Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2022

SanBio Company Limited

(TSE Growth: 4592)

September 15, 2022

Table of Contents

1 Financial Results

2 SB623 Approval in Japan and Sales Structure After Approval

3 Toward Maximizing Corporate Value

4 Q&A

SanBio
Pioneering Regenerative Medicine

New Executive Leadership

Executive Directors

SanBio Co., Ltd. Executive Chairman
Toru Kawanishi

SanBio Co., Ltd. President
SanBio, Inc. Chairman
Keita Mori

SanBio Co., Ltd.
Representative Director,
Executive Vice President,
COO
SanBio, Inc. CEO
Akihiro Tsujimura

Corporate Officers

CMO
Bijan Nejadnik

Business Head (Japan/Asia)
Naoki Tsukahara

CSO
Andrew Liu
New

Head of Production
Keizo Nakada
New

Head of Japan Regulatory Affairs & Quality Compliance Japan
Kazumi Sawaguchi
New

Head of Japan Research and Development
Shinya Hirata
New

Management Administration
Yoshihiro Kakutani

SanBio
Pioneering Regenerative Medicine

Introducing Newly Appointed Corporate Officers

Corporate Officer, Chief Strategy Officer

Andrew Liu

Mr. Andrew has many years of experience and a track record in strategic management and business development. As head of Corporate Development at Santen Pharmaceutical Co., Ltd. and listed Chinese company Chengdu Kanghong Pharmaceutical Group Co., Ltd., he was responsible for business development, corporate planning, and product portfolio strategy, creating corporate value by leading pipeline out-licensing and in-licensing, business acquisitions, investment in biotech startups, and business reorganization.
Mr. Andrew graduated from Swarthmore College with a B.A in Biochemistry and from Harvard University with an M.A. in Regional Studies, East Asia.

SanBio
Pioneering Regenerative Medicine

Introducing Newly Appointed Corporate Officers

Corporate Officer, Head of Production

Keizo Nakada

As a general manager of global manufacturing plants at organizations such as Santen Pharmaceutical Co., Ltd., Mr. Nakada oversaw the start-up of plants in China and assumed responsibility for supply capacity enhancement and productivity improvement. At Taiko Pharmaceutical Co., Ltd., Mr. Nakada played a vital role in setting up a plant within a short period of time. Meanwhile, he supervised logistics, quality control, and engineering technology, overseeing the entire supply chain for products produced both internally and by third-party manufacturers. Mr. Nakada has abundant knowledge and on-site experience related to the stable production and supply of quality pharmaceutical products.

Introducing Newly Appointed Corporate Officers

Corporate Officer, Head of Japan Regulatory Affairs & Quality Compliance Japan

Kazumi Sawaguchi

Upon earning her Ph.D. in Pharmacokinetics, Dr. Sawaguchi worked in project management for new drug development at both domestic and foreign pharmaceutical companies, participating in a wide range of development work from the launch of clinical trials to the approval stage. Thereafter, she worked for foreign pharmaceutical companies and CROs in development and regulatory affairs, and has extensive experience in PMDA consultation and application for and acquisition of approval. Dr. Sawaguchi has served as Vice president of Regulatory Affairs, Intelligence/Policy, and Quality Assurance Unit at Konica Minolta Precision Medicine Japan, Head of Regulatory Affairs at PAREXEL Consulting Japan, Head of Regulatory Affairs at Mylan Seiyaku/Mylan EPD, Senior Manager, Project Management Department at Janssen Pharmaceutical, Senior Manager, Development Strategy Office at Eisai, Senior Manager, Development Department at Daiichi Sankyo, and Executive Director at Kansai Pharmaceutical Association.

Introducing Newly Appointed Corporate Officers

Corporate Officer, Head of Japan Research and Development

Shinya Hirata

After being involved in drug discovery and pharmacological research as a researcher at Kaken Pharmaceutical and other companies, Mr. Hirata became a medical science liaison. Mr. Hirata has extensive knowledge and experience in the medical affairs field, amassed through his role in the management of investigator-initiated clinical trials, supervision of medical teams, and KOL management in the fields of ophthalmology and immuno-inflammatory diseases at Otsuka Pharmaceutical, Takeda Pharmaceutical, and Celgene.

