Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2026

SanBio Company Limited

(TSE Growth: 4592)

September 18, 2025

SanBio
Pioneering Regenerative Medicine

Table of Contents

1. Financial Results for the Second Quarter of the Fiscal Year Ending January 31, 2026

Financial Highlights: Consolidated Statements of Income

■ **The primary component was expenses related to activities for obtaining a partial change approval of AKUUGO®, resulting in total operating expenses of 1,888 million yen.**

Million Yen	FY2025.1 Q2 Results(A)	FY2026.1 Q2 Results(B)	(B)-(A)
Revenue	-	-	-
R&D expenses	1,024	1,346	322
Operating expenses	1,571	1,888	316
Operating income	▲1,571	▲1,888	▲316
Net income	▲1,309	▲1,997	▲688
Yen/US$ exchange rate	154.16	146.96	

Financial Highlights: Consolidated Balance Sheets

■ **Maintain a prudent level of Cash & cash equivalents to meet foreseeable short- to medium-term needs.**

Million yen	As of January 31, 2025(A)	As of July 31, 2025(B)	(B)-(A)
Cash & cash equivalents	2,921	2,738	▲183
Current assets	3,335	3,111	▲223
Non-current assets	111	107	▲4
Total assets	3,447	3,219	▲228
Current liabilities	732	493	▲238
Non-current liabilities	952	1,431	479
Total liabilities	1,684	1,925	240
Net assets	1,762	1,294	▲468
Total liabilities and net assets	3,447	3,219	▲228

Revision of Consolidated Earnings Forecast

■ **The primary change is an increase in manufacturing-related expenses to secure inventory of AKUUGO® at an earlier stage**

Million yen	FY2026.1 Forecast(Old)	FY2026.1 Forecast(New)
Revenue	-	-
R&D expenses	2,405	2,795
Operating expenses	3,509	3,920
Operating income	▲3,509	▲3,920
Net income	▲3,554	▲4,045
Yen/US$ exchange rate	155.00	148.00

2. Progress in the First Half Year

About “AKUUGO® suspension for intracranial implantation”

- **World’s First Therapeutic Agent for Regenerating Brain**
- **Obtained conditional and time-limited approval from the MHLW on July 31, 2024.**

