Financial Results
for the Fiscal Year Ending January 31, 2023

SanBio Company Limited

(TSE Growth: 4592)

March 17, 2023

SanBio
Pioneering Regenerative Medicine

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New Executive Leadership

Executive Directors

SanBio Co., Ltd. Executive Chairman
Toru Kawanishi

SanBio Co., Ltd. President
Keita Mori

Corporate Officers

Senior Corporate Officer, CMO
Bijan Nejadnik

Senior Corporate Officer, responsible for HR, Japan Regulatory Affairs & Quality Compliance Japan, and Japan/Asia Business*
Naoki Tsukahara

*Consolidated business activities of SanBio Asia

CSO
Andrew Liu

Head of Production
Keizo Nakada

Head of Japan Regulatory Affairs & Quality Compliance Japan
Kazumi Sawaguchi

Head of Japan Research and Development
Shinya Hirata

Management Administration
Yoshihiro Kakutani

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1. Financial Results

Consolidated Income Statement

Operating expenses increased from weakening yen vs the US dollar, higher expenditures related to work toward approval of SB623 chronic TBI program, and an increase of R&D expenses from a decision to record supplies for use in commercial production as for R&D.

Million Yen	FY2022.1 Results (A)	FY2023.1 Results (B)	(B)-(A)	FY2023.1 Forecast
Revenue	-	-	-	-
R&D expenses	4,955	6,118	1,162	6,105
Operating expenses	6,620	7,899	1,278	8,131
Operating income	▲6,620	▲7,899	▲1,278	▲8,131
Net income	▲4,677	▲5,559	▲881	▲5,684
Yen/US$ exchange rate	110.73	132.72	-	135.77

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Consolidated Balance Sheet

Secured operating fund toward approval of the SB623 chronic TBI program through equity financings initiated in the fiscal year ending January 31, 2023.

Million yen	As of January 31, 2022 (A)	As of January 31, 2023 (B)	(B)-(A)
Cash & cash equivalents	4,557	6,732	2,175
Current assets	5,351	6,967	1,615
Non-current assets	159	77	▲81
Total assets	5,510	7,045	1,534
Current liabilities	1,463	1,090	▲372
Non-current liabilities	2,012	1,525	▲486
Total liabilities	3,475	2,616	▲859
Net assets	2,035	4,428	2,393
Total liabilities and net assets	5,510	7,045	1,534

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Consolidated Earnings Forecast

Forecast significant reduction of operating expenses by optimizing business resource allocation as we proceed with approval of the SB623 chronic TBI program and prepare for product launch.

Million yen	FY2023.1 Results	FY2024.1 Forecast
Revenue	-	-
R&D expenses	6,118	3,195
Operating expenses	7,899	4,642
Operating income	▲7,899	▲4,642
Net income	▲5,559	▲4,598
Yen/US$ exchange rate	132.72	138.00

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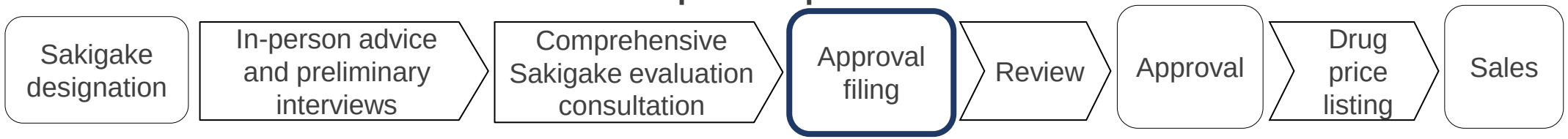
2. SB623 Approval in Japan and Sales Structure After Approval

Completed Filing for Approval in Japan

Filed for approval within the framework of the Sakigake Designation System based on positive phase 2 trial result



In-person advice and preliminary interviews

- Regulatory agencies provide guidance and advice in response to requests from SanBio

Comprehensive Sakigake evaluation consultation

- Product approval filing will be approved when the authority determines that the review following the submission of the filing can be completed within 6 months

Approval

- Aiming for early launch by making use of the conditional and time-limited approval system*

NHI drug price listing

- Price is calculated using either the comparable drug method or the cost calculation method

Sales

- Preparation underway to promptly market the product after NHI Drug Price listing

The Pharmaceutical and Medical Devices Law, which came into effect on November 25, 2014, introduced an early approval system (approval with conditions and time limits). For regenerative medicine products that are not homogeneous, if safety can be confirmed and efficacy is presumed, the system allows approval for manufacturing and sales with conditions and time limits (from Article 23-26 of the Pharmaceutical and Medical Devices Law).

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Management of production-related items toward approval

Approval filining completed in March 2022 after resolving issues related to establishment of post-launch stable supply system.

- Production process established.

Since filing completion, communication with PMDA and responses to production-related review made steady progress toward approval. However, “production yield issue" has surfaced.

- Lower production yield compared to yield level at the time of filing.

Measures to resolve the issue have been implemented to execute production run, and SanBio continue to aim for obtaining approval in the fiscal year ending January 31, 2024.

