SanBio
Pioneering Regenerative Medicine

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

September 16, 2021

SanBio Company Limited

(TSE Mothers: 4592)

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1. Financial Results

Consolidated Income Statement

R&D expenses increased due to higher manufacturing-related expenses in preparation for approval filing of SB623 for chronic effects of traumatic brain injury (TBI program)

Unit: Million yen	Q2 FY2021.1 Results (A)	Q2 FY2022.1 Results (B)	(B)-(A)	FY2022.1 Forecast
Revenue	-	-	-	-
R&D expenses	1,798	2,251	+453	3,820
Operating expenses	2,570	3,052	+482	5,786
Operating income	-2,570	-3,052	-482	-5,786
Net income	-3,207	-2,134	+1,073	-5,877
Yen/USD exchange rate	108.45	108.79	-	110.00

Consolidated Balance Sheet

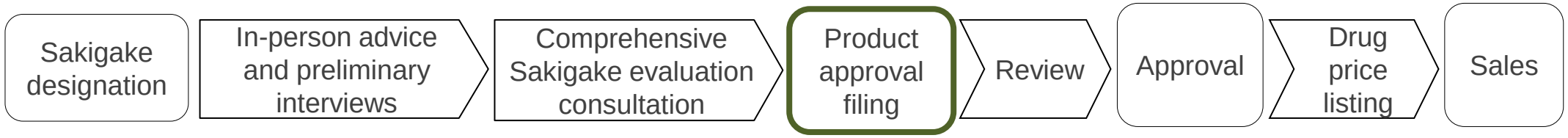
Despite declines in cash & cash equivalents and in net assets, SanBio maintained a stable financial position

Unit: Million yen	As of January 31, 2021 (A)	As of July 31, 2021 (B)	(B)-(A)
Cash & cash equivalents	12,480	8,794	-3,686
Supplies	444	453	+9
Current assets	13,131	9,515	-3,616
Non-current assets	211	193	-18
Total assets	13,343	9,709	-3,634
Current liabilities	2,468	1,857	-611
Non-current liabilities	2,525	2,300	-225
Total liabilities	4,993	4,157	-836
Total net assets	8,349	5,552	-2,797
Total liabilities and net assets	13,343	9,709	-3,634

2. SB623 Approval in Japan and Subsequent Developments

Toward Filing for Japan Product Approval

Discussions are underway with authorities 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

Product 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, but the method to be used is currently undetermined

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).

Consultations Underway with Authorities for SB623 under the Sakigake System

Priority handling of Sakigake-designated products* and points to note

*Pharmaceuticals, medical devices, in-vitro diagnostic products, regenerative medicine products

Priority consultation (two months→one month)

Sakigake-designated products can receive priority consultation, including in-person advice, from PMDA, with higher priority compared to other (non-designated) pharmaceuticals, medical devices, in-vitro diagnostic products, and regenerative medicine products.

Enhanced prior assessment (essentially a review before approval filing)

Sakigake-designated products are expected to proactively utilize the Sakigake System prior to filing for approval, to shorten the time between approval filing and approval. In principle, sponsors or developers of designated products are expected to consult concierges (see below) and use all consultation categories available under the Sakigake comprehensive evaluation provided by PMDA, from the time the products were granted the designation until approval filing.
Note that if prior assessment under the Sakigake comprehensive evaluation is inadequate (including cases in which data necessary for assessment were insufficient or actions taken to address or resolve issues raised by PMDA were inadequate), the time it takes from approval filing till approval may individually be determined based on assessment status of designated pharmaceuticals, medical devices, etc.

Priority review (12 months→six months)

Sakigake-designated products receive priority review as they are considered to “fulfill particularly high medical needs” as provided in Article 23-2-5, Paragraph 10 and Article 23-25, Paragraph 7 of the Pharmaceuticals and Medical Devices Act.

Review partner system (PMDA’s concierge)

A person nominated by PMDA as deemed appropriate for coordinating communication with MHLW and PMDA will consult on the development progress management of designated products, and will coordinate with the sponsors/developers of designated products and reviewing authorities.

Source: MHLW homepage

Note: With the 2019 revision of the Pharmaceuticals and Medical Devices Act, the Sakigake System (initially implemented as a pilot program) has been enacted into law.

Products Approved under the Sakigake Designation System

- MHLW calls for applications for Sakigake designation, and grants designation upon review and assessment of submitted products. Since the program's launch in 2015, calls for applications were made annually*1, and as of June 2021, 52 products were granted Sakigake designation.
- As of June 2021, all 17 products*2 that had filed for approval had been approved.
- Including SB623, 12 regenerative medicine products were granted the designation, and as of June 15, 2021, two had been approved under the framework of the Sakigake System (Nipro Corp.'s Stemirac and Dainichi Sankyo's Delytact).