1. Financial Results

Consolidated Income Statement

Operating expenses increased due to higher manufacturing-related expenditures for obtaining approval of the SB623 chronic TBI program and yen depreciation against the US dollar. In addition, supplies for commercial production were expensed as R&D expenses.

Unit: Million yen	Q2 FY2022.1 Results (A)	Q2 FY2023.1 Results (B)	(B)-(A)
Revenue	-	-	-
R&D expenses	2,251	3,620	1,369
Operating expenses	3,052	4,621	1,569
Operating income	-3,052	-4,621	-1,569
Net income	-2,134	-2,154	-20
Yen/USD exchange rate	108.79	126.54	–

SanBio
Pioneering Regenerative Medicine

Consolidated Balance Sheet

Raised 7.7 billion yen through equity financing in 1H

Unit: Million yen	As of January 31, 2022 (A)	As of July 31, 2022 (B)	(B)-(A)
Cash & cash equivalents	4,557	8,335	3,778
Supplies	467	-	-467
Current assets	5,351	8,508	3,157
Non-current assets	159	89	-69
Total assets	5,510	8,598	3,087
Current liabilities	1,463	1,561	98
Non-current liabilities	2,012	3,104	1,092
Total liabilities	3,475	4,666	1,190
Total net assets	2,035	3,932	1,896
Total liabilities and net assets	5,510	8,598	3,087

SanBio
Pioneering Regenerative Medicine

Revision of Consolidated Earnings Forecast for FY2023.1

Reflected 1H results and an expected increase in manufacturing-related expenditures for obtaining approval of the SB623 chronic TBI program in 2H

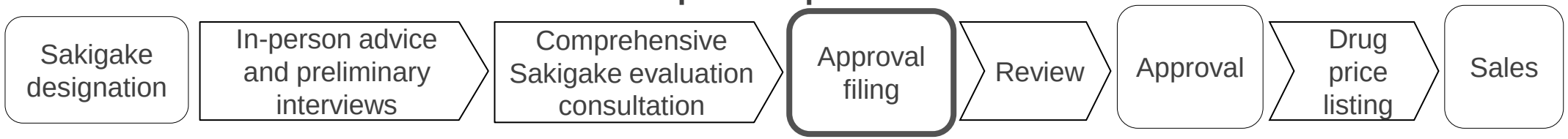
	Operating revenue	Operating income	Ordinary income	Net income attributable to owners of parent	Net income per share
Previous forecast (A) (released March 11, 2022)	(million yen) -	(million yen) **-5,858**	(million yen) **-5,991**	(million yen) **-5,997**	(million yen) **-115.79**
Revised forecast (B)	-	**-8,131**	**-4,298**	**-5,684**	**-95.36**
Change (B) – (A)	-	**-2,273**	**1,693**	**313**	
% Change (%)	-	-	-	-	
(Ref.) FY2022.1 results	-	**-6,620**	**-4,579**	**-4,677**	**-90.33**

SanBio
Pioneering Regenerative Medicine

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).

SanBio
Pioneering Regenerative Medicine

Progress in Approval Review

SanBio is responding to regulatory authorities in the approval review process to obtain approval as soon as possible

SanBio
Pioneering Regenerative Medicine

Update on Status of Manufacturing and Marketing Approval for SB623 Chronic Traumatic Brain Injury (TBI) Program in Japan

