Consolidated Financial Results for the Fiscal Year Ended January 31, 2017 [Japanese GAAP]

March 17, 2017

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Stock exchange listing: Tokyo Stock Exchange
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Scheduled date of commencing dividend payments: —
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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 Fiscal Year Ended January 31, 2017 (February 1, 2016 to January 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	
Fiscal year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
January 31, 2017	949	(19.2)	(1,932)	–	(2,166)	–	(1,835)	–
January 31, 2016	1,174	(63.6)	(1,125)	–	(1,172)	–	(988)	–

(Note) Comprehensive income: Fiscal year ended January 31, 2017: ¥(1,876) million [–%]
Fiscal year ended January 31, 2016: ¥(980) million [–%]

	Net income per share	Diluted net income per share	Return on Equity	Ordinary income to total assets	Operating income to operating revenue
Fiscal year ended	Yen	Yen	%	%	%
January 31, 2017	(40.88)	–	(33.5)	(29.7)	(203.5)
January 31, 2016	(22.67)	–	(31.5)	(23.4)	(95.8)

(Reference) Equity earnings (losses) of affiliates: Fiscal year ended January 31, 2017: ¥ – million
Fiscal year ended January 31, 2016: ¥ – million

(2) Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of January 31, 2017	6,292	4,594	72.8	101.52
As of January 31, 2016	8,271	6,366	77.0	142.66

(Reference) Equity: As of January 31, 2017: ¥4,579 million
As of January 31, 2016: ¥6,365 million

(3) Consolidated Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended	Million yen	Million yen	Million yen	Million yen
January 31, 2017	(1,796)	79	159	4,876
January 31, 2016	(1,362)	(436)	7,402	6,887

2. Dividends

	Annual dividends					Total dividends (Total)	Payout ratio (Consolidated)	Dividends to net assets (Consolidated)
	1st quarter-end	2nd quarter-end	3rd quarter-end	Year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
Fiscal year ended January 31, 2016	–	0.00	–	0.00	0.00	–	–	–
January 31, 2017	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending January 31, 2018 (Forecast)	–	0.00	–	0.00	0.00		–	

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
First half	328	(52.0)	(1,996)	–	(2,002)	–	(2,015)	–	(44.53)
Full year	662	(62.6)	(3,945)	–	(3,957)	–	(3,982)	–	(87.82)

Notes:

(1) Changes in significant subsidiaries during the period under review (changes in specified subsidiaries resulting in changes in scope of consolidation): No

(2) 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

(3) Total number of issued shares (common shares)
1) Total number of issued shares at the end of the period (including treasury shares):
January 31, 2017: 45,109,032 shares
January 31, 2016: 44,621,741 shares

2) Total number of treasury shares at the end of the period:
January 31, 2017: 84 shares
January 31, 2016: 16 shares

3) Average number of shares during the period:
Fiscal year ended January 31, 2017: 44,890,374 shares
Fiscal year ended January 31, 2016: 43,598,673 shares

(Reference) Overview of Non-Consolidated Financial Results

Non-Consolidated Financial Results for the Fiscal Year Ended January 31, 2017 (February 1, 2016 to January 31, 2017)

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

	Operating revenue		Operating income		Ordinary income		Net income	
Fiscal year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
January 31, 2017	56	–	(570)	–	(744)	–	(745)	–
January 31, 2016	–	–	(433)	–	(465)	–	(466)	–

	Net income per share	Diluted net income per share
Fiscal year ended	Yen	Yen
January 31, 2017	(16.60)	–
January 31, 2016	(10.71)	–

(2) Non-Consolidated Financial Position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of January 31, 2017	7,586	6,227	81.9	137.70
As of January 31, 2016	8,125	6,867	84.5	153.89

(Reference) Equity: As of January 31, 2017: ¥6,211 million
As of January 31, 2016: ¥6,866 million

* These financial results are outside the scope of audit procedures.

* Explanation of the proper use of the financial results forecast and other notes

The consolidated earnings forecasts of the Group for the fiscal year ending January 31, 2018 herein are based on judgments derived from information available at the time of publication of this document and certain assumptions, and actual results may vary due to various factors. For the assumptions and notes for earnings forecasts, please refer to “Earnings Forecast for the Next Fiscal Year” on page 3 of the attachment.

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1. Analysis of Operating Results and Financial Position

(1) Analysis of Operating Results

1) Operating Results during the Fiscal Year under Review

The Japanese economy during the fiscal year ended January 31, 2017 (from February 1, 2016 to January 31, 2017) saw a gradual recovery in business confidence owing to improvements in corporate earnings and the employment environment, but personal consumption remained sluggish, and the economy was limited to a moderate recovery. The overall US economy was robust, backed by continued improvements in corporate earnings as a result of recovering domestic and international demand, despite uncertainty over the economic outlook with the advent of the Trump administration.

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, 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 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.

In March 2016, the first patient (with an objective of 156 participants; double-blind trial) in the US was enrolled in a Phase 2b clinical trial of SB623 for the treatment of chronic motor deficit from ischemic stroke (“development program for treatment of chronic stroke”), and subsequent enrollments have ensued. Similarly, in July 2016, the first patient (with an objective of 52 participants; double-blind trial) in the US was enrolled in a 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”), and subsequent enrollments have ensued. Regarding the latter, the Group received approval from the US Food and Drug Administration (FDA) 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.

In Japan, we submitted a clinical trial notification concerning chronic motor deficit 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. In October 2016, we enrolled the first patient in Japan for the clinical trial for the treatment of chronic traumatic brain injury, and are currently conducting it as a global clinical trial across two countries, the US and Japan. With a planned total of 52 participants from the US and Japan, we are pressing ahead with the development of the program, aiming to complete enrollment as soon as possible.

