

---

## Press Release

---

May 13, 2025

Sumitomo Pharma Co., Ltd.

### Sumitomo Pharma Announces Reboot 2027 - Reboot for a Strong Sumitomo Pharma -

Sumitomo Pharma Co., Ltd. (the "Company") passed a resolution at its Board of Directors meeting held on May 13, 2025 to formulate "Reboot 2027 - Reboot for a Strong Sumitomo Pharma -," which outlines the activity policy for FY2025 through FY2027, as detailed below, and to withdraw the Mid-term Business Plan 2027 (FY2023-FY2027) announced in April 2023.

#### **1. Background to the Formulation of "Reboot 2027"**

Under the Mid-term Business Plan 2027, the Company has adopted the basic strategy to "Make a 'qualitative transformation' of the business structure and business practices." The Company has operated business by positioning this period as a time to build a foothold for achieving renewed growth after the loss of exclusivity (LOE) of LATUDA® in the U.S. and for establishing a position as a Global Specialized Player (GSP). Although the Company experienced a significant decline in business performance in FY2023 due to missed key milestones, it has established a growth trend with four products (ORGOVYX®, GEMTESA®, MYFEMBREE®, and RETHYMIC®) acquired through the strategic alliance with Roivant. Combined sales of these four products reached USD1 billion in FY2024. In addition, as part of a fundamental structural reform across Sumitomo Pharma Group (the "Group"), the Company implemented initiatives such as streamlining, selection and concentration, revision of R&D investment strategy, and governance reforms. These efforts and successful refinancing led to strengthen the Company's financial foundation. The Company also undertook business restructuring (formation of both joint ventures for the Asia business and the regenerative medicine/cell therapy business, and the Frontier business transfer), thereby reinforcing strategic investments in growth areas. As a result of these initiatives carried out in FY2023 and FY2024, the Company achieved a V-shaped recovery in business performance. The Company believes that the period from FY2025 to FY2027 represents a critical phase marked by key milestones toward rebuilding a "value creation cycle," including revenue base stabilization through the sales growth of three key products and the commercialization of products in the fields of regenerative medicine/cell therapy and oncology. To this end, the Company has formulated "Reboot 2027 - Reboot for a Strong Sumitomo Pharma -" as the activity policy for FY2025 through FY2027, aiming for a resurgence as an R&D-driven pharmaceutical company.

#### **2. Financial Targets under "Reboot 2027"**

By FY2027

Sales of three key products	Expand to 250 billion yen
Core operating profit	Consistently more than 25 billion yen, excluding one-time factors

	(from FY2027)
Free cash flow	Maintain profitability (FY2025–FY2027) →Return to profitability excluding sales-related income (FY2027)

As early as possible

Interest-bearing debt	Reduce to less than 200 billion less by implementing further measures
-----------------------	---

With regard to dividend policy, priority will be given to the repayment of interest-bearing debt for the time being and the Company aims to resume dividend payments at an appropriate time.

### 3. Key Initiatives under “Reboot 2027”

The Company will work to establish a P&L base by maximizing the value of existing products, centered on the three key products, and implementing thorough cost management while also maintaining positive free cash flow and securing the next revenue base through strategic selection and concentration within the development pipeline. Furthermore, to restart as an R&D-driven pharmaceutical company, the Company is committed to realizing in-house innovation in the oncology and regenerative medicine/cell therapy fields as a must-achieve goal. In addition, to continuously create and implement innovations in society, efforts will be made to improve the accuracy of success in R&D.

The position the Company aspires to establish by FY2033 is to become a company that strongly turns the “value creation cycle” and continuously translates innovation into real-world solutions focusing on disease fields in oncology, psychiatry & neurology and others, and on modalities such as small molecules and regenerative medicine/cell therapy. By turning the value creation cycle, the Company will strategically deepen and expand these strengths as well as establish a distinctive global presence in order to contribute to the betterment of healthcare and fuller lives of people worldwide.

“Reboot 2027” focuses on the main initiatives for FY2025 through FY2027, and the Company plans to develop a comprehensive growth strategy after confirming the progress of these initiatives.

\*For further details, please refer to the attached presentation materials (an excerpt from the FY2024 Financial Results and Reboot 2027 - Reboot for a Strong Sumitomo Pharma - briefing materials).

Contact:

Corporate Communications, Corporate Governance

Sumitomo Pharma Co., Ltd.

E-mail: [prir@sumitomo-pharma.co.jp](mailto:prir@sumitomo-pharma.co.jp)

# **Reboot 2027**

## **- Reboot for a Strong Sumitomo Pharma -**



# I. Review of FY2023-2024

# 1. Review of FY2023-2024

Insufficient and unsuccessful measures to address the LOE of LATUDA® led to a significant decline in performance in FY2023. Core operating profit and final profit returned to profitability in FY2024 by formulating and implementing fundamental structural reforms

Until FY2023

Measures to address  
LOE of LATUDA®

## LOE of LATUDA®

- ✓ Faster-than-expected generic erosion; sharp decline in sales

## No new drug candidates developed

- ✓ Development of several internal products discontinued. Ulotaront, SEP-4199, napabucasin, alvocidib, DSP-7888, dasotraline, etc.

## Overestimation of the potential of approved products

- ✓ Significant downward forecast revisions and impairment losses. Three key products, KYNMOBI®, Lonhala® Magnair®, TWYMEEG®, etc.

## Delay in adjusting scale and deterioration of PL:

- ✓ Excessive expenses and R&D costs worsened P&L and financials; continued borrowing through parent company guarantees

FY2024

**Expand key product business** (ORGOVYX®, GEMTESA®, and MYFEMBREE®)

**Implement fundamental structural reforms**

Streamlining,  
Selection and  
Concentration

Revision of R&D  
Investment Strategy

Governance  
Reforms

FY2022

Revenue	555.5 B yen
Core operating profit	16.4
FY profit	(96.7)

**Achieved a V-shaped recovery**

FY2024

Revenue	398.8 B yen
Core operating profit	43.2
FY profit	23.6

FY2023

Revenue	314.6 B yen
Core operating profit	(133.0)
FY profit	(314.9)



## 2. Initiatives for FY2023-2024 (PL Management through Fundamental Structural Reforms)

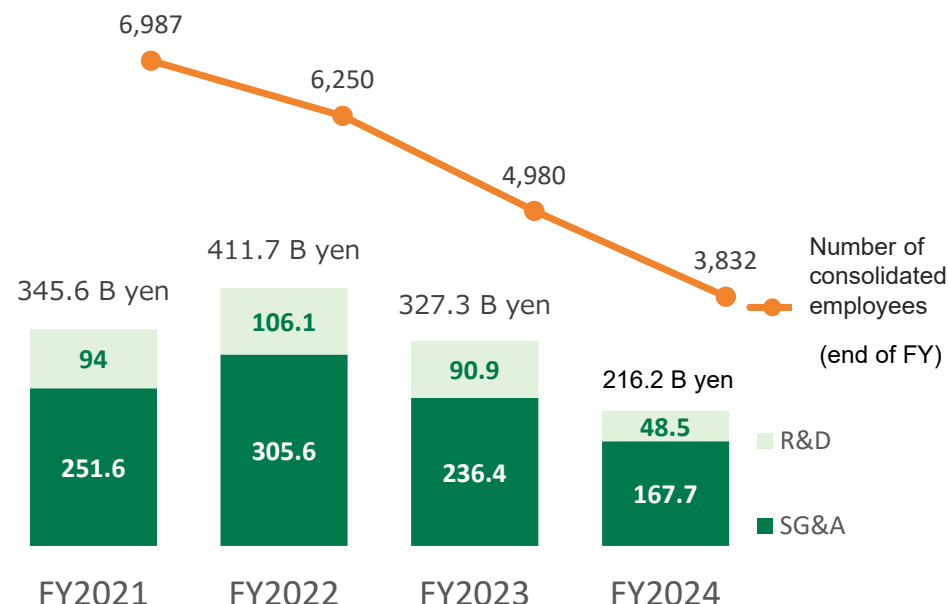
Implemented PL management through significant company-wide cost reductions and revision of R&D investment strategy

### Streamlining, Selection and Concentration

- A) Thorough cost reduction and significant workforce reduction  
Japan\*: -1,200 people (3,000→1,800)  
U.S.: -1,000 people (2,200→1,200)  
End of FY2022 → End of FY2024
- B) R&D spending cap management  
110 billion → 50 billion yen (FY22 → FY24)
- C) Sale of assets and businesses  
Sale of Roivant shares, Asia business joint venture formation, etc. (Total sales amount: 250 billion yen)

### Revision of R&D Investment Strategy

- A) Selection and Concentration of Programs  
Prioritized and reduced programs  
Focused investment in two oncology compounds
- B) Established framework for cooperation with Sumitomo Chemical in the regenerative medicine/cell therapy business  
Reduced our initial costs and acquire greater flexibility in R&D strategy



