Business and Other Risks

The following outlines the principal matters that may be considered risk factors in relation to the business operations, development, and related activities of the SanBio Group. Some items listed are not necessarily regarded by the Group as significant risks. However, in light of the importance of certain matters for making investment decisions or for gaining a sufficient understanding of the Group's business activities, we have disclosed them as risk factors from the standpoint of proactive information disclosure to investors and shareholders.

While fully recognizing the possibility of these risks, the Group's policy is to strive to avoid their occurrence and, if they do occur, to respond appropriately. However, we believe that investment decisions concerning the Company's shares should be made only after careful consideration of both this section and other disclosures. In addition, the matters described below do not represent an exhaustive list of all risks related to investment decisions, and it should be noted that the Group is also subject to various other risks beyond those described here. Furthermore, any forward-looking statements in this section are based on the judgments of the Group as of the end of the 3rd Quarter of the Fiscal Year Ending January 31, 2026.

1. Risks Related to Pharmaceutical Research and Development and the Pharmaceutical Industry

(1) Uncertainty in New Drug Development

The development of prescription pharmaceuticals entails significant research and development (R&D) investment and lengthy development periods. However, it is not uncommon for R&D to fail to progress as planned due to factors such as the inability to confirm efficacy or safety in clinical trials, leading to decisions to extend or discontinue development. In addition, not only in Japan but also in overseas markets, the development of new drugs is subject to the application of pharmaceutical-related laws and regulations in each country. Because the manufacturing and marketing of new drugs require approvals based on strict reviews in each country, if sufficient data regarding efficacy, safety, quality, and other factors cannot be obtained, product launch may be delayed from the planned timing or may have to be abandoned. This also applies when the Group licenses out pipeline products to other companies. If the launch of prescription pharmaceutical candidates researched and developed by the Group, or licensed out to other companies, is delayed or discontinued, it may have a significant impact on the Group's operating performance and financial condition.

(2) Risks Related to the Development and Manufacturing of Cell Therapeutic Agents

a. Risks Arising from Operating in the Advanced Medical Care Field

Cell therapeutic agents have not yet reached the stage of full-scale global adoption. In Japan, even at present, the number of regenerative medicine and related products—to which cell therapeutic agents belong—that have obtained regulatory manufacturing and marketing approval is limited to 20 items. At this stage, their use remains relatively limited, primarily as advanced medical technologies employed by specific medical institutions and research organizations.

Behind this current situation lie challenges and risks that are unique to cutting-edge medicine and pharmaceuticals. First, as the sciences and technologies forming the foundation of cell therapeutic agents are making rapid advances, R&D of cell therapeutic agents is also progressing at an extremely fast pace, with new R&D results and insights into safety and efficacy emerging on a daily basis. The allogeneic cell therapeutic agents that constitute the Group's core technology are, at present, highly novel regenerative medicine technologies. Moreover, even from an academic standpoint, we are confident that our products are superior to other cell therapeutic agents in terms of safety, efficacy, and potential applications. On the other hand, there are risks of constantly being overtaken by waves of rapid technological innovation, risks in manufacturing and stable supply, and risks of unforeseen adverse events. These risks may have a significant impact on the Group's business strategy and operating performance.

b. Risks Arising from Revisions to Regulatory Systems. Changes in Government Promotion Policies, and Related Developments

There is also a possibility that regulations related to cell therapeutic agents will undergo continual revisions and updates in order to respond to the latest technological innovations. For example, due to additions or amendments to laws, guidelines, or other regulatory frameworks, certain risks cannot be ruled out—such as previously approved raw materials suddenly being barred from use, pharmaceutical approvals not being granted as anticipated by the Group, or approval timelines extending significantly beyond expectations. In the event of legal violations, or if our business activities come into conflict with newly established or tightened regulations, or with unanticipated regulatory applications and other developments, there is a possibility of administrative actions by supervisory authorities, litigation-related responses, suspension of business activities, or loss of corporate credibility. Furthermore, amid a global trend toward curbing medical expenses, drug prices or reimbursement prices may be set lower than the product value anticipated by the Company. Naturally, in such cases, these factors may have a significant impact on the Group's business strategy and operating performance.