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. The contents of the article were presented at the annual meeting of the International Society for Stem Cell Research (ISSCR) held in June 2016, and at the annual meeting of the American Congress of Rehabilitation Medicine Conference held in November 2016, garnering the attention of many medical professionals and the media.

As for intellectual property, regarding its unique regenerative cell medicine SB623 and subsequent pipeline products, the Group has acquired not only the substance patent (see note) but also the patents related to production and patents covering the use of our products in specific disease indications, and is striving to secure intellectual property rights which create a competitive advantage. In the fiscal year under review, various patents were acquired, including the patent covering SB623 for the treatment of retinal degeneration (in the US), and the patent covering the treatment of traumatic brain injury (in Australia).

For the fiscal year ended January 31, 2017, operating revenue totaled ¥949 million (operating revenue of ¥1,174 million for the previous fiscal year), primarily reflecting the 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 ¥1,932million (operating loss of ¥1,125 million for the previous fiscal year), due to the recording of ¥2,058 million of clinical trial expenses and other expenses related to the two abovementioned development programs as research and development expenses. Ordinary loss was ¥2,166 million (ordinary loss of ¥1,172 million for the previous fiscal year), and net loss attributable to owners of parent was ¥1,835 million (net loss attributable to owners of parent of ¥988 million for the previous fiscal year), mainly due to the recording of ¥199 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.

Note: There are four types of pharmaceutical patents: “substance patent,” “process patent,” “formulation patent,” and “patents covering the use of our products in specific disease indications.” 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) Earnings Forecast for the Next Fiscal Year

In regard to the earnings forecast for the fiscal year ending January 31, 2018, the Group expects operating revenue of ¥662 million due to the recording of proceeds from the development support fee related to the Phase 2b clinical trial of SB623 for the treatment of chronic stroke, based on the joint development and license agreements concluded on SB623 with Sumitomo Dainippon Pharma Co., Ltd. in North America.

In terms of expenses, with regard to SB623, the Group is conducting the Phase 2b clinical trial for chronic stroke in the US and the Phase 2 global clinical trial for treatment of traumatic brain injury in the US and Japan. Due to clinical development costs related to these clinical trials, the Group expects to incur research and development expenses of ¥3,888 million. As a result, the Group forecasts an operating loss of ¥3,945 million, ordinary loss of ¥3,957 million and net loss of ¥3,982 million.

The forecast is based on an exchange rate of ¥115.00 per U.S. dollar.

The consolidated earnings forecasts of the Group for the fiscal year ending January 31, 2018 herein are based on judgments derived from information available at the time of publication of this document and certain assumptions, and actual results may vary due to various factors.

(2) Analysis of Financial Position

1) Assets, liabilities and net assets

(Current assets)

The balance of current assets at the end of the fiscal year under review was ¥6,124 million, a decrease of ¥2,066 million compared to the end of the previous fiscal year, mainly due to a decrease of ¥2,172 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the fiscal year under review was ¥167 million, an increase of ¥88 million compared to the end of the previous fiscal year, mainly due to an increase of ¥80 million in property, plant and equipment.

(Current liabilities)

The balance of current liabilities at the end of the fiscal year under review was ¥547 million, a decrease of ¥872 million compared to the end of the previous fiscal year, mainly due to decreases of ¥750 million in current portion of long-term loans payable and of ¥184 million in deferred tax liabilities.

(Non-current liabilities)

The balance of non-current liabilities at the end of the fiscal year under review was ¥1,150 million, an increase of ¥665 million compared to the end of the previous fiscal year, due to an increase of ¥850 million in long-term loans payable and a decrease of ¥184 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the fiscal year under review were ¥4,594 million, a decrease of ¥1,771 million compared to the end of the previous fiscal year, mainly due to a decrease of ¥1,835 million in retained earnings, offset by increases of ¥45 million in capital stock and capital surplus, respectively.

2) Cash flows

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the fiscal year under review were ¥4,876 million. Cash flows in each area of activity are as follows.

(Cash flows from operating activities)

Net cash used in operating activities for the fiscal year under review was ¥1,796 million (outflow of ¥1,362 million for the previous fiscal year). This was primarily due to a loss before income taxes of ¥2,166 million recorded and foreign exchange losses of ¥366 million.

(Cash flows from investing activities)

Net cash provided by investing activities for the fiscal year under review was ¥79 million (outflow of ¥436 million for the previous fiscal year). This was primarily due to proceeds from withdrawal of time deposits of ¥483 million and payments into time deposits of ¥308 million.

(Cash flows from financing activities)

Net cash provided by financing activities for the fiscal year under review was ¥159 million (inflow of ¥7,402 million for the previous fiscal year). This was primarily due to proceeds from long-term loans payable of ¥900 million and repayments of long-term loans payable of ¥800 million.