### Financial impact (FY2022→FY2024)

SG&A expenses reduced by approx. **140** billion yen

R&D expenses reduced by approx. **60** billion yen



## II. Reboot of Sumitomo Pharma

## 1. Reboot 2027

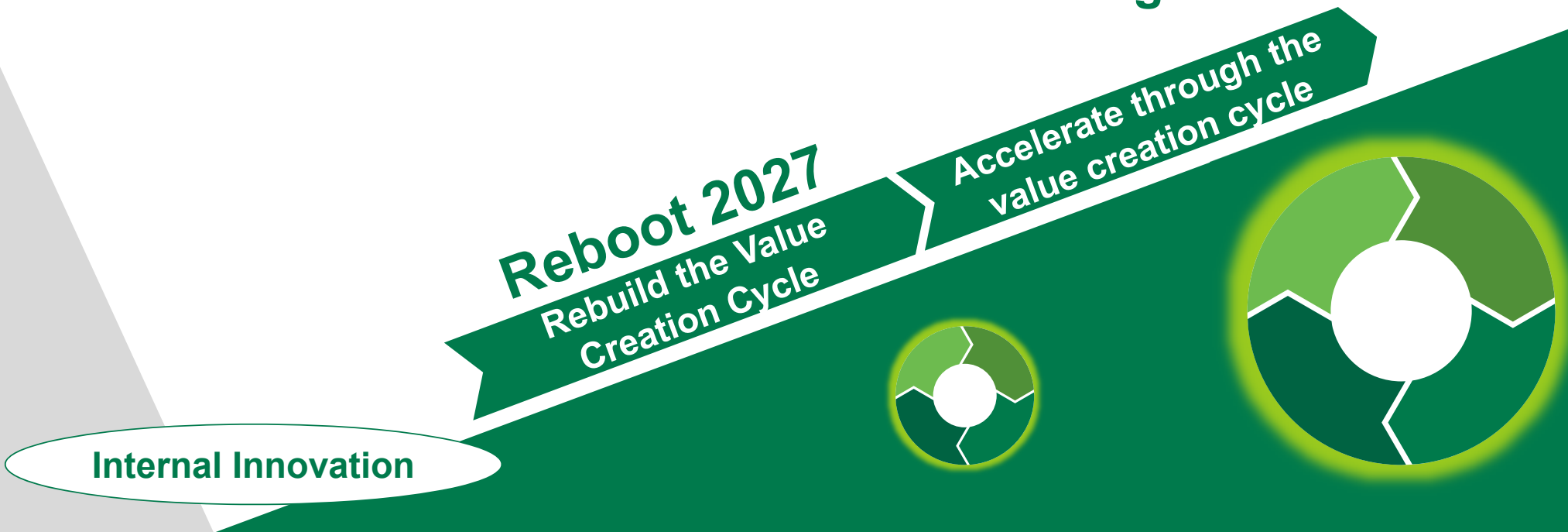
# Reboot for a “Strong Sumitomo Pharma”

Work to strengthen our platform as an R&D-driven pharmaceutical company while continuing with selective, focused investment and governance reforms

Pave the way for revival by rebuilding the Value Creation Cycle based on internal innovation

“Reboot 2027” is an initiative beginning in FY2025

“Strong Sumitomo Pharma”





## 2. Our Vision: Global Specialized Player (GSP)

Continue to create and implement innovations in society by strongly turning the Value Creation Cycle in specific fields and technologies. Establish the “Sumitomo Pharma” brand worldwide by contributing to healthy and fulfilling lives

GSP



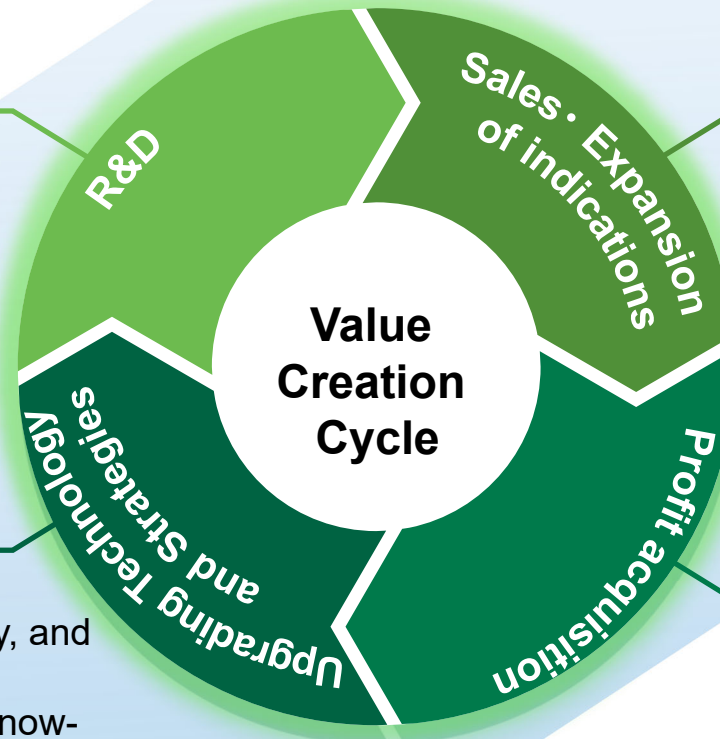
### Continuously create and bring to market innovative drugs

- Competitive drug discovery research focused on our strong areas and technologies
- Early confirmation of value in small clinical trials
- Maximize value quickly by leveraging alliances



### Deepen and expand R&D infrastructure

- Superior access to information, technology, seeds of drug discovery, and human resources
- Feedback of proprietary data and know-how



### Maximize market value and improved patient outcomes

- Deliver to the world, focusing on the U.S. and Japan
- Establish scientific evidence and become a leader in innovative/groundbreaking drug discovery

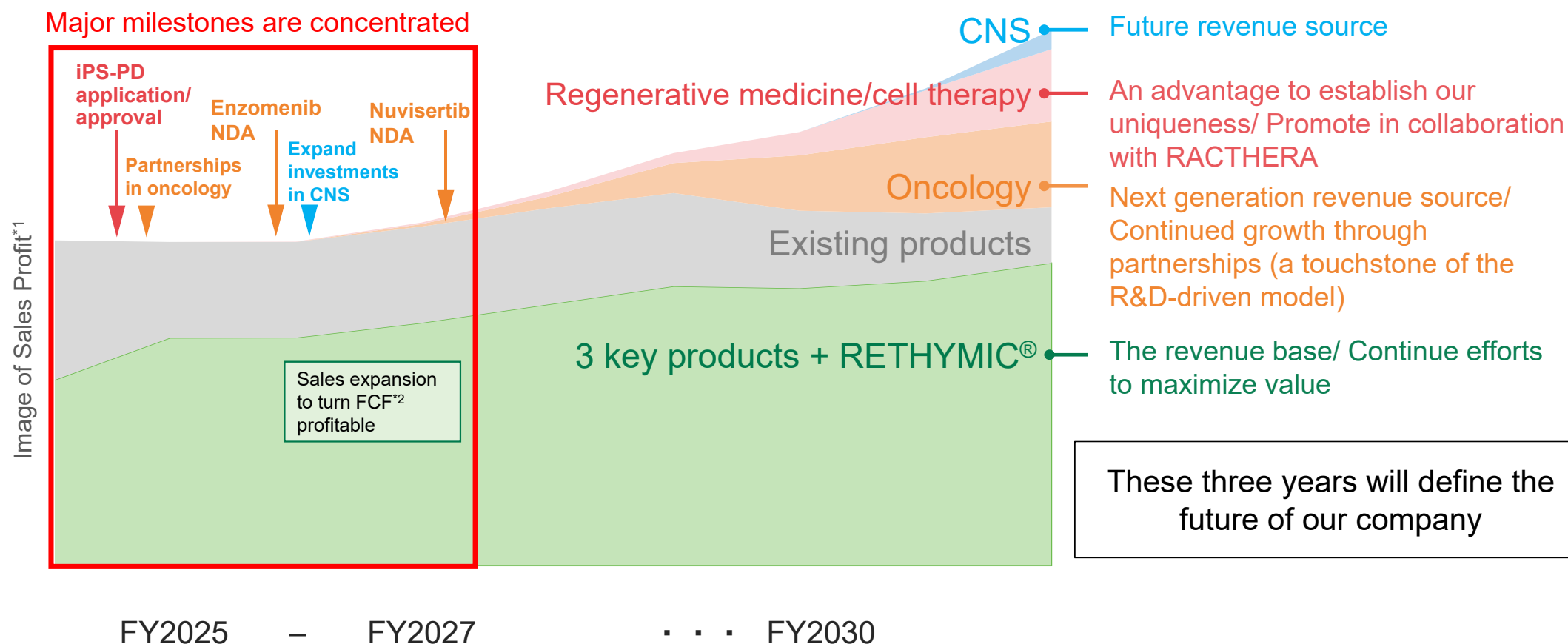


### Continued growth of portfolio brands and expand management resources

- High market share/profit margins
- Accumulate unique data and expertise

### 3. To Rebuild the Value Creation Cycle

Major milestones in the rebuilding of the Value Creation Cycle will be concentrated over the next three years  
The entire company will work together to achieve these milestones through selection and concentration, as well as through external partnerships