At present, in countries with advanced healthcare systems such as the U.S. and Japan, various promotion policies related to advanced medicine are being implemented. These promotion policies may have a major impact on the cell therapeutic agents promoted by the Company; however, as the nature and extent of such impact are not yet clear, they may also have a significant impact on the future

business development of the Group.

c. Risks Related to the Use of Raw Materials of Human or Animal Origin

The Group's cell therapeutic agents make use of human cells and tissues, and due to factors such as the inability to completely eliminate the risk of infections derived from these materials, there are risks associated with safety. In addition, the Group's cell therapeutic agents use animal-derived raw materials in culture media employed in raw materials and manufacturing processes. It cannot be ruled out that the use of such animal-derived raw materials could result in damage or complications caused by unknown viruses or other such risks. If such an event were to occur as a result of transplanting our cell therapeutic agents into patients, it may have a significant impact on the Group's business strategy and operating performance.

(3) Adverse Events and Product Liability

Pharmaceuticals carry the possibility that unexpected adverse events may occur, from the clinical trial stage and even after product launch. The Group has taken out appropriate insurance to cover various liabilities in preparation for such situations; however, there is no guarantee that insurance payouts will fully cover the amount of compensation ultimately borne by the Group. Furthermore, even in cases where claims for damages against the Group are not upheld, the mere filing of such claims and related actions may create a negative perception, potentially undermining trust in the Group and its products. If such unexpected adverse events occur, they may have a significant impact on the Group's operating performance and financial condition, as well as on its business development due to a loss of social trust.

(4) Competition

The pharmaceutical industry is subject to intense competition from numerous domestic and international companies—including large multinational corporations—as well as research institutions and other organizations amid rapid and ongoing technological innovation. In competing with these entities, the Group may not necessarily be able to maintain a consistent competitive advantage. Depending on the outcomes of competition in each of the business activities of research, development, manufacturing, and marketing, the Group's operating performance and financial condition may be significantly impacted.

(5) Measures to Control Medical Costs

In the U.S.—the most important target market for the Group's cell therapeutic agent AKUUGO®—there is ongoing downward pressure on the prices of brand name drug, stemming in part from the comprehensive healthcare reform legislation of March 2010, along with the increasing promotion of low-cost generic drug use. In Japan as well, the government has set forth a policy of curbing medical expenses in order to restrain the continued increase in healthcare costs. Measures such as periodic drug price reductions and the

promotion of generic drug use and related initiatives are being pursued. Future trends in healthcare cost policies may have a significant impact on the Group's operating performance and financial condition.

(6) Dependence on External Contractors

The Group conducts in-house those activities that constitute its core competencies, such as R&D, the design of manufacturing processes, and other related functions. At the same time, we outsource non-clinical studies, clinical trials, the manufacturing of cell therapeutic agents, and other tasks to external contractors, including contract research organizations (CROs) and contract manufacturing organizations (CMOs). With external contractors, we establish strong cooperative frameworks through contracts and close communication to ensure the support necessary for the Group's business activities. However, if changes in the business environment faced by external contractors or other factors result in the Group being unable to obtain the support it seeks, the Group's operating performance and financial condition may be significantly impacted. However, if changes in the business environment faced by external contractors or other factors result in the Group being unable to obtain the support it seeks, or if it becomes necessary to change contractors, manufacturing sites, or production facilities and regulatory confirmations or approvals are required in response—potentially causing delays—the Group's business plans, operating performance, and financial condition may be significantly impacted.

2. Risks in Business Execution

(1) Uncertainty of Revenue Model

The Group conducts its business based on a revenue model centered on joint development with major pharmaceutical companies and other partners, and the licensing-out of marketing rights. (In the case of AKUUGO®, for which we have obtained conditional and time-limited approval, we expect to market the product independently.)