ヒト体性幹細胞加工製品　薬価基準未収載

アクーゴ® 脳内移植用注

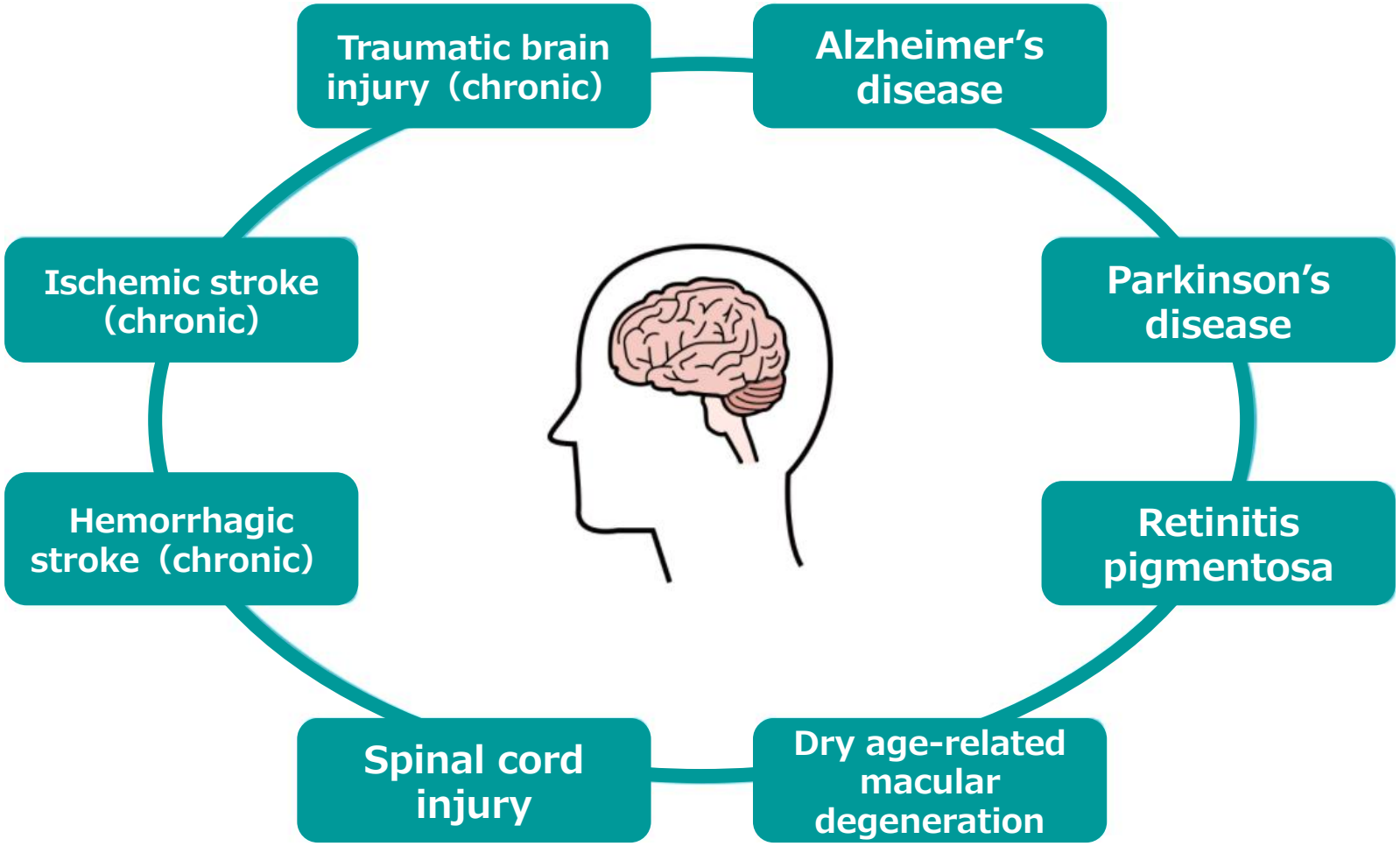
バンデフィテムセル　指定再生医療等製品

(hereafter referred to as “AKUUGO®”)

Brand name	AKUUGO® Suspension for Intracranial Implantation
Generic name	Vandefitemcel
Indications and effects	Improvement of chronic motor paralysis associated with traumatic brain injury
Dosage and administration	For adults, implant 5 x10^6 live human (allogeneic) bone marrow-derived mesenchymal stem cells (300μL of cell suspension) to perilesional brain tissues via stereotactic brain surgery using the dedicated delivery device set. Implant the cells into the perilesional area through three trajectories via a burr hole made in the skull. To each trajectory, inject 100μL of the cell suspension, depositing 20μL of the solution each across a total of five sites placed at 5–6mm intervals from the deepest site. The rate of implantation should be approximately 10μL/min. Follow the steps below for implantation. 1. Before starting the procedure, attach the guide & stop and stylet-equipped inserter from the dedicated delivery device set to the head fixation device for invasive neurosurgery. 2. Thaw the cell suspension for intracranial implantation, wash it with the dedicated preparation solution, and adjust the concentration of the cell suspension to 1.67 x 10^6 cells/100μL using the dedicated preparation solution. Cleanse the micro-syringe fixed with the cannula from the dedicated delivery device set with the dedicated preparation solution before filling it with the prepared cell suspension.
Date of marketing approval	July 31, 2024

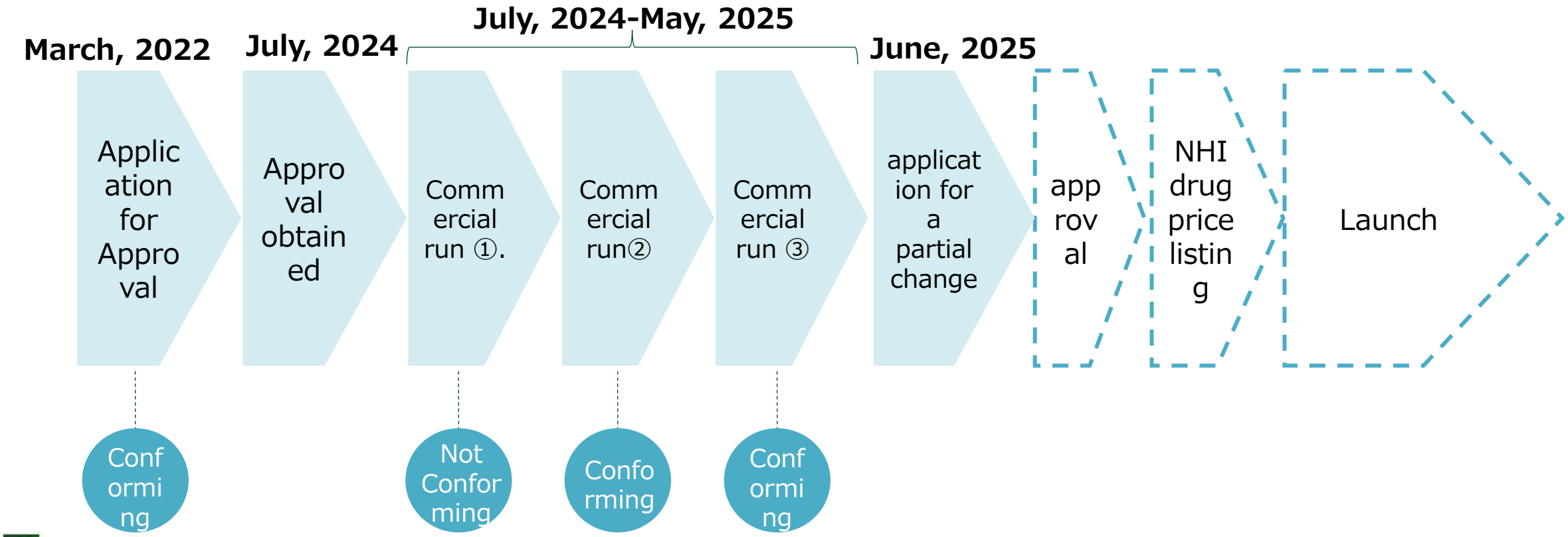
Promising pipeline of AKUUGO®, “Brain Regeneration” Therapeutics