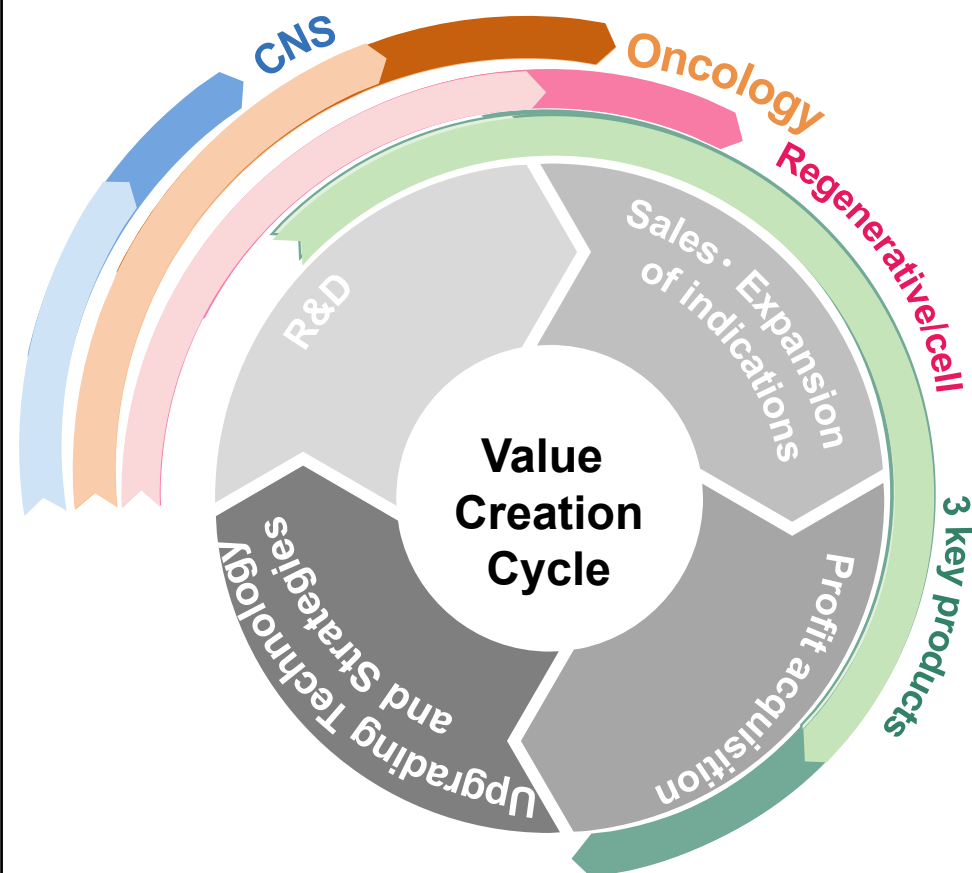
\*1: The graph shows the mid- to long-term revenue and earnings forecast before adjustment for the probability of success

\*2: FCF stands for Free Cash Flow

## 4. Rebuilding the Value Creation Cycle from FY2025 to FY2027

Stabilize the revenue base by expanding the business of the three key products (operating base not dependent on one-time revenues)

Rebuild the Value Creation Cycle by commercializing regenerative medicine/cell therapy and oncology



### Three key products

Establish the Group's revenue base through sales expansion  
Expand to 250 billion yen (FY2027)

### Regenerative medicine/cell therapy

Start the iPS cell-based drug business with the approval and launch of iPS-PD  
Expand the business in collaboration with RACTHERA

### Oncology

Dedicate resources as a top priority and promote the fastest development (by leveraging partnerships)  
enzomenib launch, nuvisertib NDA submission (FY2027)

### CNS

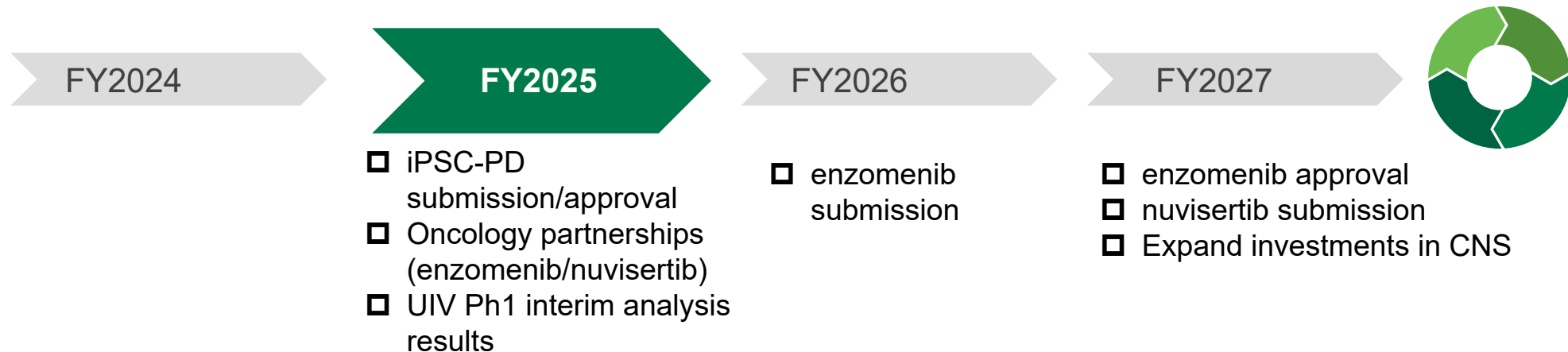
Resume development using accumulated expertise and key technologies  
Expected to become a revenue base after LOE of the three key products

## 5. Milestones for FY2025

Advance the development of two oncology compounds, possibly through partnerships, and submit and obtain approval for iPSC-PD in Japan. FY2025 is the “year to show our true value” as we work to achieve the goals to reinvigorate ourselves as an R&D-driven pharmaceutical company

### The “year to show our true value” as an R&D-driven pharmaceutical company

Rebuild the Value Creation Cycle



Our revival as an R&D-driven pharmaceutical company by achieving the FY2025 milestones

Formulation of comprehensive growth strategy after reviewing the progress of the two oncology compounds

## 6. Financial Targets

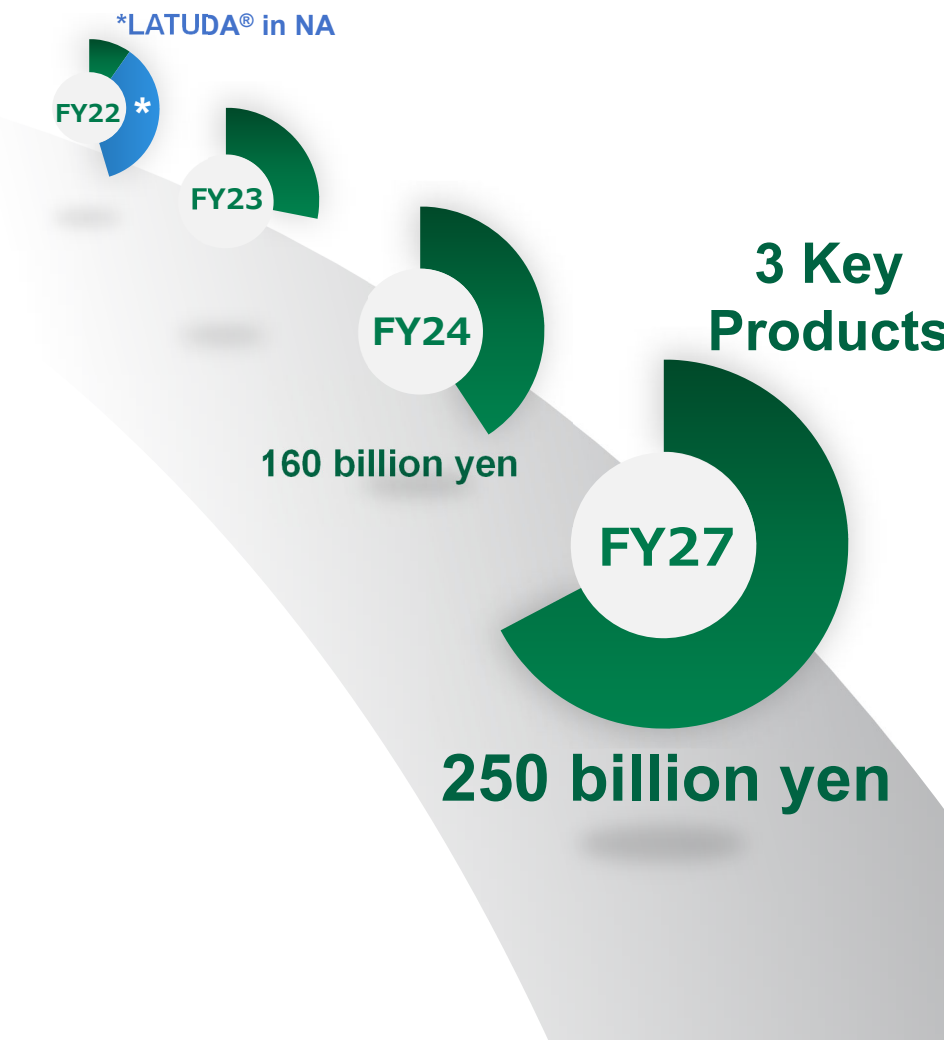
By FY 2027

PL	Sales of 3 key products	Expand to <b>250</b> billion yen*
	Core operating profit	Consistently more than <b>25</b> billion yen, excluding one-time factors (from FY2027)
CF	Free cash flow	Maintain profitability(FY2025-2027) → Return to profitability excluding sales-related income (FY2027)

As early as possible

Interest-bearing debt	Reduce interest-bearing debt to less than 200 billion yen
-----------------------	---

Dividend policy	Prioritize the repayment of interest-bearing debt for the time being and aim to resume dividend payments at an appropriate time
-----------------	---

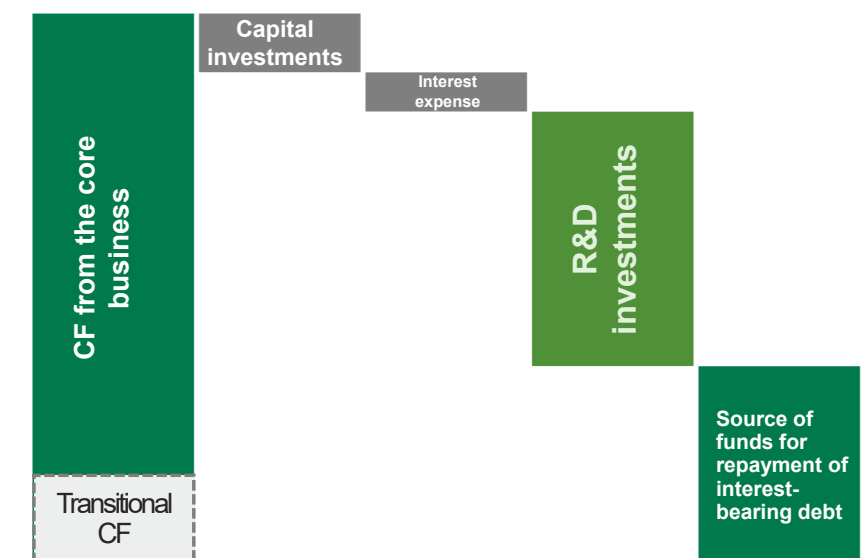


## 6. Financial Targets (2)

The management of interest-bearing debt through FY2027 will depend on the transfer income from the Asia business. Stable free CF from the core business is expected to return to profitability during the period, but key financial events lie ahead

