Financial Results
for the Fiscal Year Ending January 31, 2022

SanBio Company Limited

(TSE Mothers: 4592)

March 11, 2022

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1. Financial Results

Consolidated Income Statement

R&D expenses rose on increased spending related to manufacturing toward approval filing of SB623 chronic TBI program in Japan.

Million Yen	FY2021.1 Results (A)	FY2022.1 Results (B)	(B)-(A)	FY2022.1 Forecast
Revenue	-	-	-	-
R&D expenses	4,071	4,955	**884**	3,820
Operating expenses	5,801	6,618	**817**	5,786
Operating income	-5,801	-6,618	**-817**	-5,786
Net income	-3,385	-4,675	**-1,290**	-5,877
Yen/US$ exchange rate	106.34	110.73	-	110.00

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Consolidated Balance Sheet

Cash & cash equivalents and net assets declined. Began procuring funds in February 2022 to fortify financial base in light of future business development.

Million yen		As of January 31, 2021 (A)	As of January 31, 2022 (B)	(B)-(A)
	Cash & cash equivalents	12,480	4,557	-7,923
	Supplies	444	467	23
Current assets		13,131	5,351	-7,780
Non-current assets		211	159	-52
Total assets		13,343	5,510	-7,833
Current liabilities		2,469	1,461	-1,008
Non-current liabilities		2,525	2,012	-513
Total liabilities		4,994	3,473	-1,521
Net assets		8,349	2,037	-6,312
Total liabilities and net assets		13,343	5,510	-7,833

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Consolidated Earnings Forecast

Expects operating expenses to remain flat YoY in FY2023.1, and will prepare to obtain approval for SB623 chronic TBI program in Japan and launch the product.

Million yen	FY2022.1 Results	FY2023.1 Forecast
Revenue	-	(※)
R&D expenses	4,955	4,088
Operating expenses	6,618	5,858
Operating income	-6,618	-5,858
Net income	-4,675	-5,997
Yen/US$ exchange rate	110.73	115.00

（※）As of March 11, 2022, the NHI drug price which will be determined after the manufacture and marketing approval of the Company's regenerative medicine product SB623 for the chronic traumatic brain injury in Japan (hereinafter referred to as the "Approval") is not yet determined. For this reason, operating revenue related to SB623 is not reflected in the above financial results forecast. The Company will consider disclosing operating revenue and other data after the date of the drug price is determined. The financial results forecast figures in this document were estimated on the basis of projections until the Approval. The Company plans to revise these forecast figures to reflect its post-approval business plans once being sure that the Approval will be granted.

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2. SB623 Approval in Japan and Sales Structure After Approval

Completed Approval Filing for SB623 Chronic TBI Program in Japan
(March 7, 2022 Press Release)

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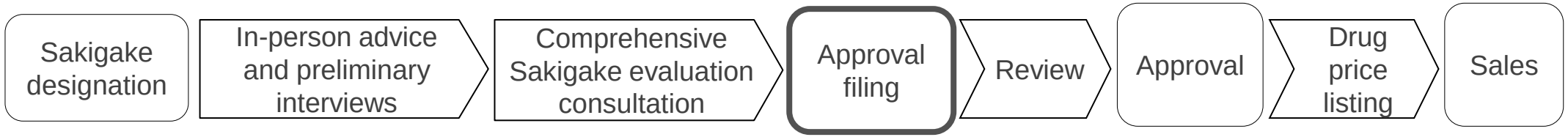
Notice regarding completion of approval filing for Japan SB623 chronic TBI program

Tokyo, Japan and Mountain View, Calif. – March 7, 2022 - The SanBio Group (SanBio Co., Ltd. of Tokyo, Japan, SanBio, Inc. of Mountain View, California, US, and SanBio Asia Pte. Ltd. of Singapore) (TSE:4592), hereby announces the completion of an application filing today with Japan's Ministry of Health, Labour, and Welfare (MHLW) for manufacture and marketing approval as a regenerative medicine product for the investigational product SB623, as a treatment for chronic motor deficit from traumatic brain injury (TBI).

This application for approval is based on efficacy and safety results from the US-Japan global Phase 2 clinical trial (Study of Modified Stem Cells in Traumatic Brain Injury, or STEMTRA). STEMTRA is a randomized, double-blind, surgical sham-controlled trial evaluating the efficacy and safety of SB623 in patients with chronic motor deficits secondary to traumatic brain injury. In this study, SB623 met its primary endpoint, with patients treated with SB623 achieving statistically significant improvement in motor function compared with sham surgery. The trial also demonstrated that SB623 was generally safe and well tolerated.

