# Consolidated Financial Results for the Fiscal Year Ended January 31, 2016 [Japanese GAAP]

March 16, 2016

Company name: SanBio Company Limited
Stock exchange listing: Tokyo Stock Exchange
Code number: 4592
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Scheduled date of the Annual General Meeting of Shareholders: April 28, 2016
Scheduled date of commencing dividend payments: —
Scheduled date of filing annual securities report: April 28, 2016
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 Fiscal Year Ended January 31, 2016 (February 1, 2015 to January 31, 2016)

(1) 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, 2016 | 1,174 | (63.6) | (1,125) | – | (1,172) | – | (988) | – |
| January 31, 2015 | 3,229 | – | 2,248 | – | 2,228 | – | 1,736 | – |

(Note) Comprehensive income: Fiscal year ended January 31, 2016: ¥(980) million [–%]
Fiscal year ended January 31, 2015: ¥1,700 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, 2016 | (22.67) | – | (31.5) | (23.4) | (95.8) |
| January 31, 2015 | 44.31 | – | – | 199.9 | 69.6 |

(Note) Equity earnings (losses) of affiliates: Fiscal year ended January 31, 2016: ¥ – million
Fiscal year ended January 31, 2015: ¥ – million

(2) Consolidated Financial Position

| | Total assets | Net assets | Equity ratio | Net assets per share |
|---|---|---|---|---|
| | Million yen | Million yen | % | Yen |
| As of January 31, 2016 | 8,271 | 6,366 | 77.0 | 142.66 |
| As of January 31, 2015 | 1,755 | (87) | (5.0) | (2.22) |

(Reference) Equity: As of January 31, 2016: ¥6,365 million
As of January 31, 2015: ¥(87) 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, 2016 | (1,362) | (436) | 7,402 | 6,887 |
| January 31, 2015 | (218) | (480) | 1,373 | 1,228 |

**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, 2015 | – | 0.00 | – | 0.00 | 0.00 | – | – | – |
| January 31, 2016 | – | 0.00 | – | 0.00 | 0.00 | – | – | – |
| Fiscal year ending January 31, 2017 (Forecast) | – | 0.00 | – | 0.00 | 0.00 | | – | |

**3. Consolidated Financial Results Forecast for the Fiscal Year Ending January 31, 2017 (February 1, 2016 to January 31, 2017)**

(% indicates changes from the previous corresponding period.)

| | Operating revenue | | Operating income | | Ordinary income | | Net income attributable to owners of parent | | Net income per share |
|---|---|---|---|---|---|---|---|---|---|
| | Million yen | % | Million yen | % | Million yen | % | Million yen | % | Yen |
| First half | 735 | 78.9 | (1,629) | – | (1,637) | – | (1,543) | – | (34.59) |
| Full year | 886 | (24.6) | (3,814) | – | (3,830) | – | (3,641) | – | (81.62) |

*** 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: No
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, 2016: 44,621,741 shares
January 31, 2015: 39,620,484 shares

2) Total number of treasury shares at the end of the period:
January 31, 2016: 16 shares
January 31, 2015: – shares

3) Average number of shares during the period:
Fiscal year ended January 31, 2016: 43,598,673 shares
Fiscal year ended January 31, 2015: 39,183,075 shares

**(Reference) Overview of Non-Consolidated Financial Results**

Non-Consolidated Financial Results for the Fiscal Year Ended January 31, 2016 (February 1, 2015 to January 31, 2016)

(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, 2016 | – | – | (433) | – | (465) | – | (466) | – |
| January 31, 2015 | – | – | (221) | – | (226) | – | (227) | – |

| | Net income per share | Diluted net income per share |
|---|---|---|
| Fiscal year ended | Yen | Yen |
| January 31, 2016 | (10.71) | – |
| January 31, 2015 | (5.79) | – |

(2) Non-Consolidated Financial Position

| | Total assets | Net assets | Equity ratio | Net assets per share |
|---|---|---|---|---|
| | Million yen | Million yen | % | Yen |
| As of January 31, 2016 | 8,125 | 6,867 | 84.5 | 153.89 |
| As of January 31, 2015 | 1,696 | (100) | (6.0) | (2.55) |

(Reference) Equity: As of January 31, 2016: ¥6,866 million
As of January 31, 2015: ¥(100) million

* Presentation regarding the implementation status of the audit procedures

These financial results are outside the scope of audit procedures under the Financial Instruments and Exchange Act. At the time of disclosure of these financial results, audit procedures for the consolidated financial statements under the Financial Instruments and Exchange Act have not been completed.