→ Seeking further financial improvement by leveraging external partnerships in the program to return dividends to shareholders and resume strategic investments

**Cash Allocation Chart:  
FY2025-2027 3-year Cumulative Total**



### Financial Issues

#### A) Repayment of interest-bearing debt

In FY2024-2025, repayment will depend only on the sale of assets and businesses. By FY2027, free CF will be stabilized by core business revenues to accelerate repayment

#### B) Response to financial events

In FY2027, in addition to refinancing, the first repayment of subordinated debt (60 billion yen) will be made in September

#### C) Resumption of shareholder returns and strategic investments

Need to return profits to shareholders (resumption of dividends) in response to recovery from the emergency

Shift to a strategy of strengthening the portfolios through strategic investments

### Measures

#### Accelerate growth through program collaboration with strategic partners

Maintain internal programs from a portfolio strategy perspective

Achieve both rapid development and value maximization while reducing cost burdens through partnerships





## III. Business Strategy

# 1. Overview of Business Strategies

Establish a P&L base by maximizing the value of existing products, with a focus on the three key products, and thorough cost management

Maintain free CF and acquire the next revenue base by selection and concentration of the development pipelines



## Maximize the value of existing products

- North America: Maximize sales and product P&L of the **three key products**
- Japan: Contribute steadily to revenue by **expanding sales of existing products + XEPLION®**

## Thorough cost management



## Strengthen the portfolios by selecting internally developed pipelines and pursuing partnering opportunities

- **Focus on the two oncology compounds:** Establish the next revenue base after the three key products
- **Seek partnering opportunities:** Maximize value, develop as quickly as possible, reduce investment capital
- **Collaboration with RACTHERA:** Promote the regenerative medicine/cell therapy business and develop it into the Group's core business

## 2. For the Early Launch of the Two Oncology Products

This will be given a top priority as the flagship program for realizing the R&D-driven pharmaceutical company. Given financial constraints, maximize value by developing the products as quickly as possible through leveraging partnerships



### Promote focused development

- ✓ Prioritized investment in the two oncology compounds
- ✓ A touchstone for the R&D-driven pharmaceutical company



### Maximize value through partnerships

- ✓ Maintain development speed and compete with competitors' products
- ✓ Manage the investment burden



### Achieve early launch

**enzomenib**  
NDA submission in FY2026,  
Launch in FY2027

**nuvisertib**  
NDA submission in FY2027

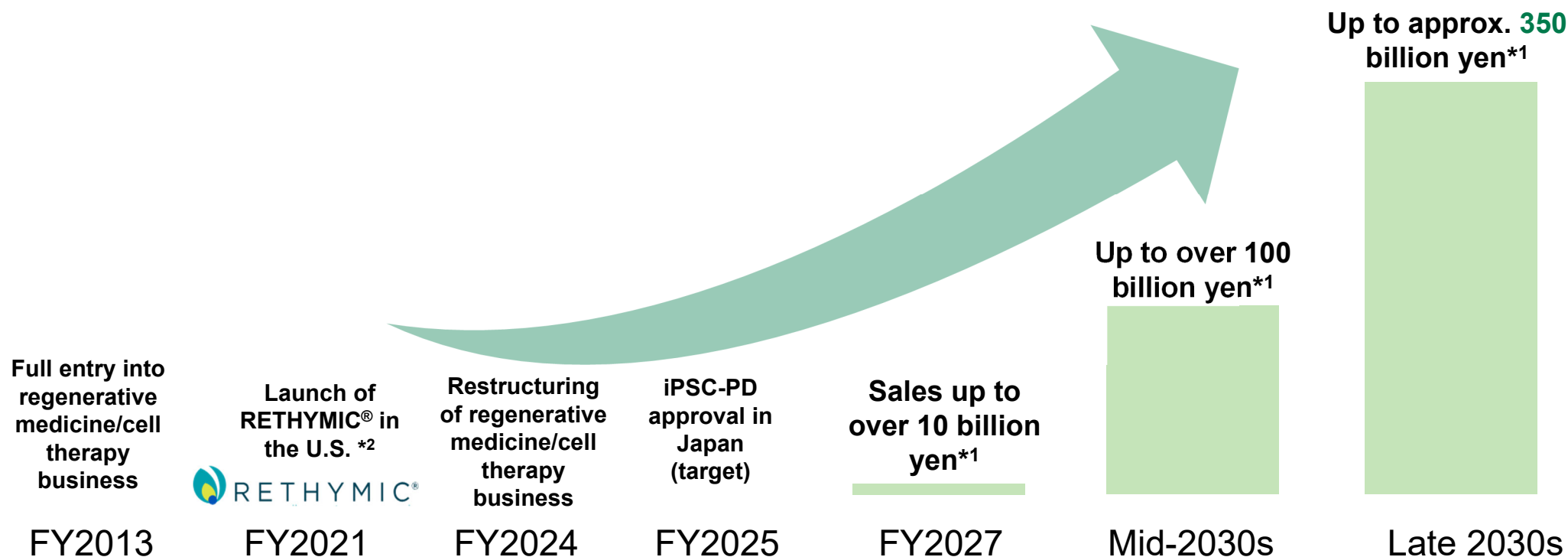
### 3. Expansion of the Regenerative Medicine/Cell Therapy Business

As a “front-runner” in regenerative medicine/cell therapy, create new value that can only be realized through regenerative medicine

Aim to expand sales to a maximum of approximately 350 billion yen\*1 in the second half of the 2030s

Establish a leading position in Japan in the field of regenerative medicine through successful product launches

Pursue advanced production technologies and cutting-edge science, expanding fields and regions to establish a global presence

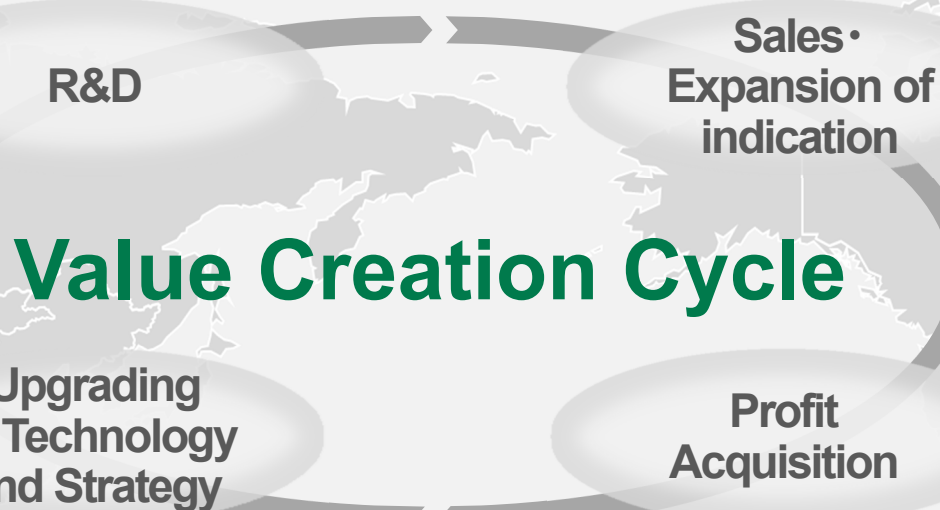


\*1 : Before adjusting for the probability of success, and whether multiple products in development are launched

\*2 : Cultured thymic tissue products approved in the U.S. for immune reconstitution in pediatric congenital athymia

## 4. Regional Strategies

Focus on Japan, which has the pharmaceutical business platform including drug discovery research, and North America, the largest market. For the organizational operations in Japan and the US, consider the balance between strengthening cooperation and delegating authority according to functional characteristics, while ensuring speed.



### Balancing unified group management and local responsiveness

Ensuring swift decision-making and execution

#### Strong cooperation among global strategic functions

- Finance
- R&D/CMC

#### Timely cooperation for efficiency

- Regulatory affairs/reliability/production
- Legal/IP/internal audit/IR
- IT&Digital
- HR

#### Focus on local responsiveness

- Sales/marketing



## IV. R&D Initiatives



# 1. Value Creation through R&D Activities

FY2025

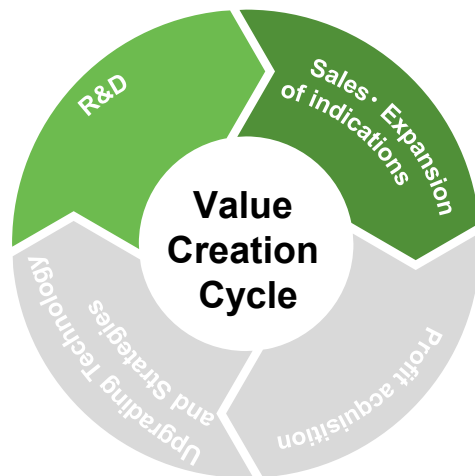
FY2026

FY2027

FY2028-FY2030

FY2031-FY2033

**Major milestones in the rebuilding of the “Value Creation Cycle” will be concentrated over the next three years**



## Launch of next-generation pipelines

- ✓ Hematological malignancies, Rare neurological & degenerative diseases

## Expansion of the regenerative medicine/cell therapy business

- ✓ HLCR011, DSP-3077, etc.