- Issue analysis and development of resolution measures now completed.
- Currenlty working closely with a partner CMO (includign on-site training by SanBio) to implement resolution measures to improve production operations.

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Issue and resolution measures toward approval

Issue	In recent production runs, production yield lower compared to the level at the time of approval filing.
Solution	Improve production operations and execute production run for confirmation.
Criteria	Achieve production yield at the time of approval filing.
Level of Difficulty	Good past track record of achieving yield comparable to the level at the time of approval filing. Current effort is to confirm and reproduce past results.
Resolution timing	Main result of resolution measures will be available in June.
Disclosure	Update will be provided in June at the time of Finncial disclosure for the first quarter of the fiscal year ending January 31, 2024.
Outlook	SanBio believes resolution of this issue is a milestone and facilitate obtaining approval in current fiscal year ending January 31, 2024 by resolving the issue.

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Establishment of In-House Facility and Acquisition of License for Packaging, Labeling and Storage of Regenerative Medicine Products

Establishment of In-House Facility and Acquisition of License for Packaging, Labeling and Storage of Regenerative Medicine Products on December 15, 2022

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December 21, 2022
SanBio Co., Ltd.

Establishment of In-House Facility and Acquisition of License for Packaging, Labeling and Storage of Regenerative Medicine Products

SanBio Co, Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that it has established an in-house facility for packaging, labeling and storage of regenerative medicine products (hereafter, the "Facility") and that on December 15, 2022, it obtained a license for packaging, labeling and storage of regenerative medicine products.

The Company's pipeline product SB623 is currently under review by regulatory authorities for approval as a treatment for chronic effects of traumatic brain injury. The Company is in the process of building a distribution network to ensure smooth and seamless delivery of the product to patients after its approval. This includes developing R-SAT®, a distribution management and administration schedule support system for regenerative medicine products. The Company decided to establish the Facility to flexibly respond to the needs of medical institutions. Following a review of its quality management systems by the regulatory authorities, the Company was granted a license to package, label and store regenerative medicine products at the Facility. This is a significant step in the Company's ongoing efforts to establish a seamless and efficient distribution network.

Looking Ahead After SB623 Approval

Progress in preparation toward the launch of SB623

- ✓ Preparation for sales and marketing activities in compliance with expected approval criteria
- ✓ Enabling TBI patients to access to SB623 as soon as it is launched in collaboration with various external stakeholders

	Current status
Drug Price	Gathering information, drafting strategies, and preparing application materials for listing on the NHI drug price list at an appropriate price
Medical Treatment Fees	Identify possible issues and solutions to facilitate determination of appropriate medical treatment fees for cell preparation and surgical procedures involved in SB623 transplantation
Sales Structure	For SB623 transplantation and post-procedure rehabilitation, planning to establish *SanBio Community Healthcare Collaboration,* which will enable medical cooperation and patient follow-up tailored to each region, from the perspective of promoting appropriate use
	CRM system now in place to facilitate appropriate promotional activities after approval
Logistics System	Obtained a patent for R-SAT® system; preparing to install and utilize the system after the launch of SB623
	In discussions with wholesalers on details for establishing a distribution scheme to ensure smooth delivery of product to cell transplantation facilities
Preparation of Materials for Promotional Activities	Creating various contents such as disease awareness videos and materials for healthcare professionals in accordance with fair competition code, to promote the use of SB623 and facilitate appropriate promotional activities provision after approval
Establishment of System for Promoting Appropriate Use	Determine personnel and facility requirements for the promotion of appropriate use
	Build an ICT-powered patient eligibility determination system
	Establish a system for post-launch gathering of safety information and reporting to regulatory authorities

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3. Toward Maximizing Corporate Value

Research Paper Awarded Hirakawa Prize from Japan Society of Neurotraumatology

Awarded to the lead author Masahito Kawabori MD, PhD, of the Department of Neurosurgery, Hokkaido University Graduate School of Medicine, for a paper discussing the results of the Phase 2 STEMTRA trial on SB623 for the indication of traumatic brain injury

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February 27, 2023

SanBio Co., Ltd.

Research Paper Awarded Hirakawa Prize from Japan Society of Neurotraumatology

SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that Masahito Kawabori, MD, PhD, of the Department of Neurosurgery, Hokkaido University Graduate School of Medicine, the lead author of a paper discussing the interim analysis of the Phase 2 STEMTRA trial on SB623 for the indication of traumatic brain injury (TBI), has been awarded the Hirakawa Prize from the Japan Society of Neurotraumatology (JSNT).

Paper Published on Data Indicating New Potential for SB623

Synergistic therapeutic effects of intracerebral transplantation of SB623 and voluntary exercise confirmed in a rat model of ischemic stroke

Journal: Stem Cell Research & Therapy

Title: Synergistic therapeutic effects of intracerebral transplantation of human modified bone marrow-derived stromal cells (SB623) and voluntary exercise with running wheel in a rat model of ischemic stroke

Publication: January 24, 2023
URL：https://stemcellres.biomedcentral.com/articles/10.1186/s13287-023-03236-4

Trial content: Rat models were subjected to ischemic stroke and assigned to four groups—an SB623 group, a voluntary exercise group (running wheel), an SB623 + voluntary exercise group, and a control group—before undergoing behavioral tests using the modified neurological severity score (mNSS) and cylinder test, followed by histological analysis and assessment of mRNA.