(Reference) Indicators relative to cash flows

	FY2014.1	FY2015.1	FY2016.1	FY2017.1
Equity ratio (%)	(413.8)	(5.0)	77.0	72.8
Equity ratio on a market value basis (%)	–	–	491.5	876.7
Cash flows to interest-bearing debt (Years)	–	–	–	–
Interest coverage ratio (Times)	–	–	–	–

Equity ratio: Equity / Total assets
Equity ratio on a market value basis: Market capitalization / Total assets
Cash flows to interest-bearing debt: Interest-bearing debt / Cash flows
Interest coverage ratio: Cash flows / Interest payments

Notes:

1. Data from fiscal years prior to FY2014.1 is not stated, as the Company was established on February 27, 2013.
2. The equity ratio on a market value basis in and before FY2015.1 is not stated, as the Company's shares were not then listed. Market capitalization is calculated by multiplying the share's closing price at the fiscal year-end by the number of issued shares at the fiscal year-end.
3. Cash flows to interest-bearing debt and interest coverage ratio are not stated, as negative operating cash flows have been recorded.
4. Calculations are based on financial data on a consolidated basis.
5. Market capitalization is based on the number of issued shares less the number of treasury shares.
6. Cash flows refer to cash flows from operating activities.
7. Interest-bearing debt includes all debt recorded in the consolidated balance sheet for which interest is paid.

(3) Basic Policy for Distribution of Profit and Dividends for FY2017.1 and FY2018.1

The Company recognizes that the return of profits to shareholders is one of its most important management policies. We determine dividends after taking into account the buildup of internal reserves in preparation for investments into research and development.

The Company has a basic principle of distributing dividends once a year at the fiscal year-end if dividends from surplus are to be paid. The General Meeting of Shareholders is the decision-making body for the payment.

Additionally, the Company stipulates in its Articles of Incorporation that payment of interim dividends is subject to the resolution of the Board of Directors, with July 31 of each year as the record date.

As to the fiscal year ended January 31, 2017, no dividend will be paid, as there is no distributable amount pursuant to Article 461 of the Companies Act and Article 149 of the Ordinance on Accounting of Companies. For the time being, the Company does not expect to pay dividends, in order to proactively engage in the research and development of medicine, and intends to use its internal reserves from profits for reinvestments.

(4) Business Risks

The following are possible major risk factors for the Group's business operation and development. Some are not necessarily regarded by the Group to be material risks. Nevertheless, matters of importance for investment decisions or for the full understanding of the Group's business activities are listed as risk factors from the standpoint of proactive information disclosure to investors and shareholders.

The Group, acknowledging that such risks may occur, will strive to avoid their occurrence and take appropriate action should they occur. However, shareholders and investors are recommended to make

investment decisions concerning the Company's shares carefully considering statements in this section as well as other sections. In addition, readers are advised that these matters do not cover all the risks for making investment decisions and various other risks are involved. Forward-looking statements provided herein are based on judgments of the Group as of the end of the fiscal year under review.

1) Risks associated with pharmaceutical research and development and the pharmaceutical industry

a. Uncertainties in the development of new medicines

Although the development of ethical medicines requires considerable investment in research and development and time, there are cases where we decide to postpone or discontinue development when research and development does not proceed as planned due to lack of beneficial effects discovered in clinical trials and for other reasons. Furthermore, operations in both Japan and overseas markets are subject to legal regulations, such as drug-related laws and the regulations of each country. An approval based on strict review is required in each country for the production and sale of any new medicine. Therefore, when we are unable to adequately obtain data mainly on efficacy, safety, or quality, we may postpone or discontinue the planned launch of the new medicine. This consideration also applies to the case where the Group licenses out products in the development pipeline to other companies. The postponement or discontinuation of the launch of ethical medicine candidates for which research and development was conducted or licensed out by the Group may have a material impact on the Group's business results and financial position.

b. Risks associated with the development of regenerative cell medicines

(a) Risks of unanticipated outcomes from a new technology

First, regenerative cell medicine is a relatively new field, and its practical application has just begun in certain countries, such as Canada. In Japan, only two regenerative medicine products have been approved for medical use. At present, clinical research and clinical trials are being conducted to a relatively limited extent, primarily by certain medical institutions and research institutes.

Behind this current background, there are issues and risks unique to cutting-edge medical care and medicine. Research and development in regenerative cell medicine is advancing at a rapid pace, with new results and knowledge concerning safety and efficacy gained on a daily basis. Regenerative cell medicine for allogeneic transplantation, the Group's core technology, is a novel technology at present. Also, from a clinical standpoint, we believe that allogeneic transplantation is superior to other regenerative cell medicines in terms of safety, efficacy and applicability. On the other hand, however, there is always the risk of being rapidly surpassed by another technological innovation, and of unexpected adverse side effects and other unanticipated adverse outcomes, which may have a material impact on the Group's business strategy and operating results.

(b) Risks from regulatory changes, such as amendments to laws and regulations, and changes in government policies

Laws and regulations concerning regenerative cell medicine may also be amended or reviewed in response to the latest technological innovations or simply to changing political pressures. For example, there is always a risk that raw materials which had been permitted for use may suddenly be restricted due to additions or revisions of laws and guidelines. Also, there is the risk that regulatory approval may not be acquired as anticipated by the Group, or that approval may take more time than expected. In addition, given the increasing concerns worldwide for medical cost containment, pharmaceutical prices and insurance reimbursement may be lower than expected or even lower than the

cost of the Company's products. Naturally, in such cases, there may be a material impact on the Group's business strategy and operating results.

At present, various policies are being implemented to promote advanced medical care in the US, Japan, and other medically advanced countries. The potential details and magnitude of these policies are uncertain, but they may have a material impact on the Group's future business development.

(c) Risk associated with use of human- or animal-derived raw materials

The Group's regenerative cell medicine uses human cells and tissues. Since the risk of infection due to human cells and tissues used cannot be completely eliminated, there is a possible safety-related risk associated with any such medicine. In addition, since our regenerative cell medicine uses animal-derived materials and media in the manufacturing process, we cannot rule out the possibility of damage caused by unknown viruses and other pathogens due to the use of such materials.

