

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

**SanBio Company Ltd.**

(TSE Growth Market: 4592)

March 25, 2026



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**(To the Media)**

**Event Announcements**

# Introducing Two New Executive Officers



**Corporate Officer,  
Head of Production**

**Tetsuya Isono**

- Engaged in process development and investigational drug manufacturing for biopharmaceutical APIs, contributing to the acquisition of global approvals
- As Plant Manager at a Major Domestic Pharmaceutical Company, established a system for the stable production and supply of biopharmaceuticals
- Strengthened global-standard quality and GMP systems and advanced the enhancement of the supply infrastructure



**Corporate Officer, Head  
of Japan Regulatory  
Affairs & Quality  
Compliance Japan**

**Souyoku Nobeyama**

- Extensive experience in research and development and reliability assurance at several foreign-affiliated pharmaceutical companies
- Oversaw all processes from regulatory submissions to post-marketing surveillance as Head of Regulatory Affairs and Quality Assurance
- Promoted the strengthening of the foundation of quality and safety in preparation for the launch of AKUUGO®

# Introduction

As a regenerative medicine product aimed at “improving chronic motor paralysis associated with traumatic brain injury,” AKUUGO® Suspension for Intracranial Implantation” obtained conditional and time-limited marketing approval in July 2024, and subsequently obtained partial change approval in December 2025 to lift the shipping restrictions.



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

# **1. Financial Results for the FY Ending January 2026 and Forecast for the Current FY**

# Financial Highlights: Consolidated Income Statement

- R&D expenses of 2,678 million yen were recorded, primarily consisting of costs related to activities aimed at obtaining marketing approval for AKUUGO®

Unit: Million yen		Fiscal Year Ended January 2025 Actual (A)	Fiscal Year Ended January 2026 Actual (B)	(B) - (A)
Operating Revenue		-	-	-
	R&D Expenses	2,357	2,678	321
Operating expenses		3,516	3,794	278
Operating Income		▲3,516	▲3,794	▲278
Net Income		▲2,882	▲3,842	▲960
USD exchange rate (JPY)		152.40	149.72	

## Financial Highlights: Consolidated Balance Sheet

- Secured approximately 16.2 billion yen in growth capital through new share issuances

	Unit: million yen	End of January 31, 2025 (A)	End of January 31, 2026 (B)	(B) - (A)
	Cash and equivalents	2,921	15,083	12,162
	Current assets	3,335	15,489	12,154
	Non-current assets	111	131	20
	<b>Total Assets</b>	<b>3,447</b>	<b>15,621</b>	<b>12,174</b>
	Current Liabilities	732	534	▲198
	Non-Current Liabilities	952	1,482	530
	<b>Total Liabilities</b>	<b>1,684</b>	<b>2,016</b>	<b>332</b>
	Net Assets	1,762	13,604	11,842
	<b>Total Liabilities and Net Assets</b>	<b>3,447</b>	<b>15,621</b>	<b>12,174</b>

## Consolidated Financial Forecast

- Operating expenses primarily consist of costs related to the manufacturing, distribution, and sales infrastructure for the promotion of AKUUGO<sup>®</sup>, as well as expenses for activities aimed at obtaining the full approval

Unit: million yen		FY2026.01 Results	FY2027.01 Forecast
Revenue		-	(※)
	R&D expenses	<b>2,795</b>	<b>4,110</b>
	Operating expenses	<b>3,920</b>	<b>5,625</b>
	Operating income	<b>▲3,920</b>	<b>▲5,625</b>
	Net income	<b>▲4,045</b>	<b>▲5,635</b>
	USD/JPY	<b>148.00</b>	<b>150.00</b>

\*Operating revenue for the current fiscal year is scheduled to be announced following the listing of AKUUGO<sup>®</sup> in the national drug price list.