Trial results: The SB623 + exercise group achieved significant neurological recovery in mNSS versus the control group. The cerebral infarct area of the SB623 + exercise group decreased significantly compared to all other groups, and the number of BrdU/Doublecortin (Dcx) double-positive cells in the subventricular zone (SVZ) and the dentate gyrus (DG), the laminin-positive area in the ischemic boundary zone (IBZ), and the mRNA level of brain-derived neurotrophic factor (BDNF) and vascular endothelial growth factor (VEGF) in the SB623 + exercise group significantly increased compared to all other groups.

Conclusion: Combination therapy of intracerebral transplantation of SB623 cells and voluntary exercise is suggested to promote robust neurological recovery and synergistically enhance endogenous neurogenesis and angiogenesis after cerebral ischemia, possibly through a mechanism involving the up-regulation of BDNF and VEGF.

Presentations at Academic Conferences

STROKE 2023

Date: March 16th to March 18th　　Venue: Yokohama

Presenter: Dr. Satoru Yabuno (Department of Neurological Surgery, University of Okayama Hospital)

Title: Synergistic therapeutic effects of intracerebral transplantation of human modified bone marrow-derived stromal cells (SB623) and rehabilitation in a rat model of ischemic stroke

The 22nd Congress of the Japanese Society for Regenerative Medicine

Date: March 23rd to March 25th　　Venue: Kyoto

Presenter: Dr. Takao Yasuhara (Associate Professor, Department of Neurological Surgery, University of Okayama Hospital)

Title: Current status of intracerebral transplantation of human modified bone marrow-derived stromal cells (SB623): cycle of clinical research and basic research

The 14th World Congress on Brain Injury

Date: March 29th to April 1st　　Venue: Dublin, Ireland

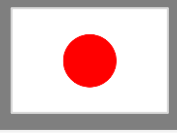
Presenter: Dr. Alan Weintraub (Rocky Mountain Regional Brain Injury System)

Title: Final analysis of the double-blind, randomized, surgical sham-controlled, Phase 2 STEMTRA Trial: 1-year safety and efficacy outcomes in patients with chronic motor deficits secondary to traumatic brain injury

SB623 Development Plans

Highest priority given to TBI program in Japan, followed by clinical trials for ischemic stroke and hemorrhagic stroke programs in Japan

Top priority

		
Traumatic brain injury (TBI)	**Approval application filed**	Considering timing for starting clinical trials*
Ischemic stroke	Plan to consult PMDA on initiating clinical trials	Planning for clinical trials*
Hemorrhagic stroke	Plan to consult PMDA on initiating clinical trials	Planning for clinical trials*

*Considering various options, including in-house development and tie-ups with other companies

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Development Status

Cell medicine	Indication		Research	Nonclinical	Phase 1	Phase 2	Phase 3	Approval filing
SB623 chronic brain injury	**Traumatic brain injury (TBI)**	**Japan**	→	→	→	→		→
		US	→	→	→	→		
	Ischemic stroke		→	→	→	→	Planning for Phase 2b or 3 study (Japan)*1	
	Hemorrhagic stroke		→	→	→	→	Planning for Phase 2b or 3 study (Japan)*1	
SB623 retinal disease	Age-related macular degeneration (dry)*2		→	→	Partnered with OcuMension Therapeutics in Greater China			
	Retinitis pigmentosa*2		→	→	Partnered with OcuMension Therapeutics in Greater China			
SB623	Parkinson's disease		→	→				
	Spinal cord injury		→	→				
	Alzheimer's disease		→					
SB618	Peripheral nerve damage, etc.		→	→				
SB308	Muscle dystrophy		→					
MSC1	Cancer		→					
MSC2	Inflammatory disease		→	→	Partnered with D&P			
	Optic neuritis *2		→	→	Partnered with OcuMension Therapeutics in Greater China			

*1: Clinical trials will begin from Phase 2b as safety has been confirmed in previous clinical trials for ischemic stroke and TBI programs.
*2: Joint development with OcuMension (Hong Kong) Limited.
*3: Formed a business partnership with D&P Bioinnovations, Inc. for the development and commercialization of regenerative esophageal implant.

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Becoming a Global Leader in Regenerative Medicine

Deliver novel therapeutics to patients as rapidly as possible and maximize corporate value

4. Q&A

Disclaimer

This presentation material, including any comments made during or following the presentation, is provided solely for the purpose of reference to those investors who make their own evaluation of the company at their own risk. This material contains estimates, such as plans, strategies and judgments, that are forward-looking statements which are made based on management's assumptions and beliefs in light of the information currently available to it and may contain risks and uncertainty. Therefore you should not place undue reliance on them in making investment decisions.

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