Current liabilities		
Current portion of long-term loans payable	66,640	66,700
Advance received	1,292,269	836,730
Provision for bonuses	—	32,733
Other	748,014	346,602
Total current liabilities	<u>2,106,923</u>	<u>1,282,766</u>
Non-current liabilities		
Long-term loans payable	2,233,380	2,700,000
Total non-current liabilities	<u>2,233,380</u>	<u>2,700,000</u>
Total liabilities	<u>4,340,303</u>	<u>3,982,766</u>
Net assets		
Shareholders' equity		
Capital stock	3,875,072	9,421,113
Capital surplus	7,586,514	13,132,556
Retained earnings	(10,754,555)	(11,796,318)
Treasury shares	(180)	(180)
Total shareholders' equity	<u>706,851</u>	<u>10,757,171</u>
Accumulated other comprehensive income		
Foreign currency translation adjustment	126,936	18,152
Total accumulated other comprehensive income	<u>126,936</u>	<u>18,152</u>
Subscription rights to shares	19,463	33,088
Total net assets	<u>853,251</u>	<u>10,808,412</u>
Total liabilities and net assets	<u>5,193,554</u>	<u>14,791,178</u>

(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, 2017	For the six months ended July 31, 2018
Operating revenue	249,924	415,597
Operating expenses		
Research and development expenses	2,001,011	1,669,146
Other selling, general and administrative expenses	398,021	362,304
Total operating expenses	2,399,033	2,031,451
Operating loss	(2,149,109)	(1,615,853)
Non-operating income		
Interest income	10,018	9,500
Foreign exchange gains	—	165,198
Subsidy income	—	472,185
Other	410	6,413
Total non-operating income	10,429	653,296
Non-operating expenses		
Interest expenses	11,211	15,868
Foreign exchange losses	121,294	—
Financing expenses	11,034	4,971
Share issuance expenses	—	56,652
Total non-operating expenses	143,540	77,492
Ordinary loss	(2,282,220)	(1,040,048)
Extraordinary income		
Gain on reversal of subscription rights to shares	7,453	279
Total extraordinary income	7,453	279
Loss before income taxes	(2,274,766)	(1,039,769)
Income taxes - current	1,255	1,993
Total income taxes	1,255	1,993
Net loss	(2,276,022)	(1,041,762)
Net loss attributable to owners of parent	(2,276,022)	(1,041,762)

Quarterly Consolidated Statements of Comprehensive Income

For the Six Months Ended July 31

(Thousand yen)

	For the six months ended July 31, 2017	For the six months ended July 31, 2018
Net loss	(2,276,022)	(1,041,762)
Other comprehensive income		
Foreign currency translation adjustment	67,104	(108,783)
Total other comprehensive income	67,104	(108,783)
Comprehensive income	(2,208,918)	(1,150,546)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(2,208,918)	(1,150,546)
Comprehensive income attributable to non-controlling interests	—	—

(3) Quarterly Consolidated Statements of Cash Flows

(Thousand yen)

	For the six months ended July 31, 2017	For the six months ended July 31, 2018
Cash flows from operating activities:		
Loss before income taxes	(2,274,766)	(1,039,769)
Depreciation	26,891	17,791
Share-based compensation expenses	8,446	17,291
Increase (decrease) in provision for bonuses	12,110	32,156
Interest income	(10,018)	(9,500)
Foreign exchange losses (gains)	39,418	(21,546)
Subsidy income	—	(472,185)
Interest expenses	11,211	15,868
Share issuance expenses	—	56,652
Financing expenses	11,034	4,971
Gain on reversal of subscription rights to shares	(7,453)	(279)
Decrease (increase) in notes and accounts receivable - trade	17,350	—
Decrease (increase) in advance payments	(64,052)	(307,350)
Increase (decrease) in accounts payable - other	330,956	(284,204)
Increase (decrease) in accrued expenses	(57,261)	(143,376)
Increase (decrease) in income taxes payable – factor based tax	1,970	21,199
Decrease (increase) in other current assets	16,751	(11,649)
Increase (decrease) in other current liabilities	(2,920)	(6,246)
Other	7,980	(4,383)
Subtotal	(1,932,350)	(2,134,560)
Interest income received	6,714	12,700
Interest expenses paid	(9,886)	(15,879)
Income taxes paid	(1,860)	(2,598)
Income taxes refund	780	2,602
Net cash provided by (used in) operating activities	(1,936,603)	(2,137,734)
Cash flows from investing activities		
Payments into time deposits	(1,837,345)	—
Proceeds from sales of property, plant and equipment	(24,164)	(3,009)
Purchase of intangible assets	(7,012)	—
Other	354	(747)
Net cash provided by (used in) investing activities	(1,868,167)	(3,756)
Cash flows from financing activities		
Net increase (decrease) in short-term loans payable	(100,000)	—
Proceeds from long-term loans payable	1,150,000	500,000
Repayments of long-term loans payable	(16,660)	(33,320)
Payments of financing expenses	(11,180)	(5,036)
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	23,476	10,932,043
Proceeds from issuance of subscription rights to shares	—	100,000
Purchase of treasury shares	(33)	—
Net cash provided by (used in) financing activities	1,045,602	11,493,686
Effect of exchange rate change on cash and cash equivalents	65,906	(74,879)
Net increase (decrease) in cash and cash equivalents	(2,693,262)	9,277,314
Cash and cash equivalents at beginning of period	4,876,574	4,654,820
Cash and cash equivalents at end of period	2,183,311	13,932,135

(4) Notes to the Quarterly Consolidated Financial Statements
(Notes on going concern assumption)

None

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

The Company received payment due to the issue of shares in accordance with the partial exercise of the 13th Share Acquisition Rights (share acquisition rights with an exercise price adjustment clause by third-party allotment) issued on April 6, 2018. As a result, capital stock and legal capital surplus each increased by ¥5,529,000 thousand. Additionally, capital stock and legal capital surplus each increased by ¥17,041 thousand due to the exercise of share acquisition rights as stock options during the six months ended July 31, 2018.

As a result, at the end of the second quarter of the fiscal year under review, capital stock was ¥9,421,113 thousand and capital surplus was ¥13,132,556 thousand.