## Three Pillars of Growth Strategy

- **Japan as “home base” –Starting point for expansion**
- **Realization of U.S. Business**
- **Success in Ischemic Stroke Program**



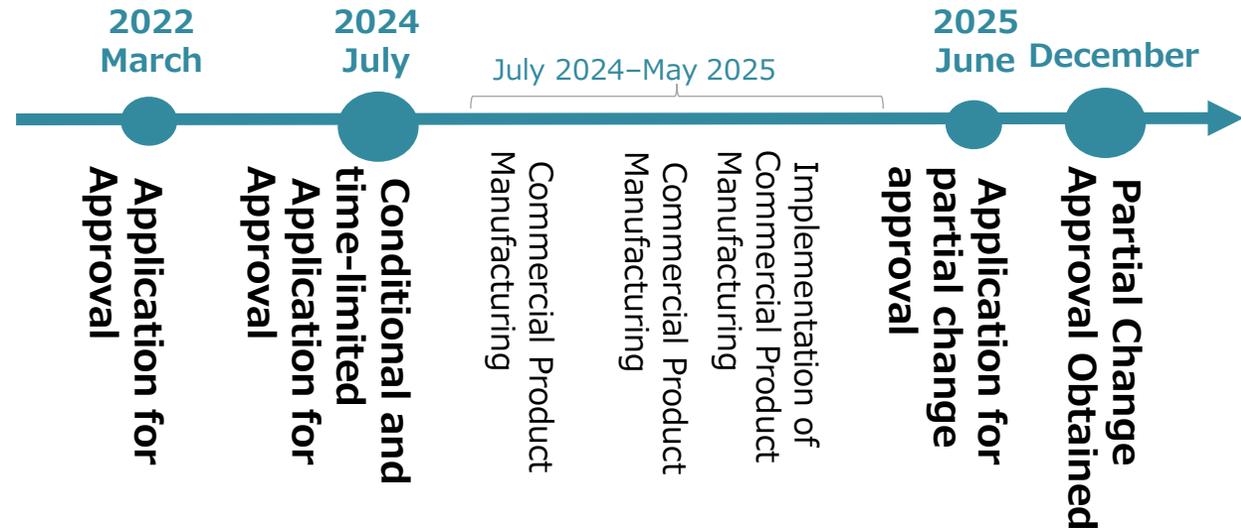
**Becoming a Global  
Leader in  
Regenerative  
Medicine**



## **2. Japan as “home base” –Starting point for expansion**

## World's First "Brain Regeneration" Treatment: AKUUGO® suspension for intracranial implantation

- The world's first therapeutic agent for brain regeneration
- Received conditional and time-limited approval from the MHLW in July 2024
- Partial change approval to the manufacturing and marketing approval completed in December 2025 (i.e., AKUUGO® became available for shipment)



### Future Outlook

NHI price listing and Launch: May 2026  
First shipment: Second half of 2026

# Japan as Hub for Further Growth

## Accumulation of Regenerative Medicine Expertise

- Promoting R&D through the accumulation of high-quality efficacy and safety data



New Lab Begins Operations at "Mitsui Link Lab Shinkiba 3"

- Establishing a Seamless Infrastructure from Cell Therapy Drug Manufacturing to Distribution and Administration to Patients
- Promoting the Appropriate Use of Regenerative Medicine Products



# Progress of Marketing and Public Relations Activities

- In October 2025, seminars were held at the Japanese Society of Neurosurgery (Yokohama) and the Japanese Society of Rehabilitation Medicine (Asahikawa), with a total of approximately 480 participants
- We are ramping up TBI awareness campaigns and plan to hold several more events for the media in the future