Any of the risks described above may have a material impact on the Group's business and financial position.

c. Side effects and product liability

Unexpected adverse side effects may occur in medicine, during the clinical trial phase and also after product launch. To prepare for such events, the Group secures appropriate insurance for various liabilities, including product liability. However, there can be no guarantee that insurance claims equivalent to the full amount of final damages borne by the Group will be paid. Furthermore, even if plaintiffs' claims for damages are sustained in courts of law, the product liability claims themselves would hurt the Group's image, which in turn may adversely affect confidence in the Group and its products. The occurrence of such unexpected adverse side effects may have a material impact on the Group's business results and financial position, as well as on the Group's business development as a result of the loss of credibility.

d. Competition

A large number of pharmaceutical companies and research institutes in Japan and elsewhere, including large global corporations, are in intense competition with each other, based partly on the progress of their technological innovations. In this competitive environment, it may not be possible for the Group to maintain an advantage over its competitors. The result of competition in business activities in research, development, production, and sales may have a material impact on the Group's business results and financial position.

e. Measures to contain medical costs

In the US, the largest market for the Group's regenerative cell medicine SB623, there is increasing pressure to lower prices of brand name drugs and to use low-cost generic medicines. In addition, in Japan as well, the has initiated a policy to restrain ever-increasing medical costs, making efforts to regularly lower medicine prices and promote the use of generic medicines. Future trends in medical cost policies may have a material impact on the Group's business results and financial position.

2) Risks in executing business operations

a. Dependence on partnership agreements concerning specific products and uncertainty of income

Regarding the regenerative cell medicine SB623, the Group licensed its development and marketing for stroke applications in Japan to Teijin Ltd., and in the US and Canada to Sumitomo Dainippon Pharma Co., Ltd. The Group's operating revenue plan is dependent on revenue from such partnership agreements.

Nevertheless, such partnership agreements may be terminated before the expiration of the term due to circumstances beyond the Company's control, such as changes to the management policies of the partners, delays in product development, or other reasons. Although conditions causing such termination of agreements have not emerged at present, the termination of these agreements is possible and may have a material impact on the Group's business results and financial position.

In addition, although we expect milestone revenue based on the achievement of certain results as pre-launch revenue, the time when such revenue is generated is uncertain due to its dependence on the progress of development. If there is a delay in development, this may have a material impact on the Group's business results and financial position.

Going forward, the Group intends to strive to achieve profitability through subsequent product developments and reduce its dependence on revenue based on the current partnership agreements. However, the achievement of alternative revenue streams is also uncertain due to its dependence on the progress of development. If there is a delay in development, it may have a material impact on the Group's business results and financial position.

b. Small organization and dependence on a small number of executive personnel

The Group is a small organization consisting of three Directors, three Corporate Auditors (including two part-time Corporate Auditors), nine employees and 28 employees in its subsidiary as of the end of January 2017. The current internal control system is adapted to this scale of organization. In the future, we intend to enhance the internal control system as we expand our business.

In particular, the Group's business activities heavily depend on Toru Kawanishi, the founder and Chairman of the Board of the Group, Keita Mori, Representative Director and President, and other current members of management, and a small number of research and development staff. Therefore, we are constantly working to secure and develop outstanding human resources. However, if this effort does not proceed as planned and if the Group experiences an outflow of human resources, it may hinder the business activities of the Group and have a material impact on the Group's business results and financial position.

c. Intellectual property rights

The Group makes use of various intellectual property rights in research and development and other business development, including patents and trade secrets. The Group recognizes that these are the rights of the Company or rights that are licensed to the Company.

There is no guarantee that all pending patent applications of the Group will succeed in being granted. Furthermore, even if a patent is granted, there is always the possibility that technology included in the Group's patent will be eliminated as a result of external research and development superior to that of the Group. If technology not included in the scope of the Group's patent rights is developed, it may have a material impact on the Group's business results and financial position.

Also, in order to prevent any infringement of patent rights owned by other companies, the Group conducts an investigation of third-party patents as it deems necessary; and to date, no lawsuit has been filed by/against third parties regarding intellectual property rights such as patent rights related to the Group's development pipeline. Nevertheless, it is difficult for research and development-oriented

companies such as the Group to completely avoid the problem of infringement of intellectual property rights, and if disputes regarding intellectual property rights arise with third parties, these may have a material impact on the Group's business results and financial position.

3) Risks associated with business results

a. Recording of negative retained earnings brought forward

The Group is a venture company mainly engaged in pharmaceutical research and development. This requires large initial investments and a relatively long period to recoup such investment, compared with other industries. As such, a venture company engaging in this industry generally tends to initially incur substantial losses. Therefore, although the Group may temporarily record profits, owing to upfront payments and development milestone revenues received on a conclusion of an agreement or in relation to progress, operating revenue and net income (loss) may fluctuate until a sales launch of new medicines under development.

The Group seeks to increase income in the future by pushing forward with development of products such as SB623. However, these efforts may fail or be delayed, and depending on the progress and results of development, the Group may not be able to record net income as planned in the future. If the Company's business does not progress as planned and fails to secure net income, there may be a significant delay in retained earnings brought forward turning positive.

b. Tendency of significant fluctuations in recording of revenue

Since the Group's operating revenue is significantly affected by upfront payments at the time of licensing out pipeline products under development such as SB623, as well as milestone revenues accompanying progress in development, depending on when the revenues were recorded and the amounts thereof, operating revenue and net income (loss) of the Group may follow an unstable pattern. We expect this trend to continue until the products under development are launched and a stable revenue base is established.

c. Capital raising

As a research and development-oriented company, the Group requires large investments in research and development, and a long period of investment is required before products can be commercialized. During this period of investment, continuous operating losses and negative cash flows from operations are common. Since inception the Company has recorded negative operating cash flows and does not currently have stable sources of revenue.