## Launch of CNS pipelines

- ✓ Launch the iPSC-PD program (DSP-1083) in the U.S.
- ✓ Launch DSP-0378

## NDA Submission and launch of two oncology compounds

- ✓ Launch of enzomenib
- ✓ NDA submission of nuvisertib

## World's first commercialization of iPS cell-derived products

- ✓ Obtain conditional and time-limited approval for iPSC-PD program (CT1-DAP001) in Japan

## 2. Promote Stable Development of the Two Oncology Products

- Launch of enzomenib and NDA submission of nuvisertib by FY2027
- We are confidently promoting development of the two oncology compounds for the following three reasons



### Right target (Drug target relevance)

- ✓ Targets clearly associated with disease and accumulated internal and external clinical evidence



### Right plan (Development strategy and clinical trial design)

- ✓ Focus on hematological malignancies, which have a high probability of successful development within the oncology area
- ✓ Select a patient population in which the treatment is more likely to be effective
- ✓ Efficacy endpoints are objective measures\* and will continue to be used in confirmatory clinical trials



### Right action (Clinical development operations)

- ✓ Promote development steadily by conducting single-arm, open-label studies while reviewing data step by step
- ✓ Promote small-scale confirmatory clinical trials in a conscientious and elaborate manner

**Accelerate indication expansion through external alliances to maximize value faster**

### 3. To Increase the Likelihood of R&D Success

Focus on diseases where the Company can maximize its strengths and promote R&D stepwise with a compact development strategy

#### Key Success Factors

#### Review of the past

#### Current/future actions

1

**Generate development candidates with high certainty**  
Right target

- Attempted to work on drug targets with uncertain disease relevance
- Selected a broad range of diseases within oncology/CNS (dispersed R&D resources)

- Carefully select more disease-relevant drug targets
- Focus on hematological malignancies, Rare neurological & degenerative diseases (improve R&D continuity)

**Early development pipelines are becoming richer and their quality is improving**

2

**Drive clinical development to success**  
Right plan  
Right action

- Accepted risks and moved into late-stage development
- Promoted large-scale confirmatory clinical trials

- Confirm efficacy signals early in studies with patients (initial POC\*)
- Obtain First approval through promoting small-scale confirmatory clinical trials in a conscientious and elaborate manner

3

**Improve the Company's overall execution capability**  
(become the Company that can get things done)

- Focused on fulfilling the role of each one's own department

- Integrated R&D Management (3→1 Division)
- Pursue the results creation throughout the Company, centered on the integrated R&D organization

## 4. To Maximize the Value of Internal Portfolios

- Maximize the value of internal portfolios through appropriate means, whether developed internally or through external partnerships
- Continually nurture pipelines while reducing the company's cost burden

### 1. Partnerships to maximize value utilizing internal development capability (co-development, etc.)

Areas	Disease Focuses (or businesses)	Policies
Oncology	Hematological malignancies	<ul style="list-style-type: none"><li>• Achieved initial POC for the two oncology compounds</li><li>• Maximizing product value through partnerships</li></ul>
CNS	Neurological rare/degenerative diseases	<ul style="list-style-type: none"><li>• Aiming to obtain initial POC with a compact development strategy</li><li>• Considering partnerships to maximize product value</li></ul>
	Regenerative medicine/cell therapy business	<ul style="list-style-type: none"><li>• Reorganization with Sumitomo Chemical has been completed<ul style="list-style-type: none"><li>✓ Secure stable funding for R&amp;D and capital investments</li><li>✓ Proactively participate in development and accelerate commercialization through group synergies</li></ul></li></ul>

### 2. Alliances leveraging partner's late-stage development capabilities (out-licensing, etc.)

Infectious diseases, existing pipelines outside disease focuses, etc

## 5. Continuous Creation of Innovative New Drugs as an R&D-Driven Pharmaceutical Company

FY2025

FY2026

FY2027

FY2028–2030

FY2031–2033

### Sumitomo Pharma's R&D capabilities

- Bases for CNS drug discovery and translational research to compete globally
- R&D cycle based on data and expertise obtained from enzomenib and nuvisertib
- Capabilities of medicinal chemistry for challenging targets
- World-leading technology and experience in iPS cells
- AI and digital technology to drive innovation



Development and CMC organization that can execute through to commercialization

### Launch of next-generation pipelines

- ✓ Hematological malignancies, Rare neurological & degenerative diseases

### Expansion of the regenerative medicine/cell therapy business

- ✓ HLCR011, DSP-3077, etc.

### Launch of CNS pipelines

- ✓ Launch the iPSC-PD program (DSP-1083) in the U.S.
- ✓ Launch DSP-0378

### NDA Submission and launch of two oncology compounds

- ✓ Launch of enzomenib
- ✓ NDA submission of nuvisertib

### Commercialization by partners

Ulotaront, DSP-0187, infectious disease programs, etc.

### World's first commercialization of iPS cell-derived products

- ✓ Obtain conditional and time-limited approval for iPSC-PD program (CT1-DAP001) in Japan



## V. Summary



## Strategic Scenario for Regrowth

# Reboot for a “Strong Sumitomo Pharma”

Return to self-sustaining growth by rebuilding the Value Creation Cycle based on internal innovation

“Strong Sumitomo Pharma”

Accelerate through the  
Value Creation Cycle

FY2024  
Emerge from the  
business crisis

FY2025 to FY2027  
Rebuild the Value Creation Cycle

Our Vision (FY2033 and beyond)

- Business operations focused on three key products
- Fundamental structural reforms (streamlining, selection and concentration revision of R&D investment strategy, governance reforms)
- Core operating and net income profitability

- Expansion of three key products
- Promote and launch oncology and regenerative medicine/cell therapy business
- Develop compounds in early stage (CNS, Oncology, etc.)
- Stable profitability of free CF

- Business structure based on internal innovation
- Sustainable rebuilding of business portfolios (Oncology, CNS, other areas)
- Robust position in regenerative medicine/cell therapy business

Accelerate strongly the Value Creation Cycle  
Build a unique global position

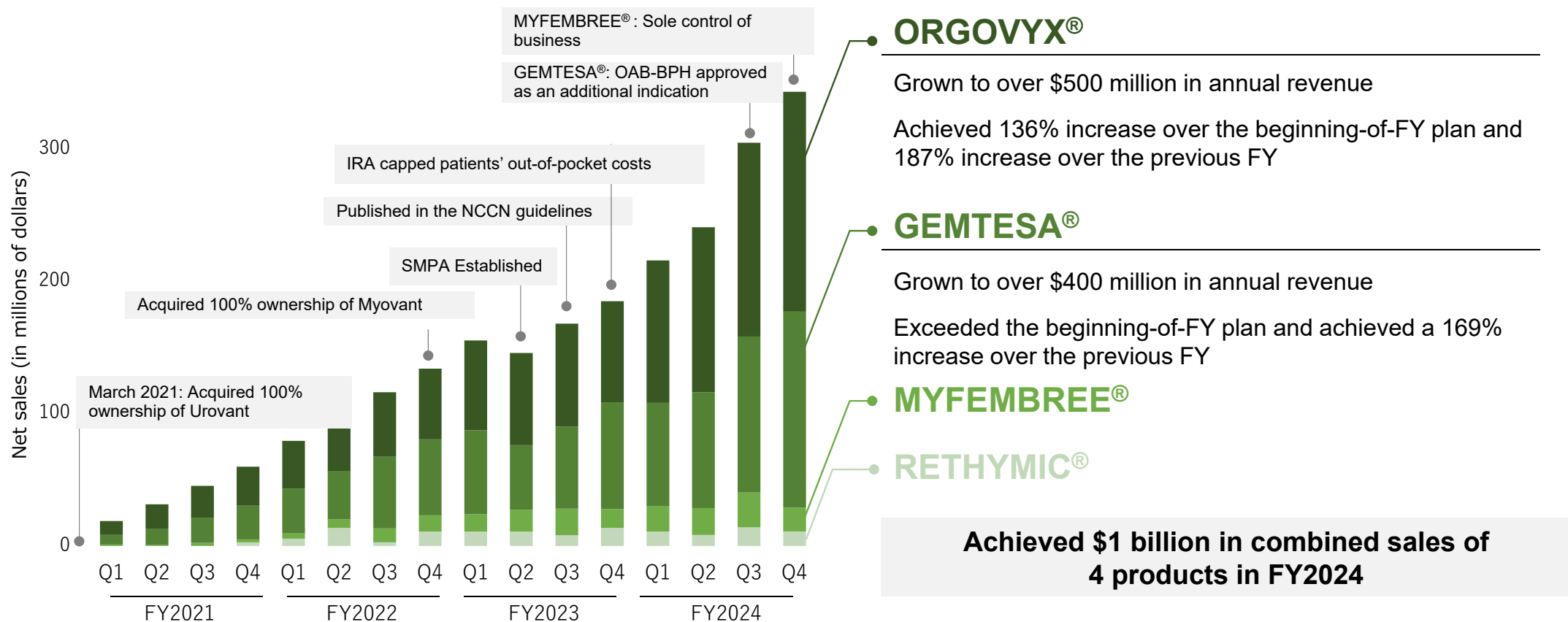


# Appendix

## Appendix (Reboot 2027)

# Initiatives for FY2023-2024 (Expansion of Existing Product Business)

Strategic alliance with Roivant in FY2019 to strengthen the revenue base after LOE of LATUDA®  
 Successfully developed and launched 4 products and established a growth trend through sales, marketing, and medical activities



The beginning-of-FY plan ratio was calculated based on the forecast released on May 14, 2024.