Focus on diseases of the central nervous system that cannot be addressed by existing medical and pharmaceutical products



Current Status of AKUUGO®

- The third manufacturing run cleared all specification requirements and was deemed compliant
- Completed filing a partial change application of marketing approval of AKUUGO®
- Assumed the approval expected in the second half of the fiscal year ending January 2026 (August2025–January 2026)



Development Progress of SB623

■ **Reached an agreement with the FDA on the Phase 3 trial design for TBI in the United States.**

			
Traumatic brain injury (TBI)	**Conditional and time-limited approval**	**Reached an agreement with the FDA on the Phase 3 trial design**	Discussion on the timing of the start of clinical trials
Ischemic stroke	Plan to discuss with PMDA to start clinical trials	Preparing to start clinical trials	Discussion on the timing of the start of clinical trials
Hemorrhagic stroke	Plan to discuss with PMDA to start clinical trials	Discussion on the timing of the start of clinical trials	Discussion on the timing of the start of clinical trials

※ All indications are at the chronic stage.

Conclusion of Committed Credit Line Agreement

- **Following the previous term, we have established commitment lines with multiple banks.**
- **The status of committed credit line agreement at present is as follows**

Bank Name	Total committed amount (of which, used credit)	Agreement date	Expiration date	Remarks
MUFG Bank, Ltd.	1.0 billion yen (- million yen)	Jul. 2025	Feb. 2027	Expenses related to the commercialization of AKUUGO®
Mizuho Bank, Ltd.	1.0 billion yen (- million yen)	Jun. 2025	Nov. 2026	The establishment of manufacture, distribution, and marketing infrastructure for AKUUGO®
Resona Bank, Limited	1.0 billion yen (- million yen)	Mar. 2025	Mar. 2027	The establishment of manufacture, distribution, and marketing infrastructure for AKUUGO® after obtaining approval for partial change

3. Future Outlook: Toward Becoming a Global Leader in Regenerative Medicine

Three Pillars of Growth Strategy

- **Japan as “home base” – starting point for expansion**
- **Restarting US clinical initiatives**
- **Re-engaging in Ischemic Stroke Treatment**

Restarting US clinical initiatives

■ Past achievements in the U.S.

Year	Event
2010	Signed an option agreement with Sumitomo Dainippon Pharma Co., Ltd. for cerebral infarction in the U.S. and Canada
2011～2015	Ischemic stroke*: Phase 1/2a trial in the U.S. (18 cases at 5 sites)
2015	Received milestone proceeds of US$5 million from co-development partner Sumitomo Dainippon Pharma under the option agreement
2016～2018	Ischemic stroke*: Phase 2 trial in the U.S. (163 cases at 65 sites)
2016	Ischemic stroke*: Phase 1/2a Paper Receives “Innovation Award 2016”.
2016～2019	Phase 2b (STEMTRA study) of traumatic brain injury in Japan, US, and Ukraine (21 sites in US, 5 sites in Japan, 1 site in Ukraine, 63 cases)
2017	Received the maximum grant available ($20M) from the California Institute for Regenerative Medicine (CIRM)
2019	Granted RMAT (Regenerative Medicine Advanced Therapy) Designation from the U.S. FDA for SB623
2022	Final Analysis of the STEMTRA Study Presented in Plenary Session at the American Academy of Neurology (AAN) Annual Meeting
2016～2018	Ischemic stroke*: Phase 2 trial in the U.S. (163 cases at 65 sites)