For this reason, during the period until stable sources of revenue are secured, the Company intends to raise capital as needed in order to strengthen its financial base. However, if the Company fails to secure capital when required, the Company may not be able to continue to implement its plans or remain in business.

d. Use of capital raised

The Group plans to use capital raised mainly for pharmaceutical research and development. However, it takes a long period for the results of research and development activities for new drugs to lead to revenue, and there is no guarantee that the expected results will be obtained from investment in research and development. As a result, there is a risk that the raised capital will not lead to expected profits.

e. Capital raising through issuance of new shares

Since the Group is a pharmaceutical research and development-oriented company, it may need to raise capital through sale of new shares in order to maintain and expand its research and development activities in the future. In that case, the stock value per share may be diluted as a result of an increase in the number of issued shares of the Company.

f. Subscription rights to shares

The Company has a stock option plan for the purpose of motivating Directors, Corporate Auditors, employees of the Company, employees of the Company's subsidiaries and outside collaborators to improve business results and boost employee morale, as well as hiring outstanding human resources. Pursuant to the provisions of Article 236, Article 238 and Article 239 of the Companies Act, the Company issues and grants share subscription rights to the Company's Directors, Corporate Auditors, employees, employees of the Company's subsidiaries, and outside collaborators, with an approval of its General Meeting of Shareholders.

As of the end of February 2017, the number of issued shares of the Company totaled 45,260 thousand shares. If existing subscription rights to shares are exercised, 1,063 thousand additional shares will be issued, and the stock value per share may consequently be diluted. Also, to recruit outstanding human resources in the future, similar incentive plans may be added. Therefore, if the subscription rights to shares to be granted in the future are exercised, the stock value per share of the Company may be also diluted.

g. Dividend policy

Pharmaceutical research and development tends to require large initial investments, and long periods of time are required to recoup such investment. Therefore, although the Group may temporarily record profits, owing to upfront payments and development milestone revenues received on a conclusion of an agreement or in relation to progress, business results are expected to fluctuate until a sales launch of new medicines under development.

Under such circumstances, the Group believes it should prioritize the investment of management resources into development to realize the early approval of medicines, which will improve corporate value and accordingly maximize shareholder value.

In FY2017.1, the Group was not in a financial position where it could pay dividends according to the provisions of the Companies Act. It does not plan to pay dividends in the next fiscal year as well.

However, the Group recognizes that the return of profits to shareholders is one of the most important management policies; and intends to implement profit distribution in the form of dividends, taking into account its operating results and financial position when SB623 and other new medicines under development are launched in the future and net income is recorded as a result of their sale.

h. Exchange rate fluctuations

The Group's main business of research and development in drug discovery is currently based in its US subsidiary. The transaction currency of the US subsidiary is the US dollar, and financial statements are also prepared in this currency. Therefore, since consolidated financial statements are translated into Japanese yen in accordance with the Accounting Standards for Foreign Currency Transactions during the process of preparation, substantial exchange rate fluctuations may have a material impact on the Group's business results and financial position.

i. Risks associated with international taxation

The Group has a capital relationship comprising the Company, a Japanese corporation, and SanBio, Inc., a US corporation, as a result of the "reversal of parent-subsidiary relationship" arrangement of January 2014 in which the Company became the parent. As such, tax treatment arising from the capital relationship and business relationship between the parent and subsidiary is subject to international taxation, specifically tax laws of both Japan and the US and the Japan-US Income Tax Convention.

The Group has advisory contracts with tax accountants and other professionals relating to tax regulations of Japan and the US, and strives to address tax risks by gathering information on tax laws which apply to the Group. Since international taxation is complicated, we cannot rule out the possibility of tax events and tax reforms related to international taxation which would be disadvantageous to the Group in the future. In that case, the future tax burden could increase, and this may have a material impact on the Group's business results and financial position.

2. Management Policies

(1) Basic Policy for Corporate Management

The Group is engaged in the research and development of regenerative medicines, upholding its corporate philosophy "SanBio Develops Regenerative Therapies Addressing Unmet Medical Needs and Creating Value for Stakeholders," and is committed to advancing the research and development of regenerative medicines. Through the early launch of its pipeline products, the Group will contribute to improving the Quality of Life (QOL) of patients as early as possible in order to achieve a happy and prosperous society.

(2) Target Management Indicators

The Group plans to launch its regenerative medicines at the earliest possible date and considers the process of management from research and development to market launch as the Company's most important management task. The Company believes that adding to its product pipeline is also indispensable for stabilizing management and enhancing corporate value. Therefore, the Group, which is still in the research and development phase, will manage its business activities in order to achieve product development milestones rather than aiming for specific ROAs, ROEs and other management indicators.

(3) Medium- and Long-term Corporate Management Strategies

While the most important management task for the Group in the medium to long-term is to realize the commercial production and sale of the regenerative cell medicine SB623 for the treatment of chronic stroke and traumatic brain injury, it also expects to expand the indications for SB623 to illnesses beyond chronic stroke and traumatic brain injury, namely retinal disorders, Parkinson's disease and spinal cord injury. Moreover, in order to add to the product pipeline, the Group is planning to engage in new medicine development for the treatment of multiple sclerosis. In order for the Group, a drug discovery venture business, to expand addressable medical indications, and at the same time develop new products, capital raising to fund research and development is essential. Therefore, the Group has adopted the strategy of maximizing corporate value by securing capital through public stock offerings and investing proceeds to fund SB623 and related research and development.