## [Completed]

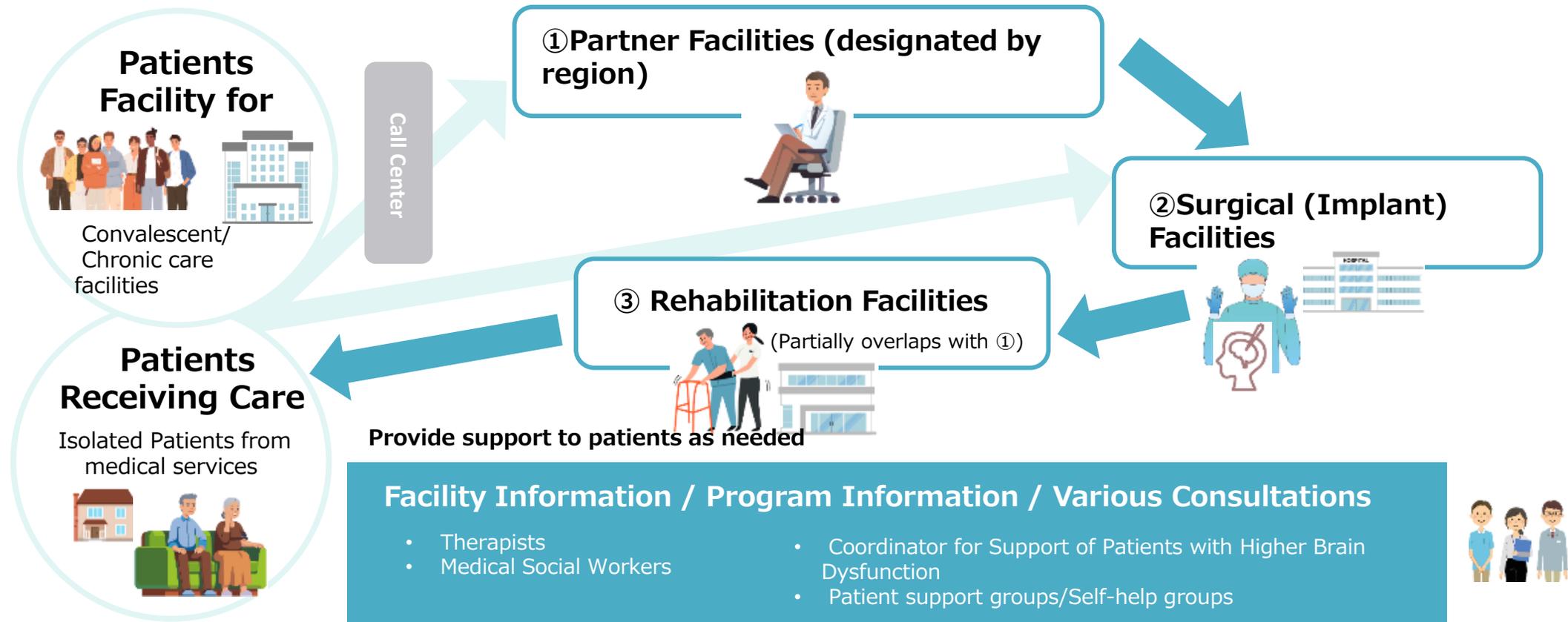
- February 7, 2026 Association of Convalescent Rehabilitation Wards (Yonago)
- February 10, 2026: Issued a media newsletter regarding International TBI Awareness Month
- February 19, 2026: Media roundtable on the Act on Support for Persons with Higher Brain Dysfunction
- February 20, 2026: Japanese Society for Traumatic Brain Injury (Nagoya)

## [Upcoming Events]

- **March 19–20, 2026: Japanese Society for Regenerative Medicine (Kobe)**
- **May 2026: Media Seminar on the Launch of AKUUGO® (Tentative)**
- **May 14–19, 2026: Japanese Congress of Neurosurgery (Kyoto)**
- **August 2026: Event for Overseas Key Opinion Leaders Visiting Japan (Tentative)**

# Establishing a system to ensure safe delivery to patients

- We are currently developing a medical information system to enable HCPs to search and receive accurate information about AKUUGO®
- Launch of a patient call center (March 2026)



### **3. Toward Becoming a Global Leader in Regenerative Medicine**

# Track record to date in the US, where the company was founded

Year	Event
2011–2015	Phase 1/2a trial for Ischemic stroke <sup>※</sup> conducted in the U.S. (5 sites, 18 patients)
2016	Phase 1/2a study on Ischemic stroke <sup>※</sup> wins the “Innovation Award 2016”
2016–2018	Conducted a Phase 2 clinical trial for Ischemic stroke <sup>※</sup> in the U.S. (approximately 60 sites, 163 patients)
2016–2019	Phase 2 trial for traumatic brain injury (STEMTRA trial) conducted in the U.S., Japan, and Ukraine (21 centers in the U.S., 5 centers in Japan, 1 center in Ukraine; 63 patients)
2017	Secured the largest grant (\$20 million) from the California Institute for Regenerative Medicine (CIRM)
2019	SB623 Receives Designation as an RMAT (Regenerative Medicine Advanced Therapy) Product from the FDA
2022	Final analysis of the STEMTRA trial presented at a plenary session during the American Academy of Neurology (AAN) Annual Meeting
2024	Positive Results from the STEMTRA trial of SB623 were published in Neurology

\* Chronic phase



Number of facilities administering the STEMTRA exam: 21  
 Red: Single facility; Blue: Multiple facilities (numbers indicate the number of facilities)