Tokyo, Japan and Mountain View Calif. – July 22, 2022 –Japan's Ministry of Health, Labour, and Welfare (MHLW) on July 20 announced that the Regenerative Medicine Subcommittee (lower panel of Pharmaceutical Affairs and Food Sanitation Council) meeting will be held on August 3. SanBio's SB623, currently undergoing review in the Sakigake Designation System for the treatment of traumatic brain injury, is not included in the topic of deliberations. SanBio's corporate policy is to refrain from setting or disclosing a target timing for approval, as there are many factors outside of the company's control. We do recognize that, based on public perceptions regarding the Sakigake Designation System, there may be expectations for a September approval among patients and family members as well as shareholders and investors. Had SB623 been included in the meeting agenda, a September approval was a possibility. We now believe that a September approval is unlikely. We pledge to work diligently as one team to facilitate the review of this truly innovative product to ensure the swiftest possible regulatory approval and achieve SanBio's first to market. We take this opportunity to reassure all stakeholders that work continues steadily to ensure that not a day is wasted in bringing approval to reality.

Looking Ahead After SB623 Approval

Progress in establishing a domestic sales structure: Completed setting up an internal compliance system for providing appropriate information in sales activities

- ✓ Prepare a sales structure in compliance with expected approval criteria (post-marketing surveillance and a system for promoting appropriate use)
- ✓ Establish a system for prompt post-launch delivery of SB623 to TBI patients 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
Establishment of sales structure	For SB623 transplantation and post-procedure rehabilitation, begin work to establish the concept of *SanBio Smart Community Healthcare Collaboration* that enables patient follow-up tailored to each region, from the perspective of promoting appropriate use
	Set up a CRM system to ensure and promote post-approval activities to provide appropriate information
Establishment of logistics system	Obtained a patent for R-SAT® system; preparing to install and utilize the system after the launch of SB623
	In discussions with each wholesaler on details for establishment of a distribution scheme that takes into account situations of each region
Preparation of materials for provision of information	Preparing various contents, including print materials and videos, for healthcare providers for post-approval promotion of appropriate use and provision of information
	Create web contents and materials on SB623 and target diseases to provide to patients
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, reporting to regulatory authorities, and risk management

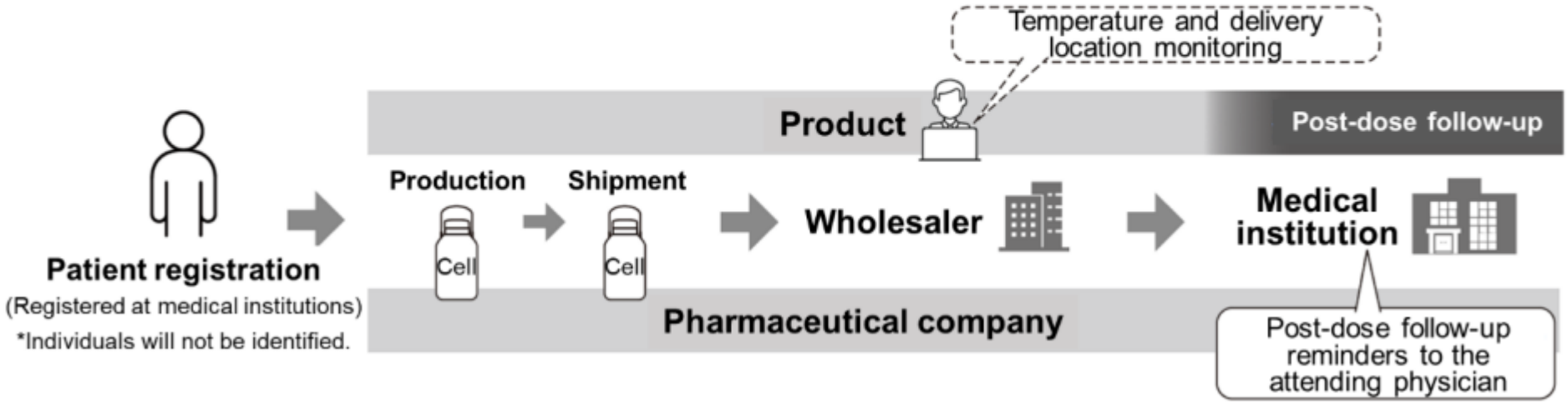
Patent granted for R-SAT®

Summary of patent acquired:
-Management system and method for regenerative medicine products (Patent No.7061762)
-Management system for regenerative medicine products that enables more reliable quality assurance and accurate control in manufacturing and distribution processes