NCCN: National Comprehensive Cancer Network; IRA: Inflation Reduction Act; OAB-BPH: Overactive bladder in men with benign prostatic hyperplasia

Appendix (Reboot 2027)

## Initiatives for FY2023-2024 (Fundamental Structural Reforms)

Implemented fundamental structural reforms across the Group to improve our business performance, refinance and strengthen our financial base

Sought to ensure both an early return to financial health and our continued viability as an R&D-driven pharmaceutical company in formulating and implementing these reforms



### Streamlining Selection and Concentration

Cost management in line with sales, and cash generation for debt repayment

- A) Cost and workforce reduction
- B) R&D spending cap management
- C) Sale of assets and businesses



### Revision of R&D Investment Strategy

Revision of R&D investment strategy while maintaining the model of an R&D-driven pharmaceutical company

- A) Selection and Concentration of programs
- B) Established framework for cooperation with Sumitomo Chemical in the regenerative medicine/cell therapy business



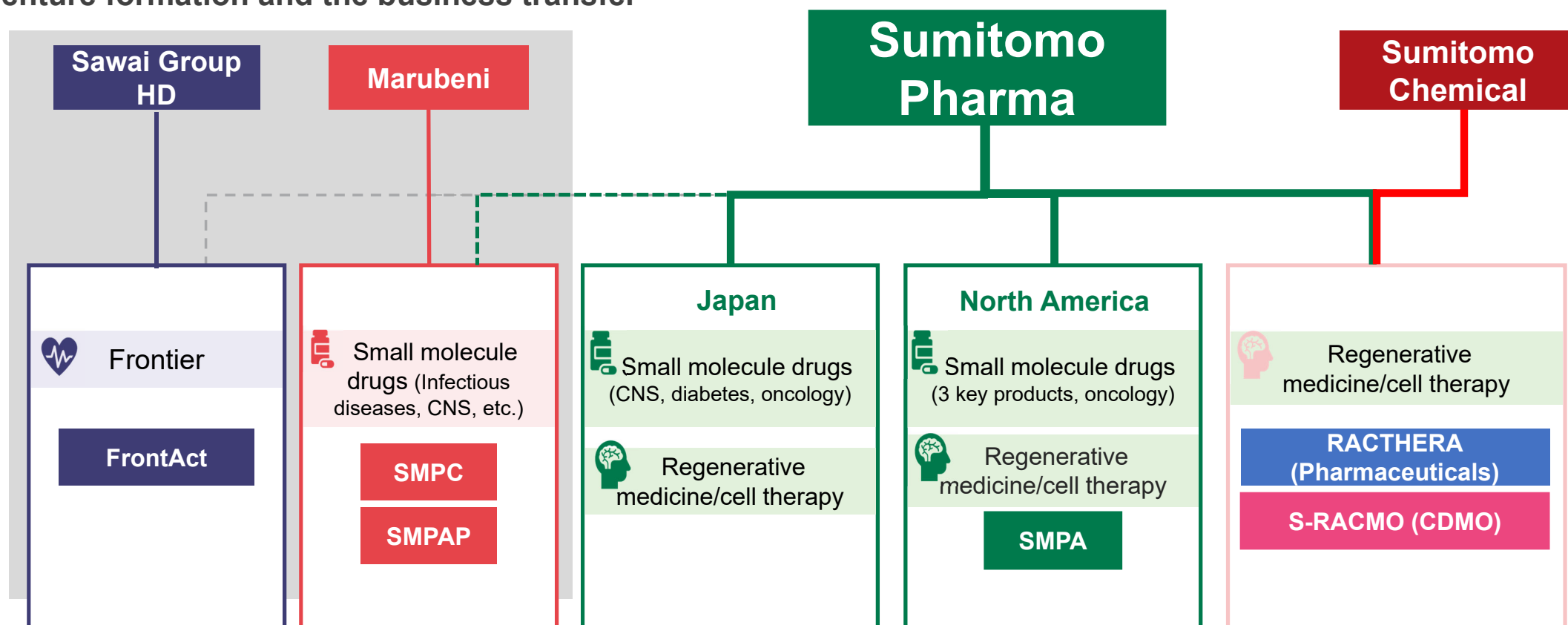
### Governance reforms

Improved framework for risk management and swift decision making

- A) Changed executive management structure, including executive officers
- B) Strengthened Japan-U.S. management cooperation (e.g., sending a Japanese CEO to SMPA)
- C) Strengthening governance (reducing the ratio of internal directors, changing the institutional design planned for FY2025)

## Initiatives for FY2024 (Asia Business Joint Venture Formation\* and Frontier Business Transfer)

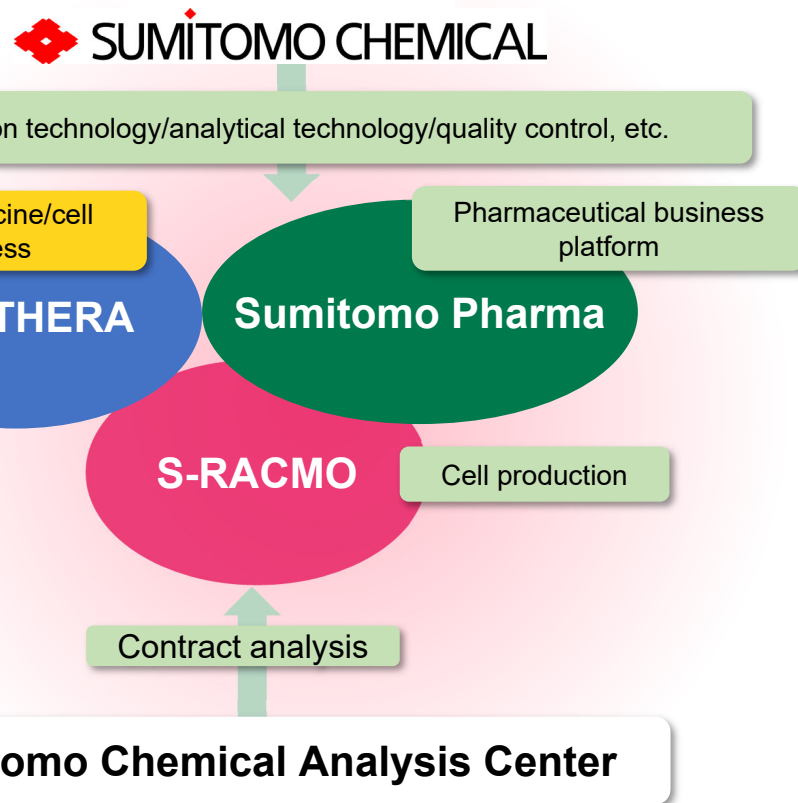
It is currently difficult to allocate the strategic investments needed for the Asia and Frontier businesses. Given our capital needs, we are driving strategic investments in other growth areas through the joint venture formation and the business transfer.



\*: Product supply to Asia will continue. Indicated on a contractual basis

## Initiatives for FY2024 (Joint Ventures in Regenerative Medicine/Cell Therapy Business)

Strategic alliance with Sumitomo Chemical secures stable funds for investment in the regenerative medicine/cell therapy business. As a leading company in the field of regenerative medicine/cell therapy, we will continue to take on the challenges of innovating and delivering hope for patients



- In collaboration with RACTHERA, leverage our pharmaceutical business platform. Aim to realize our past efforts and create innovative drugs (the first project is iPSC-PD)
- Also work with Sumitomo Chemical and S-RACMO to seek group synergies and grow the business to 350 billion yen by the 2030s
- Milestone sales of up to approximately 150 billion yen as the business grows
- JV reduces our investment burden while ensuring stable funds to invest in the business and enables us to work flexible on R&D strategies (oncology, CNS)

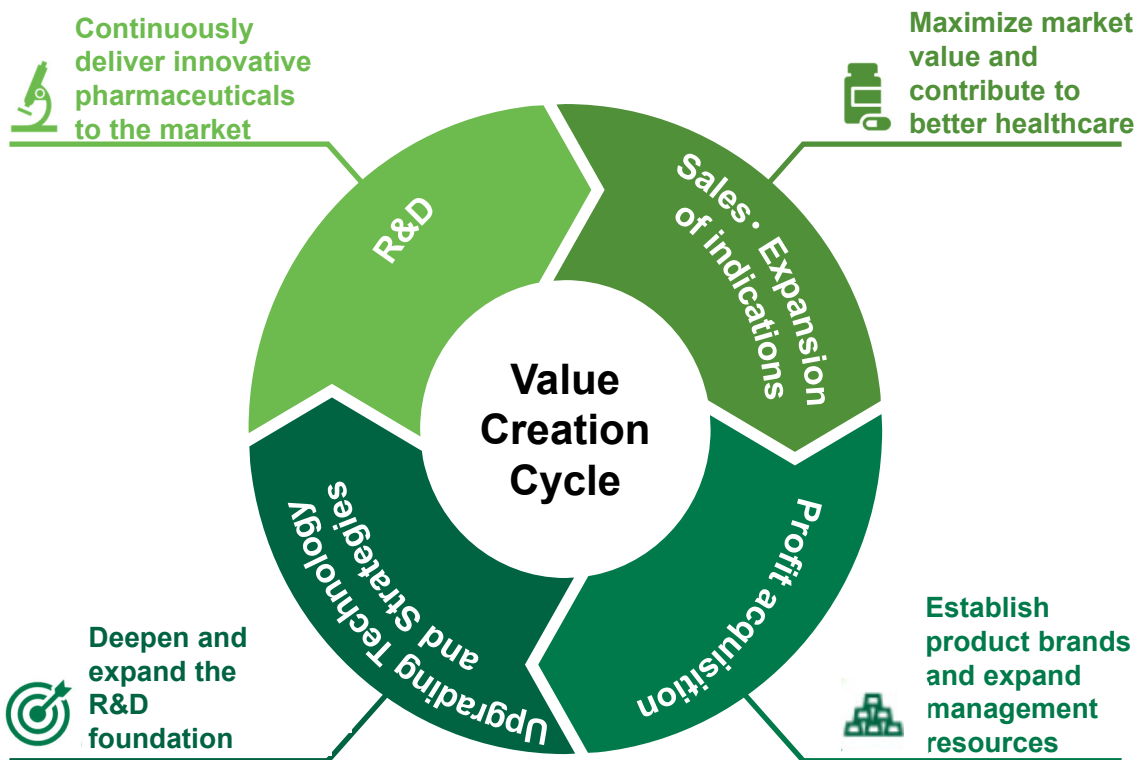


Appendix (Reboot 2027)