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

The consolidated earnings forecasts of the Group for the fiscal year ending January 31, 2017 herein are based on judgements 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 forecasts for the following fiscal year” on page 3 in 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, 2016 (from February 1, 2015 to January 31, 2016) continued a moderate recovery trend supported by improvements in the employment environment and household income. The U.S. economy, despite concerns for low crude oil prices and the appreciating dollar, remained robust, supported primarily by internal demand.

In the regenerative medicine industry, amid ongoing promotion of the 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 regulatory structure 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.

In 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 take advantage of the favorable circumstances in Japan established by the government's strong support of the regenerative medicine industry.

As for our unique regenerative cell medicine SB623, Phase I/IIa clinical trials for chronic disability resulting from ischemic stroke (“chronic stroke”) were conducted simultaneously in the U.S., regulated by the U.S. Food and Drug Administration (FDA). These trials were completed in February 2014, producing statistically significant data which confirmed the safety and efficacy of SB623. Based on these results, the Group determined to execute follow up clinical trials during the current fiscal year, and began recruitment for the Phase IIb clinical trial with 156 participants in December 2015.

With regard to the development program for treatment of chronic disability resulting from traumatic brain injury (“chronic traumatic brain injury”), the Group secured approval from the FDA to initiate Phase II clinical trials without conducting Phase I clinical trials, as safety was already confirmed in the previous Phase I/IIa clinical trials for chronic stroke, and began recruitment for a 52-patient trial in October 2015.

In Japan, the Group has been studying the feasibility of securing approval for SB623 production and sales for treatment of chronic traumatic brain injury. In July 2015, we decided to start this program, and are currently in consultation with the authorities to implement at clinical trials.

As to intellectual property rights, the Group acquired a substance patent (see note) related to its regenerative cell medicine SB623 in the U.S. on March 3, 2015. With regard to SB623 and subsequent pipeline products, we have acquired not only the substance patent but also the patents related to production and patents covering the use of our products in specific disease indications, and are striving to secure intellectual property rights which create a competitive advantage.

As a result, for the fiscal year ended January 31, 2016, operating revenue totaled ¥1,174 million (down 63.6% compared to the previous fiscal year), primarily reflecting milestone revenue of US$5 million and proceeds from development support fees related to the SB623 joint development and license agreements concluded with Sumitomo Dainippon Pharma Co., Ltd. in North America. The Group initially planned to receive US$10 million in milestone payments from its partner according to the progress made in the development of treatment for chronic stroke in the U.S. (comprising US$5 million upon establishment of the first clinical site and US$5 million upon first implantation to patients). However, due to external factor, including the progress of the screening and scheduling of the participants, implantation has been delayed beyond the fiscal year-end, so the receipt of the remaining US$5 million has accordingly been delayed to the next fiscal year.

With regard to expenses, as a result of recording ¥1,695 million in research and development expenses, mainly comprising expenses associated with the clinical trials for the treatment of chronic stroke and traumatic

brain injury in the U.S., operating loss amounted to ¥1,125 million (vs. operating income of ¥2,248 million for the previous fiscal year). Ordinary loss was ¥1,172 million (vs. ordinary income of ¥2,228 million for the previous fiscal year), and net loss was ¥988 million (vs. net income of ¥1,736 million for the previous fiscal year), due to ¥32 million of share issuance cost and ¥18 million of listing-related expenses associated with the IPO, as well as ¥18 million of interest expenses, despite ¥19 million in foreign exchange gains booked as non-operating income.

The Group consists of a single business segment, 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 "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 forecasts for the following fiscal year

In regard to the earnings forecasts for the fiscal year ending January 31, 2017, the Group expects operating revenue of ¥886 million due to the recording of milestone revenue of US$5 million upon first implantation to participants (delayed from the previous fiscal year) and proceeds from development support fees related to the joint development and license agreements concluded on SB623 with Sumitomo Dainippon Pharma Co., Ltd. in North America.