Before treatment, patient unable to raise arm

Patient can now raise arm

Patient able to resume normal activities

(YouTube)

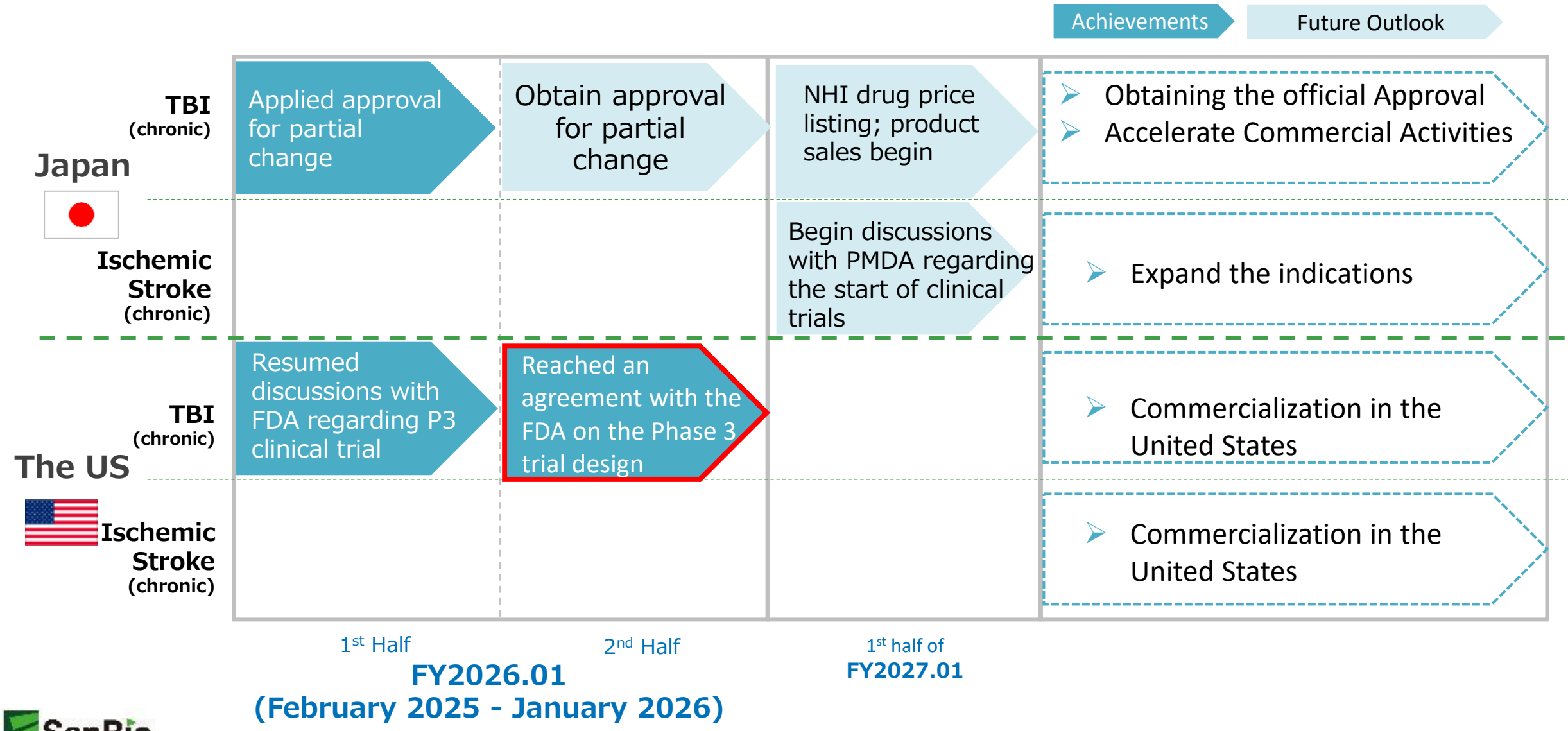
Facilities for the STEMTRA study: 21 facilities

Red - Facility Blue - Multiple facilities (numbers are number of facilities)

Major facilities :
UCLA, Stanford University, University of Pittsburgh, New York University, Northwestern University, etc. (ClinicalTrial.gov)