Major trial sites  
 UCLA, Stanford University, University of Pittsburgh, New York University, Northwestern University, etc. (Based on ClinicalTrials.gov)

# SB623 Development Progress

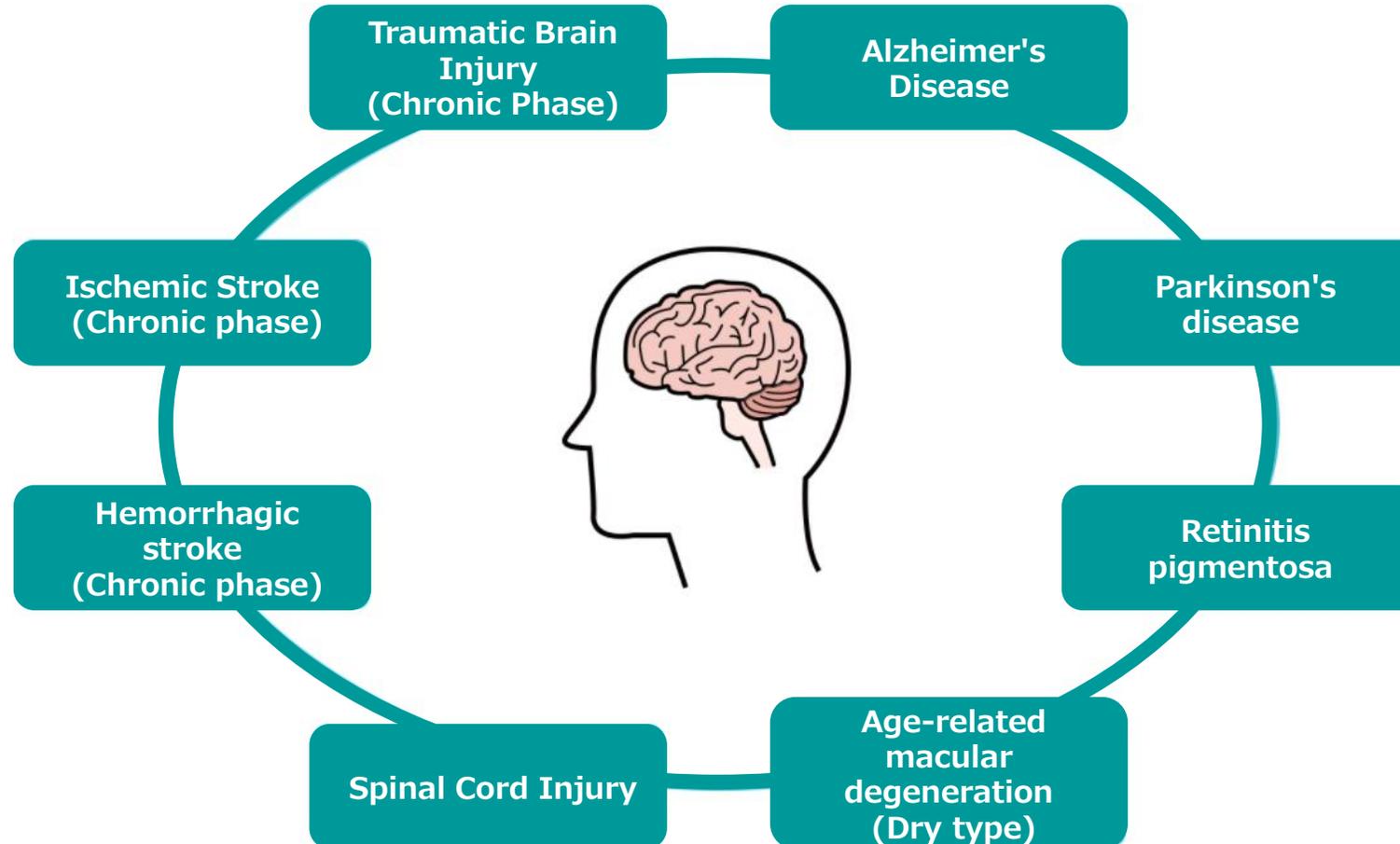
■ Agreement Reached with the FDA on Phase3 Trial Design for TBI in the U.S.