However, such a revenue model may be terminated before its contractual expiration due to changes in the management policies of counterparties, extreme deterioration in their business environments, or other circumstances beyond our control. If our business is conducted under such a revenue model in the future, the Group's operating performance and financial condition may be significantly impacted.

In addition, as a revenue model prior to product launch, we may anticipate milestone revenues based on the achievement of predetermined results. However, the timing of such revenues is uncertain, as it depends on the progress of development, and depending on such progress, the Group's operating performance and financial condition may be significantly impacted.

Furthermore, the Group plans to license out multiple pipeline products going forward to reduce the uncertainty of this revenue model. However, monetization of those pipeline programs is uncertain, as it depends on development progress, and if delays occur in such development, the Group's operating performance and financial condition may be significantly impacted.

(2) Dependence on a Small Organization and a Small Group of Core Personnel

As of the end of January 2025, the Group remains a small organization consisting of three Directors, three Auditors (including two part-time Auditors), and 29 employees, and our current internal control system is structured in accordance with this organizational scale. Going forward, we intend to strengthen our internal control system in line with the expansion of our business operations.

In addition, the Group's business activities depend heavily on the current management team—led by the Group's founders, Representative Director and Chairman Toru Kawanishi and Representative Director and President Keita Mori—as well as the heads of departments responsible for driving business, and a limited number of R&D personnel. For this reason, we are continuously working to secure and develop capable personnel. However, if we are unable to secure or develop personnel as planned, or if there is an outflow of personnel, the Group's business activities could be disrupted, and the Group's operating performance and financial condition may be significantly impacted.

(3) Intellectual Property Rights

In the course of business development, including R&D, the Group makes use of various intellectual property rights, which we recognize as either rights owned by the Company or rights for which we have legally obtained licenses to use.

In addition, there is no guarantee that all of the patent applications currently filed by the Group will be granted. Furthermore, even if patents are granted, there is always the possibility that the technologies covered by the Group's patents may be rendered obsolete by superior R&D conducted by others. If superior technologies that fall outside the scope of the Group's patent rights are developed, this may have a significant impact on the Group's operating performance and financial condition.

To prevent infringement of the patent rights of other companies, the Group conducts patent investigations that we deem necessary. To date, there have been no instances of litigation with third parties concerning patent rights or other intellectual property rights related to the Group's development pipeline. However, for R&D-driven companies such as ours, it is difficult to completely avoid issues of intellectual property infringement. If disputes regarding intellectual property rights arise with third parties, the Group's operating performance and financial condition may be significantly impacted.

(4) Planned Full Approval in Japan for Cell Therapeutic Agent AKUUGO® for Treatment of

Traumatic Brain Injury

On July 31, 2024, the Group obtained conditional and time-limited manufacturing and marketing approval for AKUUGO® from the Ministry of Health, Labour and Welfare (MHLW). To satisfy one of the approval conditions—confirmation of equivalence and homogeneity—we conducted manufacturing with the aim of achieving conformity in about two commercial production runs. In two of these runs, all standard values were met in both specification testing and characteristic analysis, confirming conformity. Based on these results, the Group submitted a partial change application to the provisions of the manufacturing and market approval of AKUUGO® and is currently seeking approval for shipment release. On October 16, 2025, the Subcommittee on Regenerative Medicine Products and Biologically Derived Technologies of the MHLW's Pharmaceutical Affairs and Food Sanitation Council reviewed and deliberated on the application for partial changes to the provisions of the manufacturing and marketing approval and the revisions to the approval conditions for the regenerative medicine product AKUUGO®, and concluded that approval would be appropriate. However, as of the preparation of this document, formal approval for shipment release has not been obtained. Going forward, we plan to promote the dissemination of AKUUGO® domestically. In parallel, during the seven-year term specified as the second approval condition under the conditional and time-limited manufacturing and marketing approval, we will conduct post-marketing clinical trials and related studies in order to obtain full approval.

However, if progress does not proceed as anticipated by the Company due to unexpected events or developments during the course of regulatory review, the Group's operating performance and future business development may be significantly impacted.