	Designated products	No information provided	Information provided				
				Approval filing unconfirmed *3*4	Cancelled	Approval application filed	Of which, approved
Total (pharmaceuticals, medical devices, in-vitro diagnostic products, regenerative medicine products)	52	13	39	17	5	17	17
Of which, regenerative medicine products	12	1	11	9	0	2	2

Source: SanBio, based on disclosed materials of MHLW, PMDA (homepage), and companies of designated products

*1: Sakigake System, initially implemented as a pilot program, was enacted into law with the 2019 revision of the Pharmaceuticals and Medical Devices Act.
*2: Does not include AVXS-001 (product name: Zolgensma), for which approval application had been filed and approval obtained (March 2020) without using the Sakigake System in effect, despite the product having received the designation.
*3: Products for which expected approval filing dates are disclosed on respective company websites, but whether approval application had been filed could not be confirmed.
*4: AVX-001, for which approval application had been filed without using the Sakigake System in effect, is included in the "Approval filing unconfirmed" category.

Status of sales infrastructure development

- Preparations are underway to establish a sales infrastructure complying with expected approval requirements (post-marketing surveillance and promotion of appropriate use).
- In collaboration with various external stakeholders, , SanBio is establishing a sales infrastructure to promptly identify and support TBI patients after launch.

	Current status
Pricing	Prepare detailed materials to negotiate appropriate drug prices
Medical fees	Address issues to establish medical fees for surgical procedures for injecting SB623 and cell preparation procedures
Build a sales infrastructure	Devise strategies to promote appropriate use by region with a focus on patient follow-up (based on actual treatment situations)
	Establish a CRM system to promote appropriate use
Establish a distribution system	Prepare to adopt R-SAT® system after launch (including the specifics)
	Establish a distribution scheme for each region
Create promotional materials	Create materials and video content to provide necessary information after launch
	Create online content for products and diseases
Develop a system for appropriate use	Draft personnel and facility requirements to promote appropriate use
	Select a vendor to develop a system for determining patient eligibility using ICT
	Create various materials necessary for post-launch promotion of appropriate use

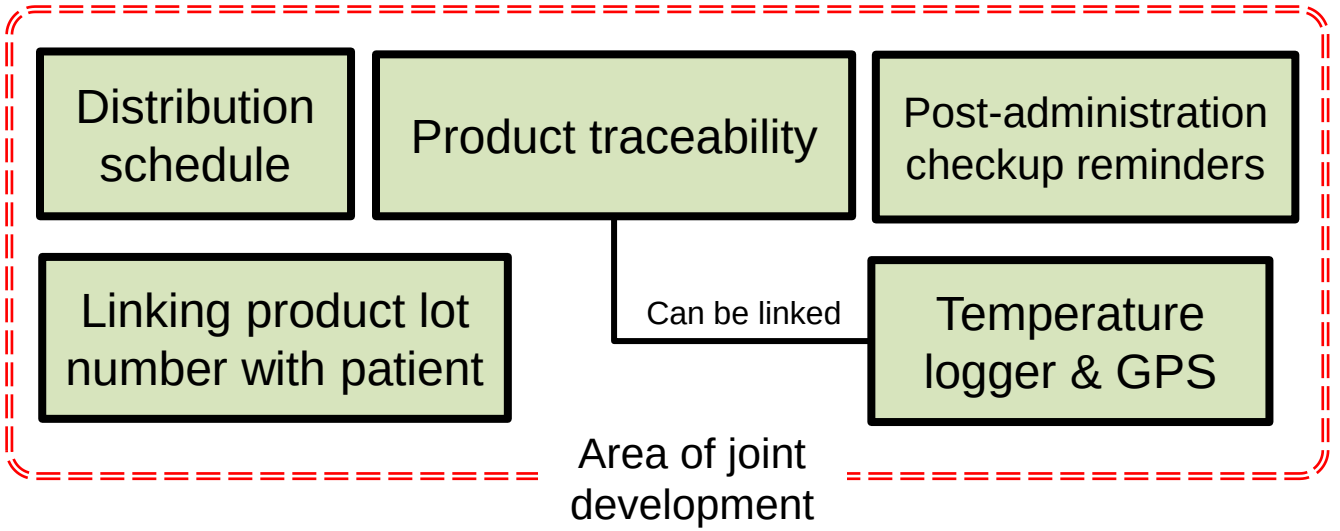
Progress in Establishing R-SAT® System

As of September 2021*

- Trademark registered for R-SAT in August 2020
- Joint patent application by Suzuken and SanBio pending (management system for regenerative medicine products, and management method for regenerative medicine products)

R-SAT®
Distribution management system for regenerative medicine products

Regenerative Medicine
Safety
Accuracy
Traceability

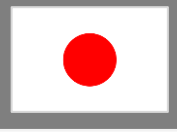


*In August 2019, SanBio concluded a basic agreement with Suzuken for commercial distribution of regenerative medicine products, and began joint development of R-SAT.

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)	**Preparing for approval filing**	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

Development Status

Cell medicine	Indication		Research	Nonclinical	Phase 1	Phase 2	Phase 3
SB623 Chronic brain injury	**Traumatic brain injury (TBI)**	**Japan**	→	→	→	→	
		U.S.	→	→	→	→	
	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	Muscular dystrophy		→				
MSC1	Cancer		→				
MSC2	Inflammatory disease		→	→			
	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.

Becoming a Global Leader in Regenerative Medicine

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

3. Q&A

Disclaimer

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