As regards expenses, clinical development costs will increase considerably from the previous fiscal year due to the start of the Phase IIb clinical trial for chronic stroke and the Phase II clinical trial for traumatic brain injury in the U.S., with clinical trials for the development program for treatment of traumatic brain injury in Japan also expected to commence. With the growth of these development programs, more human resources, mainly in development, will be required; and accordingly, the Group expects research and development expenses of ¥3,883 million. As a result, it forecasts an operating loss of ¥3,814 million, ordinary loss of ¥3,830 million and net loss of ¥3,641 million.

The forecast is based on an exchange rate at ¥120.00 per U.S. dollar.

The consolidated earnings forecasts of the Group for the fiscal year ending January 31, 2017 herein are based on judgements 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 ¥8,191 million, an increase of ¥6,933 million compared to the end of the previous fiscal year, mainly due to an increase of ¥6,505 million in cash and deposits.

(Non-current assets)

The balance of non-current assets at the end of the fiscal year under review was ¥79 million, a decrease of ¥417 million compared to the end of the previous fiscal year, mainly due to a decrease of ¥473 million in long-term time deposits.

(Current liabilities)

The balance of current liabilities at the end of the fiscal year under review was ¥1,419 million, an increase of ¥1,039 million compared to the end of the previous fiscal year, mainly due to increases of ¥800 million in current portion of long-term loans payable and of ¥237 million in accounts payable – other.

(Non-current liabilities)

The balance of non-current liabilities at the end of the fiscal year under review was ¥484 million, a decrease of ¥976 million compared to the end of the previous fiscal year, mainly due to decreases of ¥800 million in long-term loans payable and of ¥176 million in deferred tax liabilities.

(Net assets)

Total net assets at the end of the fiscal year under review were ¥6,366 million, an increase of ¥6,453 million compared to the end of the previous fiscal year, mainly due to a decrease of ¥988 million in retained earnings, offset by increases of ¥3,717 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 ¥6,887 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 ¥1,362 million (outflow of ¥218 million for the previous fiscal year). This was primarily due to loss before income taxes and minority interests of ¥1,172 million.

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(Cash flows from investing activities)

Net cash used in investing activities for the fiscal year under review was ¥436 million (outflow of ¥480 million for the previous fiscal year). This was primarily due to payments into time deposits of ¥369 million.

(Cash flows from financing activities)

Net cash provided by financing activities for the fiscal year under review was ¥7,402 million (inflow of ¥1,373 million for the previous fiscal year). This was primarily due to proceeds from issuance of common shares of ¥7,327 million.

(Reference) Indicators relative to cash flows

| | FY2014.1 | FY2015.1 | FY2016.1 |
|---|---|---|---|
| Equity ratio (%) | (413.8) | (5.0) | 77.0 |
| Equity ratio on a market value basis (%) | – | – | 491.5 |
| 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 FY2016.1 and FY2017.1

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, 2016, 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 pharmaceutical industry

a. Uncertainties in the development of new medicines

Although the development of ethical medicines require 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 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 in a new field 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 U.S.,

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 U.S., 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 government 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 U.S. 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), seven employees and 18 employees in its subsidiary as of the end of February 2016. 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. The Group has been continuously recording operating losses and net losses since its founding, except in the previous fiscal year in which the Group received an upfront payment and other progress-related payments from partners.

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 therefore 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, operating revenue and net income (loss) for past fiscal years have been generally negative and unstable. 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 the approval of its General Meeting of Shareholders.

As of the end of February 2016, the number of issued shares of the Company totaled 44.7 million shares. If existing subscription rights to shares are exercised, 1.6 million 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. The Group has been continuously recording operating losses and net losses since its founding, except during the previous fiscal year in which the Group received an upfront payment and other payments from partners. In FY2016.1, 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 U.S. subsidiary. The transaction currency of the U.S. subsidiary is the U.S. 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 U.S. 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 U.S. and the Japan-U.S. Income Tax Convention.

The Group has advisory contracts with tax accountants and other professionals relating to tax regulations of Japan and the U.S., 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 of 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 commercialize the production and sale of the regenerative cell medicine SB623 for treatment of chronic stroke, it also expects to expand the indications for SB623 to illnesses beyond chronic stroke, namely traumatic brain injury, 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, review of the legal system has begun, such as the revision of Pharmaceutical Affairs Act in which regenerative medicine products are newly regulated. Such efforts raise expectations for the advancement of regenerative medicine. In this environment, the Group will address the following management issues.