Completed Filing for Approval in Japan

Filed for approval within the framework of the Sakigake Designation System



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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Looking Ahead After SB623 Approval

Preparation status of sales structure in Japan

- ✓ Prepare a sales structure in accordance with expected approval criteria (post-marketing surveillance and a system for promoting appropriate use)
- ✓ Intends to build a sales structure to promptly deliver SB623 to TBI patients after launch in collaboration with various external stakeholders

	Current status
Pricing	Collecting detailed information and creating a dossier to negotiate and acquire the appropriate price of SB623
Review medical fees	Identify issues and explore solutions to get appropriate medical fees for SB623 cell preparation and surgical procedures when administering the product
Build sales structure	Formulate strategies to establish a structure for promoting appropriate use of SB623 depending on patient follow-up procedures of each region, taking into account treatment and postoperative rehabilitation status of TBI patients
	Build a CRM system to secure appropriate promotional activities post approval
Build logistics system	Prepare to adopt R-SAT® system post launch
	Establish a logistics scheme in consideration of conditions of each region
Create promotional materials	Prepare promotional materials such as brochures and video clips for healthcare providers to promote the appropriate use of SB623
	Create online content and materials of SB623 for patients receiving the product
Build system for appropriate use	Draft personnel and facility criteria to promote appropriate use
	Build a system for determining patient eligibility using ICT
	Build a system for collecting safety data post launch, for reporting to the regulatory agency, and for risk management

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3. Toward Maximizing Corporate Value

Comparative Data on Assessment Metrics for Patients with Chronic TBI Published

(Nov 1, 2021 Press Release,)

Expert Review of Neurotherapeutics (Volume 21, Issue 9)

Metrics defining the success of clinical trials in TBI in the chronic phase and the amount of change have not been established.

↓

Establish triangulated minimally clinically important differences (MCIDs) for the Disability Rating Scale (DRS) and Fugl-Meyer Motor Scales (FMMS) in traumatic brain injury patients with chronic motor dysfunction.

↓

To be able to scientifically assess the amount of clinically meaningful change in functional outcome (DRS) and motor impairment (FMMS) secondary to TBI

■ Establishing MCIDs

Three methods were used: Delphi panel (CMRO 2020), GRPC used as anchor, and distribution-based (STEMTRA trial).

- DRS: Improvement of 1.5 points
- FMMS Total score: Improvement of 8.4 points
- FMMS Upper Extremity Score: Improvement of 6.2 points
- FMMS lower extremity score: Improvement of 3.2 points

Table 2. MCIDs for DRS, FM-UE, FM-LE, and FMMS.

		Distribution-Based MCIDs		Anchor-Based MCIDs						
Outcome Scale	Week	N	MCID (0.5 x SD)	Youden's Index	AUC (95% CI)	Sensitivity	Specificity	MCID	Delphi Panel MCIDs	Triangulated MCIDs
DRS	24	60	−1.4	0.09	0.49 (0.31,0.67)	0.27	0.82	−2	−1	**−1.5**
	48	59	−1.4	0.18	0.53 (0.37,0.69)	0.29	0.89	−2	−1	**−1.5**
FM-UE	24	54	6.5	0.34	0.65 (0.50,0.81)	0.71	0.63	5	6	**5.8**
	48	53	6.5	0.24	0.55 (0.37,0.72)	0.61	0.63	6	6	**6.2**
FM-LE	24	56	2.7	0.26	0.60 (0.43,0.78)	0.71	0.55	2	5	**3.2**
	48	55	2.7	0.21	0.54 (0.38,0.70)	0.79	0.42	1	5	**2.9**
FMMS	24	61	9.1	0.31	0.66 (0.51,0.81)	0.69	0.62	6	10	**8.4**
	48	60	9.2	0.23	0.58 (0.43,0.73)	0.68	0.55	5	10	**8.1**

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STEMTRA TRIAL - Final Analysis Results Scheduled to be 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.

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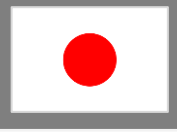
SB623 Development Plans

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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Joined NTRC as a Founding Member
(December 15, 2021 Press Release)

Joined NTRC as a founding member to establish a system for providing support for individuals living with TBI

National TBI Registry Coalition (NTRC) in the US

An organization established for the specific purpose of collaborating with the US government to create a registry (database) for individuals living with TBI in the US. The Coalition consists of multiple nonprofit and corporate organizations. https://nationaltbiregistry.org/

- Only 14 states have some kind of a registry (database) related to TBI
- Some states have developed and manage their own registry

- Surveillance of trends in TBI incidence and prevention
- Provide access to information regarding new therapies and services

Joint Development with OcuMension

In March 2020, SanBio entered into a business partnership with OcuMension of China.

- **SB623 as a treatment for dry age-related macular degeneration and retinitis pigmentosa**
- **MSC2 as a treatment for optic neuritis**

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Enter the Greater China market where there is high unmet medical need in ophthalmology

Joint development rights to SB623 and MSC2

Extensive experience and a high level of specialization in ophthalmology

OcuMension 欧康维视

Expand earnings and acquire new know-hows

Began preclinical studies (in-vivo studies) for the target indication of age-related macular degeneration

Formed a Partnership with D&P Bioinnovations, Inc.

(November 16, 2021 Press Release)

In November 2021, SanBio entered into a business partnership with the US-based D&P Bioinnovations, Inc.

- **Development and commercialization of regenerative esophageal implant, aimed at regenerating esophageal tissues in humans using MSC2**

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Commercialize a regenerative medical device implant for esophageal tissue regeneration

D&P BIO INNOVATIONS
REGENERATING DAMAGED ORGANS

Promote development of regenerative tissue/organ implant platform

License to use MSC2 (non-exclusive, non-transferable)

Commercialization rights in Japan
First negotiation rights for commercialization in other parts of Asia
Royalties on D&P's sales outside Japan

SanBio will bear the expenses for the development of manufacturing processes for MSC2.
D&P will bear the expenses for the development of the regenerative esophageal implant outside Japan.

Becoming a Global Leader in Regenerative Medicine

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

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