Date of patent acquisition:
-April 21, 2022

Distribution Management and Administration Schedule Support of Regenerative Medicine Products Using R-SAT®

Image



SanBio
Pioneering Regenerative Medicine

3. Toward Maximizing Corporate Value

STEMTRA TRIAL - Final Analysis Results Presented

The Clinical Trials Plenary Session of the Annual Meeting of American Academy of Neurology (AAN2022).

Date: April 2nd to April 7th

Venue: Seattle, Washington

Presenter: Dr. Peter McAllister,

Medical Director & Chief Medical Officer,

New England Institute for Neurology and Headache

Presentation topic: 48-week efficacy and safety data from the STEMTRA study

Outline of the STEMTRA Trial

- A Phase 2 clinical trial conducted globally in Japan and the United States. A randomized, double-blind, surgical sham--controlled, multicenter, global Phase 2 clinical trial to evaluate the efficacy of intracranial administration of SB623 cells in patients with chronic motor deficits secondary to traumatic brain injury (TBI).
- Statistically significant improvement from baseline motor status at 24 weeks after SB623 treatment (primary endpoint) compared to controls (Neurology 2021）

*The American Academy of Neurology (AAN） supports and represents more than 38,000 neurologists and neuroscience professionals worldwide.

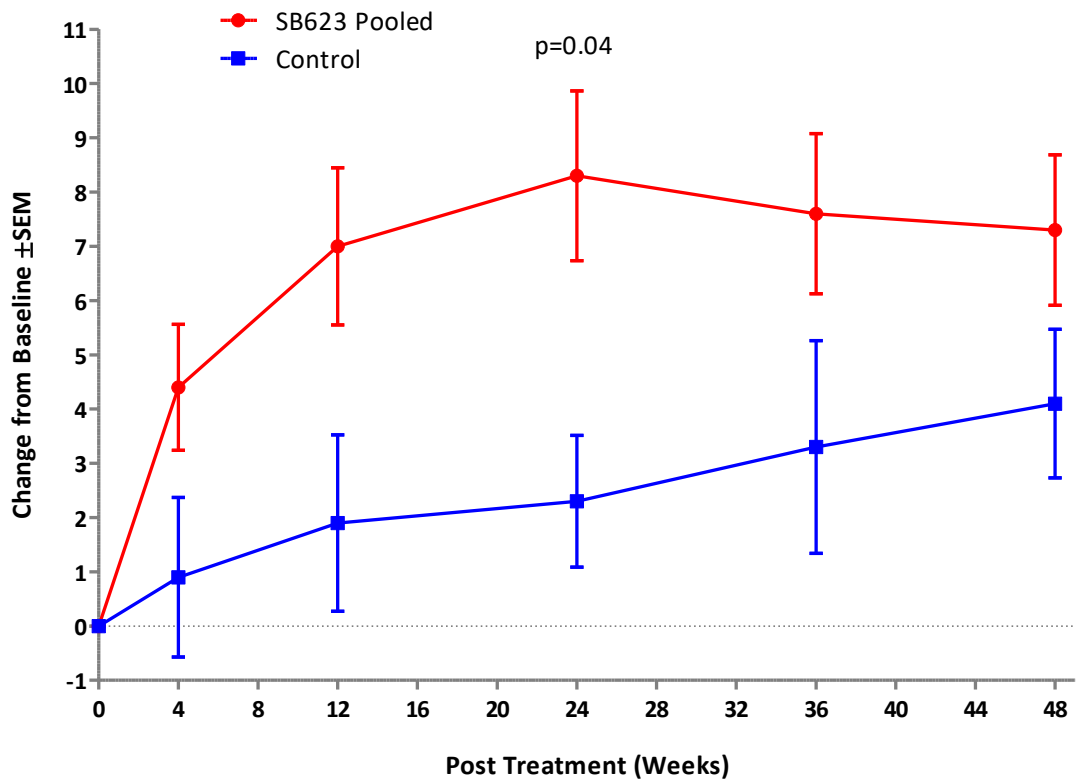
SanBio
Pioneering Regenerative Medicine

STEMTRA: Fugl-Meyer Motor Scale (FMMS)