1) Acquiring approval of the development program for treatment of stroke and traumatic brain injury using SB623 in Japan and in the U.S., and subsequently commencing commercial sales

Currently, the Group is working with Sumitomo Dainippon Pharma Co., Ltd. on joint development of a program for treatment of stroke using SB623 in North America, and it began recruitment for a Phase IIb clinical trial in December 2015 (with an objective of 156 participants). In addition, the Group is also engaged in a development program for the treatment of traumatic brain injury on its own in North America, and began recruitment for a Phase II clinical trial in October 2015 (with an objective of 52 participants). While the Group will strive to make progress and gain early approval for these two development programs in North

America, it will also prepare for early commencement of clinical trials for a development program for treatment of traumatic brain injury in Japan.

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 conducting preclinical trials for retinal degeneration and will steadily make preparations for Phase I 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 stroke, while the Group has executed 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 will also strive to expand its marketing areas for its program for treatment of 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 for chronic stroke and traumatic brain injury, as well as expand the indications for SB623 and make progress in other pipeline products. To this end, 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 outsourcing the operations of conducting clinical trials and manufacturing products to third parties. Accordingly, the Group is currently operating with a small organization, but going forward, we intend to secure appropriate human resources in an effort to expand the indications and deal with multiple 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, 2015 | As of January 31, 2016 |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and deposits | 1,228,551 | 7,733,892 |
| Advance payments | 6,233 | 438,004 |
| Other | 23,231 | 19,595 |
| Total current assets | 1,258,016 | 8,191,492 |
| Non-current assets | | |
| Property, plant and equipment | | |
| Buildings and structures | 57,252 | 58,520 |
| Machinery, equipment and vehicles | 7,596 | 7,596 |
| Tools, furniture and fixtures | 88,663 | 151,309 |
| Accumulated depreciation | (135,232) | (149,451) |
| Total property, plant and equipment | 18,279 | 67,974 |
| Intangible assets | — | 207 |
| Investments and other assets | | |
| Long-term time deposits | 473,000 | — |
| Other | 5,761 | 11,342 |
| Total Investments and other assets | 478,761 | 11,342 |
| Total non-current assets | 497,041 | 79,524 |
| Total assets | 1,755,057 | 8,271,017 |
| Liabilities | | |
| Current liabilities | | |
| Short-term loans payable | 100,000 | 100,000 |
| Current portion of long-term loans payable | — | 800,000 |
| Accounts payable - other | 25,754 | 263,606 |
| Accrued expenses | 59,680 | 15,524 |
| Provision for bonuses | 10,253 | 20,994 |
| Deferred tax liabilities | 180,922 | 184,931 |
| Other | 3,895 | 34,520 |
| Total current liabilities | 380,506 | 1,419,577 |
| Non-current liabilities | | |
| Long-term loans payable | 1,100,000 | 300,000 |
| Deferred tax liabilities | 361,845 | 184,931 |
| Total non-current liabilities | 1,461,845 | 484,931 |
| Total liabilities | 1,842,351 | 1,904,508 |
| Net assets | | |
| Shareholders' equity | | |
| Capital stock | 89,573 | 3,806,973 |
| Capital surplus | 3,801,016 | 7,518,415 |
| Retained earnings | (3,990,534) | (4,978,932) |
| Treasury shares | — | (28) |
| Total shareholders' equity | (99,944) | 6,346,428 |
| Accumulated other comprehensive income | | |
| Foreign currency translation adjustment | 11,830 | 19,362 |
| Total accumulated other comprehensive income | 11,830 | 19,362 |
| Subscription rights to shares | 819 | 718 |
| Total net assets | (87,294) | 6,366,509 |
| Total liabilities and net assets | 1,755,057 | 8,271,017 |

## (2) Consolidated Statements of Income and Comprehensive Income

### Consolidated Statements of Income

(Thousand yen)