(5) Establishment of Manufacturing, Distribution, and Marketing Systems for AKUUGO® Post-Launch

Following the acquisition of conditional and time-limited approval for AKUUGO® in Japan, the Group has begun establishing systems for manufacturing, distribution, and marketing of AKUUGO® after launch. We are also working to secure inventory of AKUUGO® in anticipation of initial demand following its market launch.

However, as AKUUGO® is a cell therapeutic agent manufactured using raw materials of human or animal origin and based on highly novel regenerative medicine technology, unforeseen events in the establishment or maintenance of its manufacturing, distribution, and sales systems could hinder the procurement of raw materials or production at contract manufacturers. In addition, if factors such as a high rate of non-conforming products during the manufacturing process prevent the Company from securing supply volumes sufficient to meet demand or from ensuring smooth administration to patients, the manufacturing, distribution, and sales of AKUUGO® may not proceed as planned, resulting in lost revenue opportunities. Further, if costs incurred in the manufacturing, distribution, or sales processes increase beyond

expectations, the Group's business plans, operating performance, and future business development may be significantly impacted.

3. Risks Related to Business Performance and Other Matters

(1) Recording of Negative Retained Earnings Carried Forward

The Group operates as a venture company whose primary business is pharmaceutical R&D. Pharmaceutical R&D requires substantial upfront spending, and because the recovery of such investment tends to take relatively longer than in many other industries, venture companies engaging in this business generally experience an initial period of losses. While the Group may recognize temporary revenue such as upfront or development milestone payments depending on the conclusion of partnerships and the progress of development, until the marketing of new pharmaceuticals under development commences, our operating revenue and net income (loss) may remain unstable.

The Group aims to expand future profits by advancing the development of our pipeline, including AKUUGO®. However, depending on the progress and results of development, net income for the period may not be recorded as planned in the future. In addition, if our business does not progress as planned and net income cannot be achieved, the timing of a return to positive retained earnings carried forward may be significantly delayed.

(2) Tendency for Revenues to Fluctuate Significantly

The Group's operating revenue is heavily influenced by the receipt or non-receipt of upfront payments at the time of out-licensing, as well as milestone revenues tied to the progress of our pipeline products currently under development, including AKUUGO®. As a result, depending on the timing and amount of such income recognition, operating revenue and net income (loss) may remain unstable. This tendency is expected to continue until the pipeline products currently under development are launched and establish a stable revenue base.

(3) Cash Flow Management

Operating as an R&D-driven company, the Group requires substantial R&D funding, and the burden of these expenses results in a prolonged period of upfront spending. During this period, there is a tendency to continuously record operating losses, and cash flows from operating activities generally remain negative. The Group has likewise continued to generate negative operating cash flows and, at present, does not yet possess sufficiently stable sources of revenue.

In addition, the Group's borrowings include term loan agreements that are subject to certain financial covenants and other compliance requirements, as described in "Section 5: Financial Condition – 1. Consolidated Financial Statements and Others – (1) Notes to the Consolidated Financial Statements (Consolidated Balance Sheet Items)." If any of these covenants are breached and the Company is unable to take measures to avoid the loss of the benefit of time, the Group would lose the benefit of time with respect to the relevant borrowings, and the Group's financial condition and operating performance may be significantly impacted.

At the end of each fiscal year, the Group holds sufficient cash and deposits in consideration of the business plan for the following fiscal year. However, until stable sources of revenue are secured, our policy is to raise funds and take other measures at appropriate times as necessary to strengthen our financial base. If we are unable to secure funding at the required timing, significant concerns may arise regarding the continuation of the Group's business.

(4) Use of Procured Funds

In addition to the funds raised through the public offering at the time of our listing, the Group has allocated funds obtained through sources such as indirect financing and the receipt of subsidies to business expenses, primarily for pharmaceutical R&D and for the establishment of manufacturing, distribution, and marketing systems for SB623 following its launch. However, while R&D activities related to new drug development require a long period of time before generating revenue, there is no guarantee that the expected outcomes of R&D investments will be achieved. In addition, unexpected events may cause delays in the Company's plans, and as a result, the allocated funds may not lead to the anticipated profits.

