March 28, 2020
SanBio Co., Ltd.

Financial Results Briefing for Fiscal Year Ended January 31, 2020: Q&A Summary

Financial results for fiscal year ended January 31, 2020

Question	Answer
There was a roughly ¥400 million gap between the reported operating income and the revised forecast issued in December 2019. Could you explain what caused the discrepancy?	The discrepancy was mainly attributable to the booking of manufacturing-related R&D expenses that were expected to be recorded next fiscal year.

Fundraising

Question	Answer
Could you provide your views on fundraising efforts going forward, and the expected timing? Please also elaborate if such fundraising will conflict with financial covenants attached to existing bank financing.	While working toward domestic approval for our SB623 program for the treatment of chronic motor deficit from traumatic brain injury (TBI) ("TBI program"), we were able to also secure funding to initiate the global Phase 3 clinical trial for the TBI program. Some of our bank financing is contingent on not incurring losses in two consecutive years, but we are exploring a range of fundraising options, including avenues in case this requirement is not met. In addition, our policy is to raise funds by selecting the optimal methods based on the circumstances, including subsidies, out-licensing, project finance, bank loans, and equity. Finally, we are not disclosing the timing and scale of future fundraising efforts.

Change in expected timing of filing for domestic approval of TBI program

Question	Answer
Could you provide quantitative information on the timing of approval filing and progress with preparations? In addition, please share your views on the probability of filing for approval by January 2021.	Much will depend on the judgment of the authorities, and we are unable to disclose the specific timing of the approval filing. It is difficult to express our degree of progress in quantitative terms, but we will announce our progress at the appropriate timing. In addition, we believe filing for approval by January 2021 is possible, and are making preparations along those lines.
In the past, SanBio outsourced manufacturing to PCT, LLC (currently Hitachi Chemical Advanced Therapeutics Solutions, LLC [HCATS]). PCT has been acquired by Hitachi Chemical Co., Ltd., which is currently your contract manufacturing organization (CMO). Since Hitachi Chemical and PCT (currently HCATS) are effectively the same CMO, why is the technology transfer taking time?	Some time has elapsed since we outsourced manufacturing to PCT, and changes in team composition were also a factor. As a result, the technology transfer is taking more time than we had initially anticipated.
Can you explain why you changed your CMO to Hitachi Chemical?	We formed a partnership with Hitachi Chemical because it has acquired a well-established regenerative medicine company, it has strong technical capabilities, and it has built a structure to support stable supply over the long term.
Can you explain in which clinical trials the products manufactured by the first CMO (PCT, currently HCATS) and the second CMO (US-based company) were utilized?	The products manufactured by the first CMO were used in the Phase 1/2a clinical trial for the ischemic stroke program, and those manufactured by the second CMO in the Phase 2b clinical trial for the ischemic stroke program, and Phase 2 clinical trial for the TBI Program.
Is it possible the switch in CMO will change drug quality?	While we cannot entirely rule out that possibility, we believe this will not occur.

Can you provide detailed information about the issue of inadequate standard testing?	When transitioning from the clinical trial stage to the commercialization stage, we believe testing methods for product standards need to be tightened. Regenerative medicine and cell products feature larger and much more complex molecules than small molecule compounds, and corresponding standards have yet to be formulated in the industry. Consequently, for standard testing in the commercialization stage, we are currently establishing testing methods in consultation with the Pharmaceuticals and Medical Devices Agency (PMDA). This does not mean there are quality issues with our products.
Which of the following three issues do you regard as the most difficult to deal with? (1) Delays in technology transfer to new CMO, (2) establishment of a management structure for commercial production, or (3) inadequate standard testing.	We put the three issues at the same level of difficulty, but we believe that we can deal with all of these provided we invest the necessary time.
Were the three issues mentioned in the previous question not apparent in December 2019, when you announced the change in timing of approval filing?	We have been aware of the three issues for a while, and have made preparations to resolve them. However, we were unable to adequately summarize all information by December 2019. We have now summarized all information, and therefore made a new disclosure.
Did the diversification of manufacturing bases have an impact on the approval filing in Japan?	There is no correlation between the two. We took steps with a view to developing drugs for global markets.

Global expansion of TBI Program

Question	Answer
Are you considering out-licensing at an early stage in China?	We are considering a range of options, but we would like to find a partner company that shares our vision and values, and with which we can work over the long term.

Are the approval filing in Japan and the schedule of global Phase 3 clinical trials interdependent?	We do not have to prioritize one above the other, and we are taking steps to achieve both as soon as possible.
When developing drugs for global markets, is there a possibility you will face the same issues as for the approval filing in Japan?	That is a possibility, but we are making preparations to ensure a smooth process.

Ischemic stroke and brain hemorrhage programs

Question	Answer
Could you give us an update on where you stand in your examination of the program for chronic motor deficit from ischemic stroke?	We continue to examine our future strategy internally.
Will you publish detailed results from the Phase 2b clinical trial for the program for chronic motor deficit from ischemic stroke?	We will announce results in accordance with the reporting requirements of the relevant authorities in each country, but the company does not intend to disclose detailed results.
Stemedica Cell Technologies, Inc. (in the US) has reported positive results for its Phase 1/2a clinical trial for chronic ischemic stroke. What is your view of this as a competitor?	Many patients suffer from chronic ischemic stroke, so we believe there is a large market in which multiple products can co-exists without any problems.