| | For the fiscal year ended January 31, 2015 | For the fiscal year ended January 31, 2016 |
|---|---|---|
| Operating revenue | 3,229,211 | 1,174,644 |
| Operating expenses | | |
| Research and development expenses | 623,415 | 1,695,792 |
| Other selling, general and administrative expenses | 357,048 | 604,095 |
| Total operating expenses | 980,464 | 2,299,888 |
| Operating income (loss) | 2,248,746 | (1,125,243) |
| Non-operating income | | |
| Interest income | 272 | 1,862 |
| Foreign exchange gains | — | 19,831 |
| Other | 14 | 77 |
| Total non-operating income | 287 | 21,771 |
| Non-operating expenses | | |
| Interest expenses | 5,421 | 18,126 |
| Foreign exchange losses | 13,943 | — |
| Share issuance cost | — | 32,446 |
| Listing-related expenses | — | 18,356 |
| Other | 1,122 | — |
| Total non-operating expenses | 20,487 | 68,929 |
| Ordinary income (loss) | 2,228,546 | (1,172,401) |
| Extraordinary losses | | |
| Loss on retirement of non-current assets | 269 | 1 |
| Total extraordinary losses | 269 | 1 |
| Income (loss) before income taxes and minority interests | 2,228,276 | (1,172,403) |
| Income taxes - current | 284 | 1,185 |
| Income taxes - deferred | 491,726 | (185,191) |
| Total income taxes | 492,010 | (184,005) |
| Income (loss) before minority interests | 1,736,265 | (988,397) |
| Net income (loss) | 1,736,265 | (988,397) |

Consolidated Statements of Comprehensive Income

(Thousand yen)

| | For the fiscal year ended January 31, 2015 | For the fiscal year ended January 31, 2016 |
|---|---|---|
| Income (loss) before minority interests | 1,736,265 | (988,397) |
| Other comprehensive income | | |
| Foreign currency translation adjustment | (35,690) | 7,531 |
| Total other comprehensive income | (35,690) | 7,531 |
| Comprehensive income | 1,700,574 | (980,865) |
| Comprehensive income attributable to | | |
| Comprehensive income attributable to owners of parent | 1,700,574 | (980,865) |
| Comprehensive income attributable to minority interests | — | — |

(3) Consolidated Statements of Changes in Net Assets

For the fiscal year ended January 31, 2015 (From February 1, 2014 to January 31, 2015)

(Thousand yen)

| | Shareholders' equity | | | |
|---|---|---|---|---|
| | Capital stock | Capital surplus | Retained earnings | Total shareholders' equity |
| Balance at beginning of current period | 2,500 | 3,713,942 | (5,726,800) | (2,010,357) |
| Changes of items during period | | | | |
| Issuance of new shares | 87,073 | 87,073 | | 174,147 |
| Net income | | | 1,736,265 | 1,736,265 |
| Net changes of items other than shareholders' equity | | | | |
| Total changes of items during period | 87,073 | 87,073 | 1,736,265 | 1,910,413 |
| Balance at end of current period | 89,573 | 3,801,016 | (3,990,534) | (99,944) |

| | 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 | 47,520 | 47,520 | — | (1,962,836) |
| Changes of items during period | | | | |
| Issuance of new shares | | | | 174,147 |
| Net income | | | | 1,736,265 |
| Net changes of items other than shareholders' equity | (35,690) | (35,690) | 819 | (34,870) |
| Total changes of items during period | (35,690) | (35,690) | 819 | 1,875,542 |
| Balance at end of current period | 11,830 | 11,830 | 819 | (87,294) |

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 |
| Purchase of treasury shares | | | | (28) | (28) |
| Net income | | | (988,397) | | (988,397) |
| 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 |
| Purchase of treasury shares | | | | (28) |
| Net income | | | | (988,397) |
| 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 |

(4) Consolidated Statements of Cash Flows

(Thousand yen)