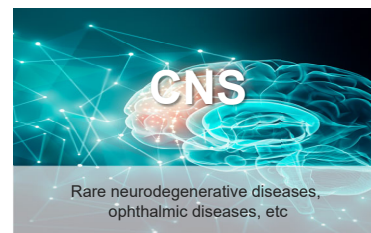
## Our Vision (FY2033 and beyond)

To strongly accelerate the Value Creation Cycle, continuously amplify innovation, and implement it in society Through the acceleration of the cycle, strategically deepen and expand strengths, and establish a unique global position

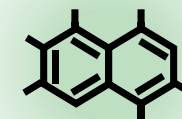
Moving through all stages of the value creation cycle for continuous cutting-edge innovation



Strategically deepen and expand strengths



**Small molecules**



Molecular design and synthesis capabilities based on accumulated experience and expertise

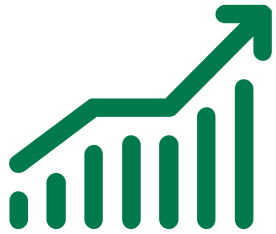
**Regenerative medicine /cell therapy**



Presence, technology, and expertise gained through pioneering initiatives

## Individual Businesses (North America)

Aiming for further growth as the core of the Group's business activities and as the revenue base supporting the Group



### Maximizing the value of existing products

- Three key products : Maximizing sales and product profitability through the execution of strong sales strategies with excellent return on investment
- RETHYMIC® : Enhancing product supply to patients through the establishment of in-house processing facilities



### Pursuing continuous operational efficiency improvements

- Continuing rigorous cost management
- Simplifying the governance structure
- Maintaining efficient commercial structure to support approval and launch of enzomenib

## Key Products (North America)

Maximize the value of key products, with a focus on ORGOVYX® and GEMTESA®

### ORGOVYX®

Indications: Advanced prostate cancer

**ORGOVYX®**  
(relugolix) 120 mg tablets



### Drive demand and brand preference across Urology and Oncology

- Urology: Establish firm position in Androgen Deprivation Therapy
- Oncology: Expand market share supported by clinical differentiation
- Patients: Disseminate educational resources regarding changes in out-of-pocket costs due to Medicare Part D drug benefit modifications

### GEMTESA®

Indications: Overactive bladder;  
Overactive bladder associated with prostatic hyperplasia

**GEMTESA®**  
(vibegron) 75 mg tablets



### Establish standard of care OAB treatment for men and women with overactive bladder

- Keep emphasizing clinical differentiation: Simple dosing regimen, no blood pressure warning in the label, no drug-drug interactions with CYP2D6 substrates, and crushable tablet
- Expansion of prescriptions for men: Increase awareness in male patients by leveraging new indication (overactive bladder in men being pharmacologically treated for benign prostatic hyperplasia)
- Optimize the balance between price and volume: Implement balanced pricing strategies in response to market changes

## Individual Businesses (Japan)

### Contributions to the “rebuilding” of the Company

**Secure revenues through our strengths and key products, and make regenerative medicine/cell therapy our core business**

**1**

#### **Maximize the value of key products\* and new products**

- Maximize product value by leveraging the sales base and relationships in the areas of strength (CNS/diabetes/rare diseases)
- Prepare for the launch of the oncology business
- Improve customer satisfaction through omni-channel information and conduct evidence-based medical activities

**2**

#### **Focus on launching and expanding the regenerative medicine/cell therapy business**

- Smooth launch of CT1-DAP001/ DSP-1083 (Parkinson's disease) business
- Contribution to clinical studies for CT1-DAP001/ DSP-1083 approval
- Contribution to the next products (HLCR011, DSP-3077)

**3**

#### **Adapt operations to change**

- Build and operate a system that adapts to changes in product and workforce mix
- Respond flexibly to changes in healthcare policy
- Strategic alliances to ensure business continuity

## Key Products (Japan)

Maximize the value of key products, with a focus on LATUDA®, TWYMEEG®, and XEPLION®/XEPLION® TRI

### CNS: LATUDA®

Indications:  
Schizophrenia and  
bipolar I depression



#### To be the best drug for schizophrenia and bipolar I depression

- Contribute to acute treatment (inpatient and outpatient) by improving positive symptoms
- Contribute to the treatment of bipolar I depression by improving depressive symptoms

### Diabetes: TWYMEEG®

Indications: Type 2  
diabetes



#### Contribute to the treatment of elderly patients with type 2 diabetes through the use in combination with DPP-4 inhibitors

- The only glucose-dependent insulin secretagogue that can be used in combination with DPP-4 inhibitors
- Revised package insert (April 2025) will allow use in patients with renal impairment

### CNS: XEPLION®/XEPLION® TRI

Indications: Schizophrenia

#### Contribute to the treatment of more patients with schizophrenia through the addition to the CNS product line

- Marketing alliance with Janssen Pharmaceuticals will contribute to preventing relapse and rehospitalization and reducing the medication burden for patients

## Promote Stable Development of the Two Oncology Compounds

- Dedicate resources to R&D activities to obtain initial approval as a top priority**

### enzomenib (DSP-5336)

Mechanism of action	Menin-MLL binding inhibitor
Target disease (development phases)	Acute myeloid leukemia (monotherapy: Phase II, combination: Phase I)
Aimed Positioning	Best-in-class drug among menin-MLL inhibitors
Features of Developed Compounds	<p><u>Clinical data</u></p> <ul style="list-style-type: none"> <li>✓ CR/CRh rates of &gt;40% were achieved in patients with MLL rearrangement or NPM1 mutation as monotherapy</li> <li>✓ No dose-limiting toxicities observed and well tolerated</li> </ul> <p><u>Key points of differentiation</u></p> <ul style="list-style-type: none"> <li>✓ Superior efficacy expected for specific patient populations</li> <li>✓ Low concern about QTc prolongation and differentiation syndrome</li> </ul>

### nuvisertib (TP-3654)

Mechanism of action	PIM1 kinase inhibitor
Target disease (development phases)	Myelofibrosis (monotherapy, combination with JAK inhibitor: Phase I/II)
Aimed Positioning	First-in-class myelofibrosis treatment that selectively inhibits PIM1 kinase
Features of Developed Compounds	<p><u>Clinical data</u></p> <ul style="list-style-type: none"> <li>✓ Monotherapy reduced spleen size by at least 25% in 22.2% of patients. Systemic symptom scores improved by ≥50% in 44.4% of patients</li> <li>✓ No dose-limiting toxicities observed, hemoglobin levels and platelet counts improved</li> </ul> <p><u>Key points of differentiation</u></p> <ul style="list-style-type: none"> <li>✓ The new mechanism and low hematologic toxicity concerns make it a potential optimal combination drug with JAK inhibitors</li> <li>• In addition to alleviating myelofibrosis symptoms and splenomegaly, it may prevent bone marrow fibrosis</li> </ul>

## iPS-PD Program (Allogeneic iPS Cell-Derived Dopaminergic Neural Progenitor Cells)

- Seek to make this an innovative treatment option to improve motor symptoms in people with Parkinson's disease
- The results of an investigator-initiated clinical trial conducted by Kyoto University have been published in Nature (April, 17,2025)
- Consultation for the SAKIGAKE comprehensive evaluation is underway, intending to obtain approval by the end of FY2025
- World's first practical application of iPS cell-derived products

### Target disease

- Parkinson's disease

### Features of developed products

- High-purity iPS cell-derived dopamine neural progenitor cells
- Evidence of the efficacy of cell transplantation
  - ✓ Long-term efficacy with embryonic cells\*
  - ✓ Concern of side effects by foreign substances overcome with iPS cells
- Highly efficient cell production realized
  - ✓ Concentrate our manufacturing technology and innovative equipment at S-RACMO

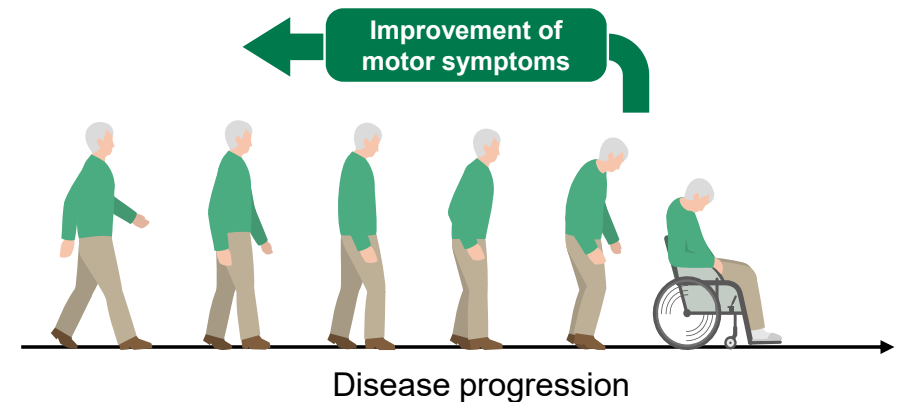
### Milestones through FY2027



Target approval in FY2025



Advance Phase I/II studies





Enzomenib (DSP-5336): Menin-MLL Binding Inhibitor

Seek manufacturing and marketing approval in Japan and the U.S. for relapsed/refractory AML with MLL rearrangement and NPM1 mutation