(4) Issues to be Addressed

The Japanese government has designated regenerative medicine as one of the pillars of the nation's growth strategies. As a result, while generous government support and subsidies are provided for scientific/basic research in the field of regenerative medicine, reviews of the legal system are being conducted, such as the revision of the Pharmaceutical Affairs Act in which regenerative medicine products are newly regulated. Such efforts indicate that advancement of the regenerative medicine industry is becoming a reality. In this environment, the Group will address the following management issues.

1) Acquiring approval of the development programs for treatment of stroke and traumatic brain injury using SB623 in Japan and the US, and subsequently commencing commercial sales

Currently, based on a joint development agreement with Sumitomo Dainippon Pharma Co., Ltd., the Group is working on developing the development program for treatment of chronic stroke using SB623 in the US. Accordingly, recruitment for a Phase 2b clinical trial began in December 2015 (with an objective of 156 participants), and the first patient was enrolled in March 2016. In addition, the Group is also independently engaged in the development program for treatment of chronic traumatic brain injury.

Recruitment for a Phase 2 clinical trial began in October 2015 (with an objective of 52 participants) in the US, and the first patient was enrolled in July 2016. As to the development program for treatment of chronic traumatic brain injury, after obtaining the approval from the PMDA to conduct clinical trials in Japan in April 2016, we enrolled the first patient in Japan in October of the same year. Currently, the program is being conducted as a global clinical trial across two countries, the US and Japan. Going forward, the Group will continue striving to make progress and gain early approval for these two development programs.

2) Expanding the indications for SB623 and progress in other pipeline products

The Group plans to gradually expand the indications for SB623 from chronic stroke and traumatic brain injury to other diseases, including retinal degeneration (age-related macular degeneration and other retinal indications), Parkinson's disease, spinal cord injury and Alzheimer's disease.

Currently, the Group is in the preclinical trial stage of programs for the treatment of retinal degeneration, spinal cord injury and Parkinson's disease, and will continue making preparations for Phase 1 clinical trials. Furthermore, in addition to SB623, the Group also possesses regenerative cell medicines SB618 (functionally enhanced mesenchymal stem cells) and SB308 (muscle stem cells) as the next medicine candidates and intends to promptly commence research and development on these candidates.

3) Expanding the sales area of SB623

As to its SB623 development program for treatment of chronic stroke, while the Group has taken steps to market SB623 in North America (including Canada) and Japan through the conclusion of licensing agreements with Sumitomo Dainippon Pharma Co., Ltd. and Teijin Ltd. respectively, the Group intends to expand the marketing area to other regions, such as Europe, Asia, and South America, by seeking partnerships with pharmaceutical companies which cover such areas.

The Group is also reviewing measures that it can implement to expand its marketing areas for its development program for treatment of chronic traumatic brain injury.

4) Capital raising

As stated above, the Group needs to steadily raise capital in order to accelerate its development of SB623 for treatment of chronic stroke and traumatic brain injury, as well as expand the indications and marketing areas for SB623 and make progress in other pipeline products. To this end, with the aim of securing and increasing ways to raise capital, the Group will diversify its capital raising by securing the necessary capital on the stock market as well as borrowing from banks.

5) Securing human resources

Under the Group's research and development structure, the Company directly engages in its core competency of research and development and design of regenerative medicine production processes, while ensuring that the operations of conducting clinical trials and manufacturing products are conducted efficiently by the effective utilization of external subcontractors. Although the Group is currently operating with a small organization, going forward, it intends to secure appropriate and sufficient human resources, so as to respond to accelerated development, an expansion of indications and progress made in pipeline products.

3. Basic Policy on Selection of Accounting Standards

The Group will prepare its consolidated financial statements based on Japanese GAAP for the time being, given its comparability from period to period and between companies.

The Group plans to appropriately respond to the application of International Financial Reporting Standards (IFRS) upon considering the circumstances in Japan and overseas.

4. Consolidated Financial Statements

(1) Consolidated Balance Sheets

(Thousand yen)

	As of January 31, 2016	As of January 31, 2017
Assets		
Current assets		
Cash and deposits	7,733,892	5,561,424
Accounts receivable - trade	–	17,350
Advance payments	438,004	495,531
Other	19,595	50,257
Total current assets	8,191,492	6,124,564
Non-current assets		
Property, plant and equipment		
Buildings and structures	58,520	71,465
Machinery, equipment and vehicles	7,596	–
Tools, furniture and fixtures	151,309	215,533
Accumulated depreciation	(149,451)	(147,538)
Construction in progress	–	8,912
Total property, plant and equipment	67,974	148,371
Intangible assets	207	7,701
Investments and other assets		
Other	11,342	11,776
Total investments and other assets	11,342	11,776
Total non-current assets	79,524	167,849
Total assets	8,271,017	6,292,414
Liabilities		
Current liabilities		
Short-term loans payable	100,000	100,000
Current portion of long-term loans payable	800,000	49,980
Accounts payable - other	263,606	158,019
Accrued expenses	15,524	202,014
Provision for bonuses	20,994	13,327
Deferred tax liabilities	184,931	–
Other	34,520	24,053
Total current liabilities	1,419,577	547,395
Non-current liabilities		
Long-term loans payable	300,000	1,150,020
Deferred tax liabilities	184,931	–
Total non-current liabilities	484,931	1,150,020
Total liabilities	1,904,508	1,697,415
Net assets		
Shareholders' equity		
Capital stock	3,806,973	3,852,012
Capital surplus	7,518,415	7,563,454
Retained earnings	(4,978,932)	(6,814,228)
Treasury shares	(28)	(146)
Total shareholders' equity	6,346,428	4,601,091
Accumulated other comprehensive income		
Foreign currency translation adjustment	19,362	(21,642)
Total accumulated other comprehensive income	19,362	(21,642)
Subscription rights to shares	718	15,548
Total net assets	6,366,509	4,594,998
Total liabilities and net assets	8,271,017	6,292,414