			
<b>Traumatic brain injury (TBI)</b>	Obtained Conditional and time-limited approval	Agreement with the FDA on Trial Design	Discussion on the timing of the start of clinical trials
<b>Ischemic stroke</b>	Plan to discuss with PMDA to start clinical trials	Preparing to start clinical trials	Discussion on the timing of the start of clinical trials
<b>Hemorrhagic stroke</b>	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

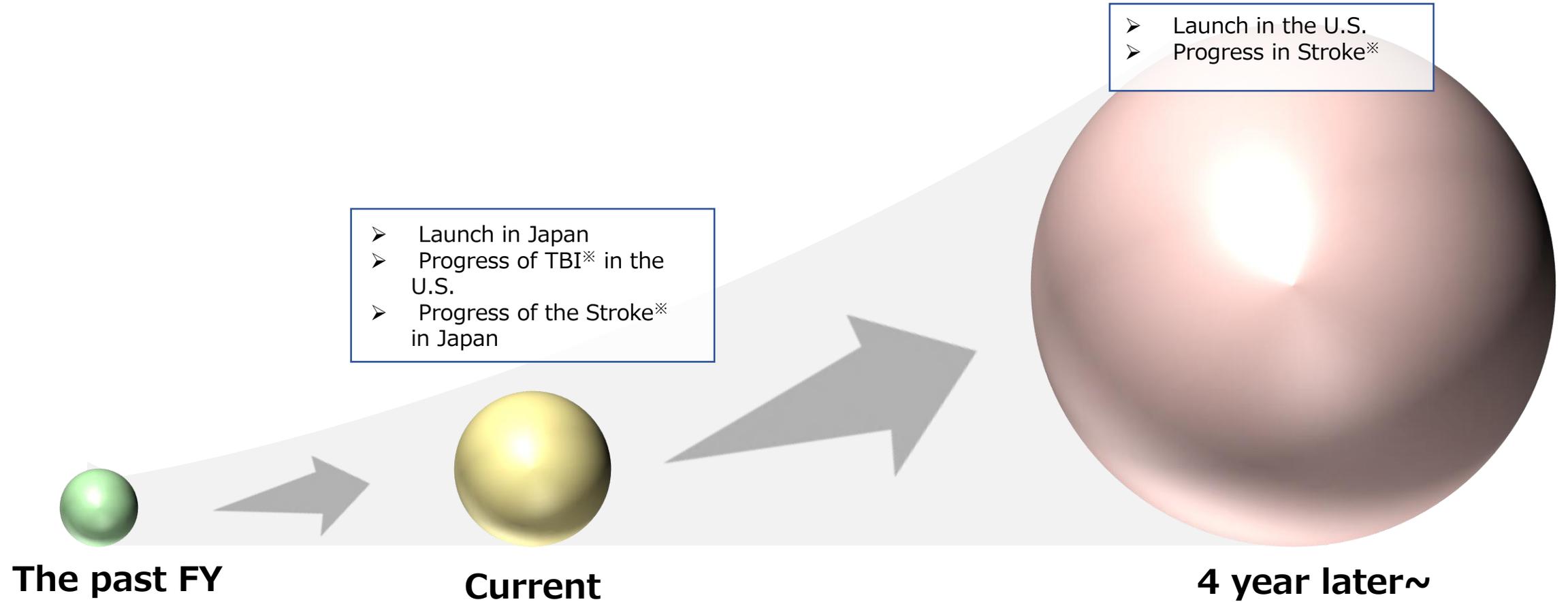
\*All diseases are in the chronic phase

## Prospects for the Ischemic Stroke Program

- A post-hoc analysis of the Phase 2b trial has provided insights for the next clinical trial
- Discussions with the PMDA regarding a clinical trial aimed at adding Ischemic Stroke as an indication are scheduled for this fiscal year



# Image of Corporate Growth



\*Chronic

## 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)

## Notice to the Media

- We are planning to hold the following event in the near future. Further details will be announced at a later date.

### **Launch Seminar of AKUUGO® suspension for intracranial implantation**

**Date: Around May–June 2026**

**Content (Proposed): Presentations by founding scientist Dr. Okano and the principal investigator, followed by an explanation of AKUUGO® by SanBio**

**Format: Hybrid (in-person and online)**

### **Activities Related to the Visit of Overseas KOLs**



**Dr. David O. Okonkwo,  
Professor of  
Neurosurgery**

**Date: Around August 2026**

**Format: To be determined**

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The Q&A session for members of the press  
will begin at 5:00 PM.

Please wait a moment.



# Q&A

(For members of the press)

# Important Notice

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