* Chronic phase

Roadmap for Maximizing Corporate Value



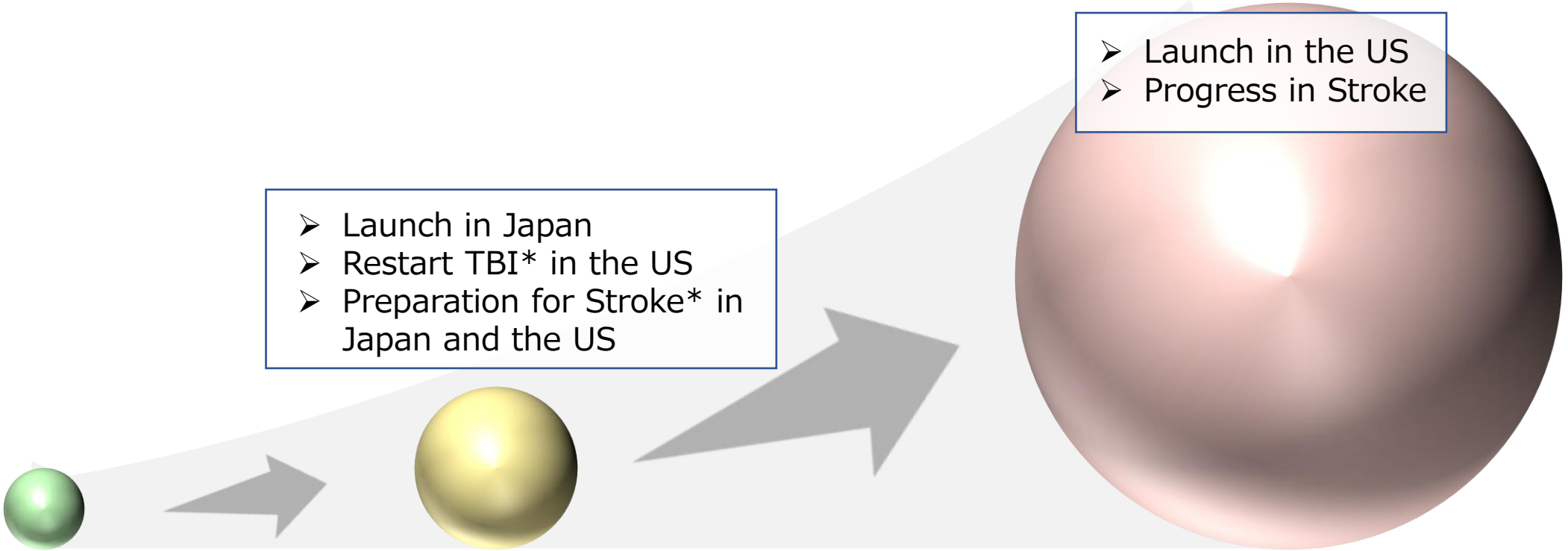
Projected events from this fiscal period to the next

	FY2026.01 (August 2025 - January 2026)	FY2027.01 (February 2026 - July 2026)
Japan	• Obtain approval for partial change (Shipping Release)	• NHI drug price listing; product sales begin of AKUUGO® • Begin discussions with PMDA regarding the start of a clinical trial of chronic Ischemic Stroke
United States	• Agree with FDA on the design of P3 Clinical Trial of chronic TBI	• Preparation for TBI Clinical Trial

Image of Company Growth

- Launch in Japan
- Restart TBI* in the US
- Preparation for Stroke* in Japan and the US

- Launch in the US
- Progress in Stroke



Current

	Region	Area	Total patients
Launch	-	-	-
	-	-	-
Before launch (During development and before shipment)	**Japan**	**TBI**	**60,000**
	-	-	-

Current FY – Next FY

	Region	Area	Total patients
Launch	**Japan**	**TBI**	**60,000**
	-	-	-
Before launch (During development and before shipment)	**US**	**TBI**	**5.51 million**
	Japan・US	**Stroke**	**8.04 million**

4 years later~

	Region	Area	Total patients
Launch	**Japan・US**	**TBI**	**5.57 million**
	Japan・US	**Stroke**	**8.04 million**
Before launch (During development and before shipment)	-	-	-
	-	-	-

SanBio's Vision

Becoming a global leader in regenerative medicine

SanBio Develops Regenerative Medicines, Creating Benefits for Patients and Value for Stakeholders.

Q&A
(For institutional investors and analysts)

Financial Results Briefing for the Fiscal Year Ending January 31, 2026

SanBio Company Limited

(TSE Growth: 4592)

Question and Answer session for the press
is available at
will begin at 5:00 p.m.

Please wait a moment.

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Q&A
(For the press)

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