(2) Consolidated Statements of Income and Comprehensive Income

Consolidated Statements of Income

(Thousand yen)

	For the fiscal year ended January 31, 2016	For the fiscal year ended January 31, 2017
Operating revenue	1,174,644	949,543
Operating expenses		
Cost of revenue	–	17,168
Research and development expenses	1,695,792	2,058,346
Other selling, general and administrative expenses	604,095	806,257
Total operating expenses	2,299,888	2,881,772
Operating loss	(1,125,243)	(1,932,229)
Non-operating income		
Interest income	1,862	8,606
Foreign exchange gains	19,831	–
Other	77	203
Total non-operating income	21,771	8,810
Non-operating expenses		
Interest expenses	18,126	12,549
Foreign exchange losses	–	199,650
Share issuance cost	32,446	–
Listing-related expenses	18,356	–
Financing expenses	–	30,599
Total non-operating expenses	68,929	242,799
Ordinary loss	(1,172,401)	(2,166,218)
Extraordinary losses		
Loss on retirement of non-current assets	1	–
Total extraordinary losses	1	–
Loss before income taxes	(1,172,403)	(2,166,218)
Income taxes - current	1,185	1,210
Income taxes - deferred	(185,191)	(332,132)
Total income taxes	(184,005)	(330,922)
Net loss	(988,397)	(1,835,296)
Net loss attributable to owners of parent	(988,397)	(1,835,296)

Consolidated Statements of Comprehensive Income

(Thousand yen)

	For the fiscal year ended January 31, 2016	For the fiscal year ended January 31, 2017
Net loss	(988,397)	(1,835,296)
Other comprehensive income		
Foreign currency translation adjustment	7,531	(41,004)
Total other comprehensive income	7,531	(41,004)
Comprehensive income	(980,865)	(1,876,300)
Comprehensive income attributable to:		
Comprehensive income attributable to owners of parent	(980,865)	(1,876,300)
Comprehensive income attributable to non-controlling interests	–	–

(3) Consolidated Statements of Changes in Net Assets

For the fiscal year ended January 31, 2016 (From February 1, 2015 to January 31, 2016)

(Thousand yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of current period	89,573	3,801,016	(3,990,534)	–	(99,944)
Changes of items during period					
Issuance of new shares	3,717,399	3,717,399			7,434,798
Net loss attributable to owners of parent			(988,397)		(988,397)
Purchase of treasury shares				(28)	(28)
Net changes of items other than shareholders' equity					
Total changes of items during period	3,717,399	3,717,399	(988,397)	(28)	6,446,372
Balance at end of current period	3,806,973	7,518,415	(4,978,932)	(28)	6,346,428

	Accumulated other comprehensive income		Subscription rights to shares	Total net assets
	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at beginning of current period	11,830	11,830	819	(87,294)
Changes of items during period				
Issuance of new shares				7,434,798
Net loss attributable to owners of parent				(988,397)
Purchase of treasury shares				(28)
Net changes of items other than shareholders' equity	7,531	7,531	(101)	7,430
Total changes of items during period	7,531	7,531	(101)	6,453,803
Balance at end of current period	19,362	19,362	718	6,366,509

For the fiscal year ended January 31, 2017 (From February 1, 2016 to January 31, 2017)

(Thousand yen)

	Shareholders' equity				
	Capital stock	Capital surplus	Retained earnings	Treasury shares	Total shareholders' equity
Balance at beginning of current period	3,806,973	7,518,415	(4,978,932)	(28)	6,346,428
Changes of items during period					
Issuance of new shares	45,039	45,039			90,078
Net loss attributable to owners of parent			(1,835,296)		(1,835,296)
Purchase of treasury shares				(118)	(118)
Net changes of items other than shareholders' equity					
Total changes of items during period	45,039	45,039	(1,835,296)	(118)	(1,745,336)
Balance at end of current period	3,852,012	7,563,454	(6,814,228)	(146)	4,601,091

	Accumulated other comprehensive income		Subscription rights to shares	Total net assets
	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at beginning of current period	19,362	19,362	718	6,366,509
Changes of items during period				
Issuance of new shares				90,078
Net loss attributable to owners of parent				(1,835,296)
Purchase of treasury shares				(118)
Net changes of items other than shareholders' equity	(41,004)	(41,004)	14,829	(26,174)
Total changes of items during period	(41,004)	(41,004)	14,829	(1,771,510)
Balance at end of current period	(21,642)	(21,642)	15,548	4,594,998

(4) Consolidated Statements of Cash Flows

(Thousand yen)

