Financial Results
for the Fiscal Year Ending January 31, 2024

SanBio Company Limited

(TSE Growth: 4592)

March 19, 2024

SanBio
Pioneering Regenerative Medicine

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1. Financial Results

Consolidated Income Statement

Foreign exchange gains of 1,746 million yen were recorded as non-operating income, resulting in a net loss of 2,644 million yen.
Other than that, the company's performance was generally in line with the forecast at the beginning of the period.

Million Yen	FY2023.1 Results (A)	FY2024.1 Results (B)	(B)-(A)	FY2024.1 Forecast
Revenue	-	-	-	-
R&D expenses	6,118	2,849	▲3,268	3,195
Operating expenses	7,899	4,539	▲3,359	4,642
Operating income	▲7,899	▲4,539	3,359	▲4,642
Net income	▲5,559	▲2,644	2,915	▲4,598
Yen/US$ exchange rate	132.72	141.91	-	138.00

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Consolidated Balance Sheet

Secured working capital for the expenses related to the manufacturing and marketing approval of SB623 Chronic Traumatic Brain Injury Program, and the establishment of manufacturing, logistics, and sales structure in Japan following its launch.

Million yen	As of January 31, 2023 (A)	As of January 31, 2024 (B)	(B)-(A)
Cash & cash equivalents	6,732	4,454	▲2,278
Current assets	6,967	4,937	▲2,029
Non-current assets	77	109	32
Total assets	7,045	5,047	▲1,997
Current liabilities	1,090	905	▲184
Non-current liabilities	1,525	1,349	▲176
Total liabilities	2,616	2,254	▲361
Net assets	4,428	2,792	▲1,636
Total liabilities and net assets	7,045	5,047	▲1,997

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Consolidated Earnings Forecast

Operating expenses of ¥3,339 million are expected mainly for the expenses related to the activities for manufacturing and marketing approval of SB623 Chronic Traumatic Brain Injury Program, and the establishment of manufacturing, logistics, and sales structure in Japan following its launch.

Million yen	FY2024.1 Results	FY2025.1 Forecast
Revenue	-	-
R&D expenses	2,849	2,040
Operating expenses	4,539	3,339
Operating income	▲4,539	▲3,339
Net income	▲2,644	▲3,359
Yen/US$ exchange rate	141.91	148.00

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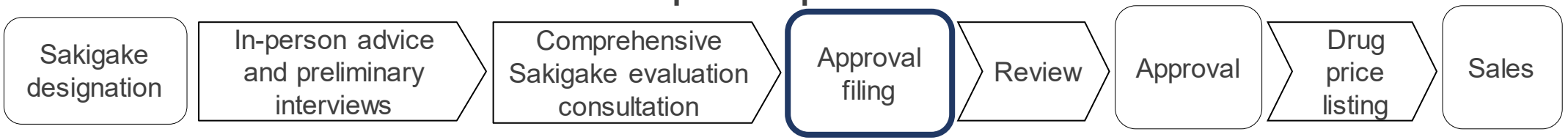
2. SB623 Approval in Japan and Sales Structure After Approval

Completed Filing for Approval in Japan (March 2022)

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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Further Update on Status（released on 18, March）

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March 18, 2024
SanBio Co., Ltd.

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

On January 25, 2024, SanBio Co., Ltd. (the "Company") provided an update on the progress toward obtaining marketing approval of SB623 to treat chronic traumatic brain injury (TBI) in Japan, stating it aims to achieve approval by March 2024 and is actively engaged in the review process.

Today, the Ministry of Health, Labour and Welfare announced that the Pharmaceutical Affairs and Food Sanitation Council's Subcommittee on Regenerative Medicine Products (the "Subcommittee") will hold a meeting on March 25, and we learned that SB623, our development regenerative medicine product "AKUUGO suspension for intracranial implantation," is included in the agenda for the meeting. When the approval of a product is deliberated in the Subcommittee, the agenda usually includes the phrase "regarding the approval or disapproval of the manufacturing and marketing authorization." However, this phrase is not included in the current agenda. Moreover, the outcome of the deliberations will not be known until after the Subcommittee meeting on March 25. Therefore, the Company requests your cautious handling of today's announcement.

Looking Ahead After SB623 Approval

Progress in preparation toward the launch of SB623

- ✓ Preparation of the sales structure in accordance with the conditions of approval
- ✓ 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	Consider 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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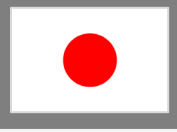
3. Toward Maximizing Corporate Value

SB623 Development Plans

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

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