Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2024

SanBio Company Limited

(TSE Growth: 4592)

September 15, 2023

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Pioneering Regenerative Medicine

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1. Financial Results

Consolidated Income Statement

Operating expenses were ¥3,084 million, mainly consisting of manufacturing-related costs incurred toward approval of SB623 chronic TBI program

Million Yen	Q2 FY2023.1 Results(A)	Q2 FY2024.1 Results (B)	(B)-(A)
Revenue	-	-	-
R&D expenses	3,620	2,112	▲1,508
Operating expenses	4,621	3,084	▲1,536
Operating income	▲4,621	▲3,084	1536
Net income	▲2,154	▲1,787	367
Yen/US$ exchange rate	126.54	136.67	-

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Consolidated Balance Sheet

Maintain a certain level of cash necessary for obtaining the approval in the fiscal year ending January 31, 2024.

Million yen	As of January 31, 2023(A)	As of July 31, 2023(B)	(B)-(A)
Cash & cash equivalents	6,732	4,624	▲2,108
Current assets	6,967	4,798	▲2,168
Non-current assets	77	76	▲1
Total assets	7,045	4,875	▲2,170
Current liabilities	1,090	1,325	▲235
Non-current liabilities	1,525	1,320	▲205
Total liabilities	2,616	2,646	29
Net assets	4,428	2,229	▲2,199
Total liabilities and net assets	7,045	4,875	▲2,170

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Differences between Consolidated Earnings Forecast and Actual Results for the First Half of FY2024.1

Operating loss increased due to manufacturing-related costs incurred toward approval of SB623 chronic TBI program, also due to expenses for restructuring including personnel reduction at the US subsidiary SanBio, Inc.

	Operating revenue	Operating income	Ordinary income	Net income attributable to owners of parent	Net income per share
Previous forecast（A）(released March 16, 2023)	–	(million yen) ▲2,398	(million yen) ▲2,341	(million yen) ▲2,344	(yen) ▲36.85
Actual results（B）	–	▲3,084	▲1,930	▲1,787	▲27.59
Change（B）-（A）	–	▲686	411	557	
% Change（%）	–	–	–	–	
(Ref.) Q2 FY2023.1 results	–	▲4,621	▲774	▲2,154	▲39.26

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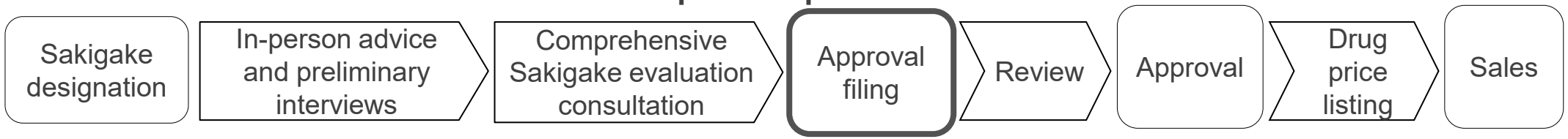
2. SB623 Approval in Japan and Sales Structure After Approval

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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Progress in Approval Review

SanBio confirmed improvement in the yield in the most recent production run and continues to aim to obtain approval by the end of this fiscal year.

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August 31, 2023
SanBio Co., Ltd.

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

On June 14, 2023, SanBio Co., Ltd. (the "Company") provided an update on the progress of its Japan-based SB623 development program for the treatment of chronic effects of traumatic brain injury (TBI), stating that it was focused on resolving issues related to the production yield (smaller yield compared with the time of application filing) and cooperating with regulatory authorities in production-related reviews. The Company also announced that it expected to be able to determine whether the yield issues can be resolved by August 2023, based on the results of the production process employing measures designed to address the issues. The Company hereby provides another progress update, to ensure timely disclosure to concerned patients and their families, as well as shareholders and investors who await the approval of SB623.

SB623 is undergoing approval review under the framework of the Sakigake Designation System as a treatment for chronic effects associated with TBI. Toward obtaining approval,

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

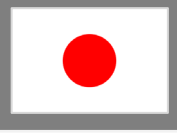
	Current status
Drug price	Gathering information, drafting strategies, and preparing application materials for listing on the NHI drug price list at an appropriate price
Medical treatment fees	Identify possible issues and solutions to set appropriate medical treatment fees for cell preparation and surgical 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

3. Toward Maximizing Corporate Value

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

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