- ✓ Presented new clinical data from Phase I/II study at American Society of Hematology (ASH) 2024 (≥40% CR+CRh rates achieved in the 300 mg BID arm)
- ✓ Recommended Phase II dose set at 300 mg BID, and the data package for a marketing application has been agreed with the FDA
- ✓ Received the orphan drug designation in Japan

Target disease	<ul style="list-style-type: none"><li>Relapsed/refractory AML*3 with MLL*1 rearrangement or NPM1*2 mutation</li></ul>
Features of developed products	<ul style="list-style-type: none"><li>Developed through an industry-academia collaborative program with Kyoto University. Its translational research is being advanced through the AMED ACT-M*4 project</li><li>A competitor drug with the same mechanism of action has already been approved by the FDA. Thus, this drug is expected to have a high probability of clinical success</li><li>Having potential to be best-in-class in both efficacy and safety<ul style="list-style-type: none"><li>✓ Expecting superior efficacy for specific patient groups</li><li>✓ Low concerns about QTc prolongation and differentiation syndrome</li></ul></li></ul>
Milestones through FY2027	<ul style="list-style-type: none"><li>Launch in Japan and the U.S.</li></ul>

Latest Phase II efficacy data at recommended dose (300 mg BID)

	MLLr	NPM1m
	300 mg BID n = 15	300 mg BID n = 7
Objective Response Rate (CR + CRh + CRi + MLFS)	73.3% (11/15)	57.1% (4/7)
Composite CR (CR + CRh + CRi)	53.3% (8/15)	42.9% (3/7)
CR + CRh	40.0% (6/15)	42.9% (3/7)

CR: Complete remission; CRh: Complete remission with partial hematologic recovery; CRi: Complete remission with incomplete blood count recovery; MLFS: Morphologic leukemia-free state; BID: Twice a day

Adapted from the data presented at ASH 2024

## Appendix (Reboot 2027)

### Nuvisertib (TP-3654): PIM1 Kinase Inhibitor

**Confirm synergistic effects when used in combination with JAK inhibitor, establish POC in myelofibrosis with high unmet need, and submit for manufacturing and marketing approval in Japan and U.S.**

- ✓ Presented new clinical data from Phase I/II study at ASH 2024 (Improvements in important efficacy measures were observed with monotherapy, even in patients who did not respond to JAK inhibitor and in those with poor prognostic factors such as low hemoglobin and platelet counts)
- ✓ Start patient enrollment in the combination therapy cohort with momelotinib (JAK inhibitor), which is approved in Japan, the U.S., and Europe.
- ✓ Received the orphan drug designation in Japan

#### Target disease

- Myelofibrosis

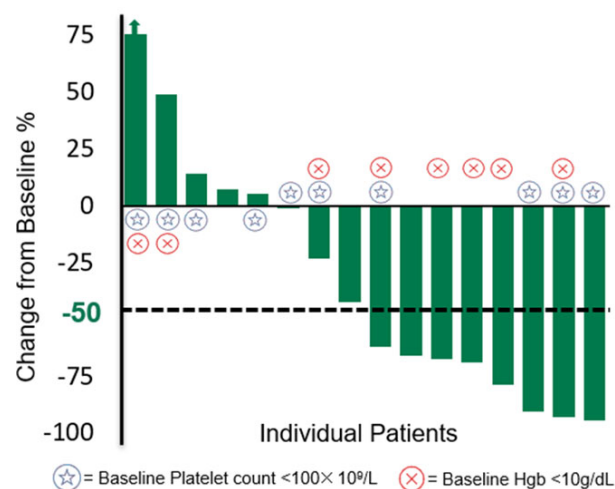
#### Features of developed products

- May be a drug with a novel mechanism of action in myelofibrosis, for which JAK inhibitors are the only available treatment
- In addition to alleviating myelofibrosis symptoms and splenomegaly, it may modulate cytokines, prevent bone marrow fibrosis, and modify the disease
- It is well tolerated, has low hematologic toxicity concerns and may be optimal in combination with standard JAK inhibitor treatment

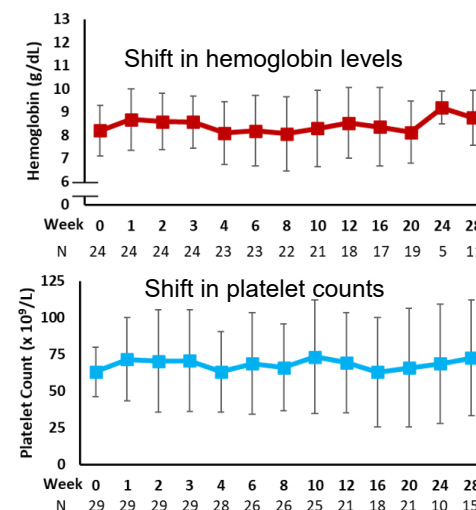
#### Milestones through FY2027

- Application for approval

**Total symptom score improved by  $\geq 50\%$  in 44.4% (8/18) of patients**



**Low hematologic toxicity (sustained hemoglobin level and platelet count)**



Adapted from the data presented at ASH 2024

## fH1/DSP-0546LP: Universal Influenza Vaccine

### Leverage our TLR7 adjuvant technology platform to develop next-generation influenza vaccines

- ✓ Promote open innovation that integrates internal/external knowledge and technologies, leveraging public funding
- ✓ Phase I study underway in Europe

#### Target disease

- Influenza prevention

#### Features of developed products

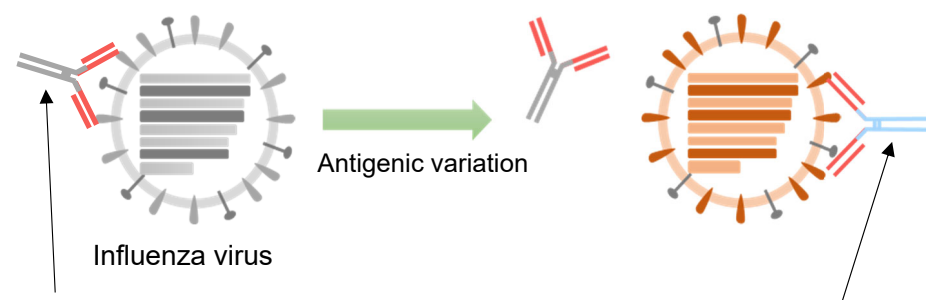
- The combination of a novel antigen (post-fusion hemagglutinin antigen: fH1) and a novel adjuvant (TLR7: DSP-0546LP) is expected potentially to enhance the quantity, quality, and durability of the immune response and to be effective against a broad range of influenza viruses
- Expected potentially to be effective not only against seasonal influenza but also novel and potentially pandemic strains\*

\*Conventional influenza vaccines lose effectiveness due to viral mutations, making it necessary to select strains and produce vaccines to immunize against the strains predicted to circulate each year. They may also not respond well to emerging strains of influenza.

#### Milestones through FY2027

- Phase I interim analysis results to be reported (FY2025)
- Decision to proceed to human challenge study (Phase II) based on Phase I results to be made

#### Features of the Universal Influenza Vaccine



Antibodies induced by conventional vaccination

It is expected that the universal influenza vaccine will actively induce antibodies against conserved regions that are less prone to mutation, which are common across different types of influenza viruses

Source: Modified from Sumitomo Chemical Journal 2022

## DSP-0378: $\gamma$ -Aminobutyric Acid (GABA)<sub>A</sub> Receptor Positive Allosteric Modulator

Seek regulatory approval as soon as possible for a new class of GABAergic treatment with strong efficacy potential for refractory epilepsy

- ✓ A single ascending dose study was completed, confirming favorable safety and pharmacokinetics
- ✓ Pharmacological effects in the brain based on GABAergic neurotransmission were confirmed

### Target disease

- Progressive myoclonus epilepsies and developmental and epileptic encephalopathy

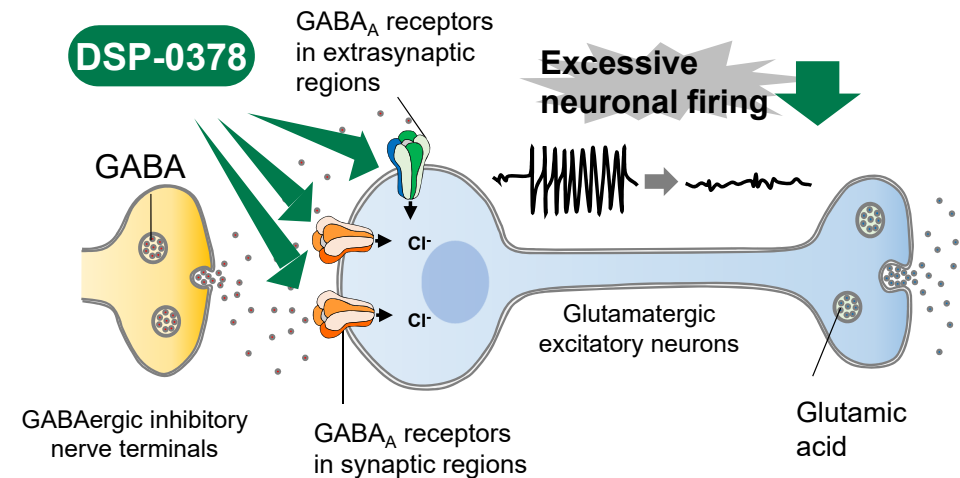
### Features of developed products

- It has potent and broad antimyoclonus and antiepileptic effects by inhibiting excessive neuronal firing through activation of different subtypes of GABA<sub>A</sub> receptors expressed in synaptic and extrasynaptic regions
- The mode of action is different from common GABA<sub>A</sub> receptor potentiators such as benzodiazepines and neurosteroids

### Milestones through FY2027

- Results of the Phase 1b trial revealed

### Mechanism of action of DSP-0378



\*:Image