- **Primary efficacy endpoint was achieved**
- Change of FMMS score from baseline was significantly higher for SB623-treated compared to control patients at 24 weeks
- Least square mean (SE) at 24 weeks:

  8.3 (1.4) vs. 2.3 (2.5), p=0.04
- Change of FMMS score from baseline was not significantly different for SB623-treated compared to control patients at 4, 12, 36, and 48 weeks
- Least square mean (SE) at 48 weeks:

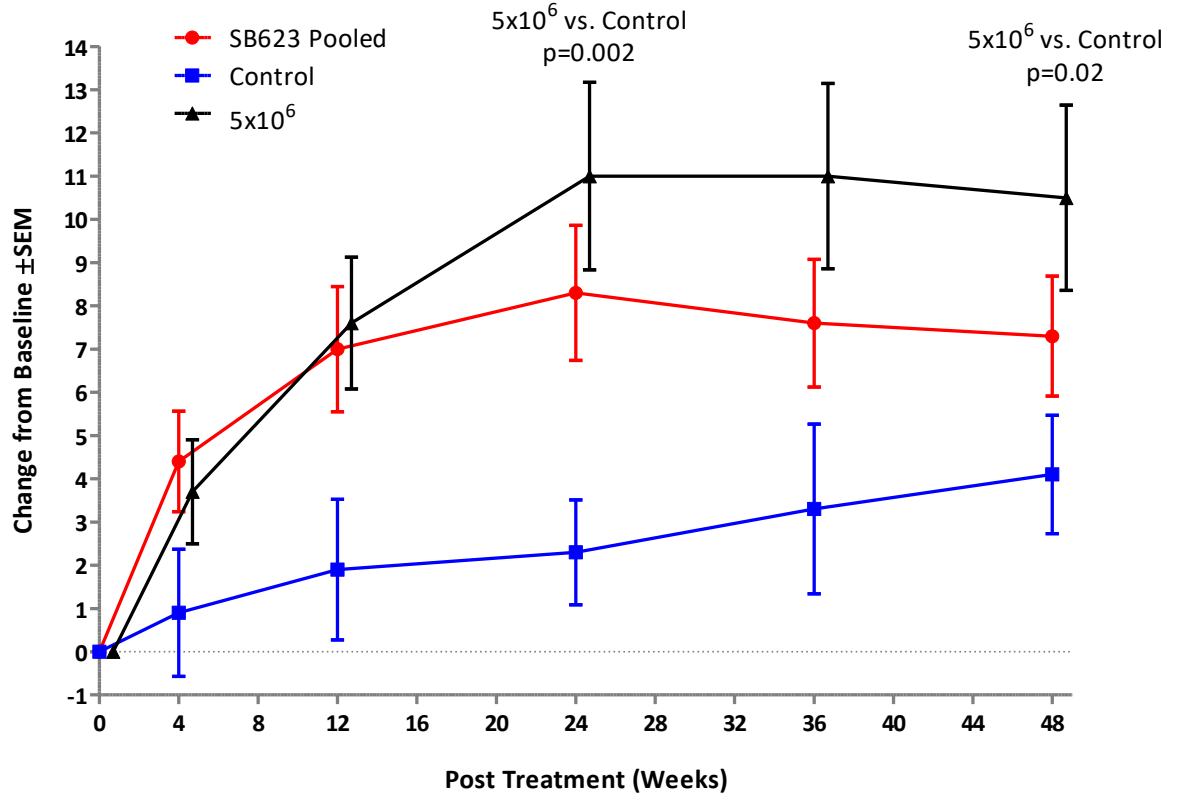
  7.5 (1.3) vs. 4.1 (2.2), p=0.20
- Change of FMMS score from baseline was significant for SB623-treated but not control patients at 48 weeks