(5) Financing Through Issuance of New Shares

Operating as an R&D-driven pharmaceutical company, the Group plans to raise funds primarily through capital increases in a flexible manner, anticipating the expansion of future R&D activities. As of the end of January 2025, there were no unexercised stock acquisition rights related to financing. However, at the Board of Directors meeting held on February 14, 2025, the Company resolved to issue new shares through a third-party allotment and to issue the First Series of Unsecured Convertible Bonds with Stock Acquisition Rights. Accordingly, through the issuance of new shares by third-party allotment, 1,088,000 new shares were issued on the payment date of March 3, 2025. In addition, following the issuance of the First Series of Unsecured Convertible Bonds with Stock Acquisition Rights, if the stock acquisition rights attached to the convertible bonds are exercised in the future, up to 2,113,000 new shares may be issued, and the value per share of the Company's stock may be diluted.

(6) Stock Acquisition Rights

To enhance the motivation and morale of our Directors, Auditors, employees, employees of our subsidiaries,

and external contractors toward improving our business performance, as well as from the perspective of securing talented personnel, the Group has adopted a stock option program. In accordance with Articles 236, 238, and 239 of the Companies Act, and with the approval of the General Meeting of Shareholders, we issue and grant stock acquisition rights to our Directors, Auditors, employees, employees of our subsidiaries, and external contractors.

As of the end of July 2025, the Company's total number of issued shares was 72,027,000. If the aforementioned stock acquisition rights are exercised, 198,000 new shares will be issued, and the value per share of the Company's stock may be diluted. Furthermore, to secure talented personnel going forward, we may maintain similar incentive plans. Accordingly, if stock acquisition rights granted in the future are exercised, the value per share of the Company's stock may also be diluted.

(7) Dividend Policy

Pharmaceutical R&D requires substantial upfront spending, and recovery of such investment tends to take a long period of time. While the Group may record revenue on a temporary basis such as upfront or development milestone payments depending on the conclusion of partnerships and the progress of development, our business performance is expected to remain unstable until the marketing of new drugs under development commences.

Under these circumstances, we believe that prioritizing the allocation of management resources to development and achieving early regulatory approval will contribute to enhancing corporate value and, ultimately, to maximizing shareholder value.

For the fiscal year ended January 2025, we were not in a financial position to pay dividends under the provisions of the Companies Act. In addition, we do not plan to pay dividends in the current consolidated fiscal year.

We recognize shareholder returns as an important management priority. In the future, when new drugs currently under development, including SB623, are launched and net income is recorded from their sales, we intend to consider profit distribution through dividends, taking into account our operating performance and financial condition.

(8) Foreign Exchange Fluctuations

The Group has a U.S. subsidiary whose functional currency is the U.S. dollar, and its financial statements are also prepared in that currency. Accordingly, in the process of preparing consolidated financial statements, those financial statements are translated into Japanese yen in accordance with accounting standards for foreign currency transactions and related matters. As a result, if there are significant fluctuations in exchange rates, the Group's operating performance and financial condition may be impacted.

(9) Risks Related to International Taxation

Since the "inverted parent-subsidiary structure" in January 2014, the Group's capital structure has consisted of the Company, a Japanese corporation, and SanBio, Inc., a U.S. corporation. Accordingly, the tax treatment arising from the capital and transactional relationships between parent and subsidiary is subject to international taxation, specifically the tax laws of Japan and the U.S., as well as the application of the Japan-U.S. Tax Treaty.

Accordingly, the Group enters into advisory agreements with tax accountants and other specialists in each country, collects information on applicable tax laws, and makes efforts to identify and eliminate tax risks. However, due to the complexity of international taxation, tax matters unfavorable to the Group may arise, or international tax systems may be amended in the future in ways that are disadvantageous to the Group. In such cases, our future tax burden may increase, and the Group's operating performance and financial condition may be impacted.