	For the fiscal year ended January 31, 2016	For the fiscal year ended January 31, 2017
Cash flows from operating activities:		
Loss before income taxes	(1,172,403)	(2,166,218)
Depreciation	14,137	26,758
Share-based compensation expenses	–	15,053
Increase (decrease) in provision for bonuses	10,765	(6,462)
Interest income	(1,862)	(8,606)
Foreign exchange losses (gains)	(37,364)	366,347
Interest expenses	18,126	12,549
Share issuance cost	32,446	–
Financing expenses	–	30,599
Loss on retirement of non-current assets	1	–
Decrease (increase) in inventories	(1,264)	1,264
Decrease (increase) in notes and accounts receivable - trade	–	(17,350)
Decrease (increase) in advance payments	(432,211)	(73,628)
Increase (decrease) in accounts payable - other	234,770	(106,086)
Increase (decrease) in accrued expenses	(45,668)	178,120
Increase (decrease) in advances received	11,966	(11,966)
Decrease (increase) in other current assets	5,995	(31,738)
Increase (decrease) in other current liabilities	17,644	(912)
Other	–	654
Subtotal	(1,344,920)	(1,791,622)
Interest income received	1,196	7,874
Interest expenses paid	(18,092)	(10,436)
Income taxes paid	(265)	(1,990)
Net cash provided by (used in) operating activities	(1,362,083)	(1,796,175)
Cash flows from investing activities		
Payments into time deposits	(369,930)	(308,480)
Proceeds from withdrawal of time deposits	–	483,480
Purchase of property, plant and equipment	(60,095)	(97,363)
Proceeds from sales of property, plant and equipment	–	2,882
Other	(6,174)	(1,345)
Net cash provided by (used in) investing activities	(436,199)	79,172
Cash flows from financing activities		
Proceeds from long-term loans payable	–	900,000
Repayments of long-term loans payable	–	(800,000)
Payments of financing expenses	–	(30,453)
Proceeds from issuance of common shares	7,327,553	–
Proceeds from issuance of shares resulting from exercise of subscription rights to shares	74,697	89,855
Other	(28)	(118)
Net cash provided by (used in) financing activities	7,402,223	159,283
Effect of exchange rate change on cash and cash equivalents	55,311	(453,508)
Net increase (decrease) in cash and cash equivalents	5,659,251	(2,011,228)
Cash and cash equivalents at beginning of period	1,228,551	6,887,802
Cash and cash equivalents at end of period	6,887,802	4,876,574

(5) Notes to the Consolidated Financial Statements

(Notes on going concern assumption)

None

(Changes in accounting policies)

(Adoption of accounting standards for business combinations)

Effective from 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, consolidated financial statements for the previous fiscal year have been reclassified.

(Segment information)

<Segment information>

I. For the fiscal year ended January 31, 2016 (from February 1, 2015 to January 31, 2016)

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

II. For the fiscal year ended January 31, 2017 (from February 1, 2016 to January 31, 2017)

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

<Related information>

Fiscal year ended January 31, 2016 (from February 1, 2015 to January 31, 2016)

1. Information by products and services

This information is omitted because operating revenue to external customers from a single product and service category accounted for more than 90% of the operating revenue recorded in the consolidated statements of income.

2. Information by geographical segment

(1) Operating revenue

This information is omitted because operating revenue to external customers in Japan accounted for more than 90% of operating revenue recorded in the consolidated statements of income.

(2) Property, plant and equipment

(Thousand yen)

Japan	US	Total
4,848	63,126	67,974

3. Information by major customer

(Thousand yen)

Name of customer	Operating revenue	Name of related segment
Sumitomo Dainippon Pharma Co., Ltd.	1,174,644	Regenerative cell therapy using allogeneic stem cells

Fiscal year ended January 31, 2017 (from February 1, 2016 to January 31, 2017)

1. Information by products and services

This information is omitted because operating revenue to external customers from a single product and service category accounted for more than 90% of the operating revenue recorded in the consolidated statements of income.

2. Information by geographical segment

(1) Operating revenue

This information is omitted because operating revenue to external customers in Japan accounted for more than 90% of operating revenue recorded in the consolidated statements of income.

(2) Property, plant and equipment

(Thousand yen)

Japan	US	Total
–	148,371	148,371

3. Information by major customer

(Thousand yen)

Name of customer	Operating revenue	Name of related segment
Sumitomo Dainippon Pharma Co., Ltd.	893,178	Regenerative cell therapy using allogeneic stem cells

<Information concerning impairment loss on non-current assets by reporting segment>

Fiscal year ended January 31, 2016 (from February 1, 2015 to January 31, 2016)

None

Fiscal year ended January 31, 2017 (from February 1, 2016 to January 31, 2017)

None

<Information concerning amortization and unamortized balance of goodwill by reporting segment>

Fiscal year ended January 31, 2016 (from February 1, 2015 to January 31, 2016)

None

Fiscal year ended January 31, 2017 (from February 1, 2016 to January 31, 2017)

None

<Information concerning gain on bargain purchase by reporting segment>

Fiscal year ended January 31, 2016 (from February 1, 2015 to January 31, 2016)

None

Fiscal year ended January 31, 2017 (from February 1, 2016 to January 31, 2017)

None

(Per share information)

(Yen)

	For the fiscal year ended January 31, 2016	For the fiscal year ended January 31, 2017
Net assets per share	142.66	101.52
Net (loss) per share	(22.67)	(40.88)

(Notes) 1. Diluted net income per share is not stated, despite the existence of potential shares, due to the posting of net loss per share.

2. The basis for calculating net loss per share is as follows.

	For the fiscal year ended January 31, 2016	For the fiscal year ended January 31, 2017
Net (loss) attributable to owners of parent (Thousand yen)	(988,397)	(1,835,296)
Amount not attributable to common shareholders (Thousand yen)	—	—
Net (loss) attributable to owners of parent associated with common shares (Thousand yen)	(988,397)	(1,835,296)
Average number of shares during the period (Shares)	43,598,673	44,890,374
Outline of potential shares that were not included in the calculation of diluted net income per share because they have no dilutive effects	None	2 series of subscription rights to shares (total number of subscription rights to shares: 112,800)

(Significant subsequent events)

None