| | For the fiscal year ended January 31, 2015 | For the fiscal year ended January 31, 2016 |
|---|---|---|
| Cash flows from operating activities | | |
| Income (loss) before income taxes and minority interests | 2,228,276 | (1,172,403) |
| Depreciation | 5,625 | 14,137 |
| Increase (decrease) in provision for bonuses | 10,253 | 10,765 |
| Interest income | (272) | (1,862) |
| Foreign exchange losses (gains) | 4,640 | (37,364) |
| Interest expenses | 5,421 | 18,126 |
| Share issuance cost | 1,122 | 32,446 |
| Loss on retirement of non-current assets | 269 | 1 |
| Decrease (increase) in inventories | — | (1,264) |
| Decrease (increase) in notes and accounts receivable - trade | 535 | — |
| Decrease (increase) in advance payments | 1,065 | (432,211) |
| Increase (decrease) in accounts payable - other | (28,468) | 234,770 |
| Increase (decrease) in accrued expenses | (13,741) | (45,668) |
| Increase (decrease) in advances received | (2,416,415) | 11,966 |
| Decrease (increase) in other current assets | (12,154) | 5,995 |
| Increase (decrease) in other current liabilities | 1,969 | 17,644 |
| Subtotal | (211,872) | (1,344,920) |
| Interest income received | 232 | 1,196 |
| Interest expenses paid | (6,806) | (18,092) |
| Income taxes paid | (58) | (265) |
| Net cash provided by (used in) operating activities | (218,504) | (1,362,083) |
| Cash flows from investing activities | | |
| Payments into time deposits | (473,000) | (369,930) |
| Purchase of property, plant and equipment | (3,105) | (60,095) |
| Other | (4,305) | (6,174) |
| Net cash provided by (used in) investing activities | (480,411) | (436,199) |
| Cash flows from financing activities | | |
| Net increase (decrease) in short-term loans payable | 100,000 | — |
| Proceeds from long-term loans payable | 1,100,000 | — |
| Proceeds from issuance of common shares | 149,674 | 7,327,553 |
| Proceeds from issuance of shares resulting from exercise of subscription rights to shares | 23,441 | 74,697 |
| Other | 729 | (28) |
| Net cash provided by (used in) financing activities | 1,373,845 | 7,402,223 |
| Effect of exchange rate change on cash and cash equivalents | 115,015 | 55,311 |
| Net increase (decrease) in cash and cash equivalents | 789,944 | 5,659,251 |
| Cash and cash equivalents at beginning of period | 438,607 | 1,228,551 |
| Cash and cash equivalents at end of period | 1,228,551 | 6,887,802 |

(5) Notes to the Consolidated Financial Statements

(Notes on going concern assumption)

There is no relevant information.

(Segment information)

<Segment information>

Fiscal year ended January 31, 2015 (from February 1, 2014 to January 31, 2015)

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

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 allogeneic stem cells.

<Related information>

Fiscal year ended January 31, 2015 (from February 1, 2014 to January 31, 2015)

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 | U.S. | Total |
|---|---|---|
| 6,116 | 12,162 | 18,279 |

3. Information by major customer

(Thousand yen)

| Name of customer | Operating revenue | Name of related segment |
|---|---|---|
| Sumitomo Dainippon Pharma Co., Ltd. | 3,229,211 | Regenerative cell therapy using allogeneic stem cells |

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 | U.S. | 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 |

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

Fiscal year ended January 31, 2015 (from February 1, 2014 to January 31, 2015)

There is no relevant information.

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

There is no relevant information.

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

Fiscal year ended January 31, 2015 (from February 1, 2014 to January 31, 2015)

There is no relevant information.

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

There is no relevant information.

<Information concerning gain on bargain purchase by reporting segment>

Fiscal year ended January 31, 2015 (from February 1, 2014 to January 31, 2015)

There is no relevant information.

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

There is no relevant information.

(Per share information)

(Yen)

| | For the fiscal year ended January 31, 2015 | For the fiscal year ended January 31, 2016 |
|---|---|---|
| Net assets per share | (2.22) | 142.66 |
| Net income (loss) per share | 44.31 | (22.67) |

(Notes) 1. Diluted net income per share for the fiscal year ended January 31, 2015 is not stated, despite the existence of potential shares, as average market prices during the period could not be calculated because shares of the Company were not listed on any stock exchange during the period.

2. Diluted net income per share for the fiscal year ended January 31, 2016 is not stated, despite the existence of potential shares, due to the posting of net loss per share.

3. The basis for calculating net income or loss per share is as follows.

| | For the fiscal year ended January 31, 2015 | For the fiscal year ended January 31, 2016 |
|---|---|---|
| Net income (loss) (Thousand yen) | 1,736,265 | (988,397) |
| Amount not attributable to common shareholders (Thousand yen) | — | — |
| Net income (loss) associated with common shares (Thousand yen) | 1,736,265 | (988,397) |
| Average number of shares during the period (Shares) | 39,183,075 | 43,598,673 |
| Outline of potential shares that were not included in the calculation of diluted net income per share because they have no dilutive effects | 5 series of subscription rights to shares (total number of subscription rights to shares: 2,689,709) | 4 series of subscription rights to shares (total number of subscription rights to shares: 1,688,452) |

(Significant subsequent events)

There is no relevant information.