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 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 research, 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 on, e.g., 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

Regenerative cell medicine is a relatively new field, and its practical application has just begun in certain countries, such as Canada. In Japan, only a few 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.

There are issues and risks inherent 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 using allogeneic cells, the Group's core technology, is a novel technology at present. From a clinical standpoint, we believe that the allogeneic cell treatment model 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, other unanticipated adverse outcomes or emergence of new technology making our model less effective, 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. 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 the use of human cells and tissues 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 business competition 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. Uncertainty of income model

Regarding the regenerative cell medicine SB623, the Group is pursuing a business plan based on an income model in which income is derived from co-development with and licensing out of marketing rights to entities such as major pharmaceutical companies.

Nevertheless, such income model may cease to continue due to circumstances beyond the Company's control, such as changes to the management policies of the partner, delays in product development, or other reasons. Pursuing business operations under this income model going forward may have a material impact on the Group's business results and financial position.

In addition, although milestone revenue is sometimes expected based on the achievement of certain results under a pre–launch income model, the time when such revenue is generated is uncertain due to its dependence on the progress of development, and depending on the progress of development there may be a material impact on the Group's business results and financial position.

Going forward, in order to mitigate the uncertainty arising from this income model, the Group intends to license out multiple pipelines. However, the achievement of alternative revenue streams from such licensing out 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 four Directors, three Corporate Auditors (including two part–time Corporate Auditors), and 30 employees, as well as 44 employees at its subsidiary, as of the end of January 2020. 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. 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.

d. Scheduled timing of application for manufacturing and marketing approval for regenerative cell medicine SB623 for traumatic brain injury in Japan

In the chronic motor deficit from traumatic brain injury project in Japan, the Group plans to apply for manufacturing and marketing approval for SB623 as a regenerative medicine as soon as possible, using the nation's conditional and term-limited authorization system for regenerative medicine products. However, there may be a material impact on the Group's business results and future business development if this does not proceed as anticipated, such as due to more time than anticipated being required for establishing the commercial production system or an unforeseeable circumstance arising before the application for approval.

e. Establishing of post-launch system for manufacture, distribution and sales of SB623

Based on the development status of the US-Japan traumatic brain injury project, the Group has begun work on establishing the post-launch system for the manufacture, distribution, and sales of SB623.

However, given that SB623 contains raw ingredients derived from human or animal sources and is a regenerative cell medicine manufactured based on highly novel regenerative

technology, there may be a material impact on the Group's business results and future business development if the establishing of such post-launch system does not proceed as anticipated such as due to an unforeseeable circumstance arising during such process.

(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 tends to initially incur substantial losses. Although the Group temporarily records operating revenues such as upfront payments from partners and milestone revenues accompanying progress in development, operating revenues and net income (loss) may be unstable until the sales of new medicines under development are commenced.

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 by the ability to receive milestone revenues accompanying progress in development, operating revenue and net income (loss) may be unstable, depending on the timing of their record and their amounts. 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.

Also, the borrowings of the Company include loan commitment agreements, which contain provisions that impose certain financial covenants and other covenants. If the Company comes to be in breach of any of these covenants and is unable to take measures to avoid acceleration of its obligations, the obligations of the Company in respect of such borrowings may be accelerated, which may have a material impact on the Group's business results and financial position.

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 procured

The Group has been using capital procured from the public offering at the time of listing, as well as other sources such as bank loans and subsidies mainly for pharmaceutical research and development as well as for establishing the post-launch system for the manufacture, distribution and sales of SB623. 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. Also, delays in the Company's plans can arise due to unforeseen circumstances. As a result, there is a risk that funds used in such activities 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 to hire 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 January 2020, the number of issued shares of the Company totaled 51.785 million shares. If existing subscription rights to shares are exercised, 0.646 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 further be 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. Although the Group temporarily records operating revenues such as upfront payments from partners and milestone revenues according to the progress in drug development, business results are expected to be unstable until the sales of new medicines are commenced. Under such circumstances, the Group believes that its corporate as well as shareholder value will be maximized if it prioritizes the development and approval for SB623 through concentrating its management resources in the process.

In the year ended 31 January 2020, the Group was not in a financial position to pay dividends according to the provisions of the Companies Act. Currently, it does not plan to pay dividends for the year ended 31 January 2020.

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 the sales.

h. Exchange rate fluctuations

The Group's main business of research and development in drug discovery is currently based mainly in its U.S. subsidiary. The transaction currency of the U.S. subsidiary is the U.S. dollar, and its 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, however, 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 an impact on the Group's business results and financial position.

j. Risks associated with novel coronavirus infectious disease (COVID-19)

The Group is aiming to commercialize its unique regenerative cell medicine SB623 and is proceeding with development on a global basis, mainly in Japan and the U.S. but also in other regions such as Europe.

Delays may arise in the Group's development of the regenerative cell medicine SB623 or in the establishing of post-launch system for the manufacture, distribution and sales thereof as a result of restrictions on the various business activities of the Group due to the recent spread of the novel coronavirus infectious disease (COVID-19), and if those circumstances are prolonged there may be a material impact on the Group's business results and financial position.