SanBio
Pioneering Regenerative Medicine

STEMTRA: FMMS 5x10^6 vs. Control at 24 and 48 Weeks

- Change of FMMS score from baseline was significantly higher for the 5x10^6 SB623 group (n=15) compared to control patients at 24 weeks (p=0.002) and 48 weeks (p=0.02)
- 5x10^6 SB623 dose will be the focus for future clinical development



STEMTRA Study: Presentations on Final Analysis Results at Academic Conferences

A*STAR Advances in Cell and Gene Therapy (A*CGT) Symposium

Date: May 11–12 Venue: Online

Presenter: Masahito Kawabori, M.D. (Department of Neurosurgery, Hokkaido University Hospital)

Title: Safety and Clinical Outcomes of Implanted Modified Bone Marrow-Derived Mesenchymal Stem Cells (SB623) in Patients with Chronic Motor Deficits from Traumatic Brain Injury

The 59th Annual Meeting of the Japanese Association of Rehabilitation Medicine

Date: June 23–25 Venue : Yokohama

Presenter: Yasuaki Karasawa, M.D. (Department of Neurosurgery, University of Tokyo Hospital)

Title: Phase II STEMTRA Study: Results of Implanted Allogenic Bone Marrow-Derived Mesenchymal Stem Cells (SB623) in Patients with Chronic Motor Deficit Associated with TBI

The 39th Annual Symposium of the National Neurotrauma Society

Date: June 26–29 Venue: Atlanta, Georgia, USA

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

Title: One-Year Efficacy and Safety Outcomes in Patients with Chronic Traumatic Brain Injury: Final Analysis of the Phase 2 STEMTRA Trial

Paper Published on Data Indicating New Potential for SB623

Transplantation of encapsulated SB623 cells demonstrated therapeutic effects in rat models of acute ischemic stroke

Journal: CNS Neuroscience & Therapeutics

Title of paper: Transplantation of modified human bone marrow-derived stromal cells affords therapeutic effects on cerebral ischemia in rats

Date published: August 25, 2022
URL: https://onlinelibrary.wiley.com/doi/10.1111/cns.13947

Overview: Modified neurological severity score (mNSS) and histological analyses were performed in rat models of acute ischemic stroke in control group, empty capsule group, SB623 group, and encapsulated SB623 group.

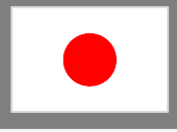
Results: Statistically significant improvement in mNSS was observed in SB623 and encapsulated SB623 groups compared to other groups. Histological analysis found that the infraction area in SB623 and encapsulated SB623 groups was reduced. In encapsulated SB623 group, increased cell viability and neurogenesis were observed in the subventricular zone, and the increase was statistically significantly greater compared to other groups.

Observation: SB623 with or without encapsulation demonstrated therapeutic effects on ischemic stroke. Encapsulated SB623 showed greater levels of neurogenesis and increased viability inside the capsules. The study revealed that the secretory function of transplanted SB623 cells, and not their cell-cell interactions, was the key mechanism mediating their therapeutic effects on ischemic stroke.

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

SanBio
Pioneering Regenerative Medicine

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.

SanBio
Pioneering Regenerative Medicine

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.

SanBio cautions you that actual results may differ substantially from those discussed in this material due to various factors. We do not guarantee the accuracy or completeness of the information herein. Unless otherwise stated, estimates or forecasts are solely those of our company and subject to change without notice. We accept no liability whatsoever for any direct or consequential loss arising from any use of this report.

SanBio Company Limited
Management Administration
Contact: info@sanbio.jp


SanBio
Pioneering Regenerative Medicine