# Conference on Q2 FY2024
## (April 1, 2024 to September 30, 2024)
# Financial Results

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Sumitomo Pharma Co., Ltd.

October 30, 2024

Sumitomo Pharma
Innovation today, healthier tomorrows

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Sumitomo Pharma Group's Philosophy

## Continue to Challenge for the Betterment of Healthcare and Fuller Lives of People Worldwide

**To contribute broadly to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide**

**Innovation today, healthier tomorrows**

# Agenda

- Financial Results for Q2 FY2024
- Initiatives towards the Reconstruction
- Research and Development
- Q&A

# Financial Results for Q2 FY2024

# Financial Highlights for Q2 FY2024

- Revenue
  - Increased by 18.4% YoY: Increased by sales expansion of ORGOVYX® in the U.S.
- Costs
  - SG&A expenses: (decreased by 29.8% YoY): Decreased by the restructuring of the group companies in North America, etc.
  - R&D expenses: (decreased by 44.6% YoY): Decreased by the selection and concentration of the pipeline
- Core operating profit (loss)
  - Improved by 65.8 billion JPY YoY: Improved by the initiatives for reducing costs in addition to increase in revenue

- Initiatives to address the challenges towards reconstruction
  - Streamlining the business structure in Japan: To a workforce of approx. 2,000 employees* from Dec. 2024 due to the early retirement program offer, etc. (business structure improvement expenses 4.2 billion JPY)
- Status of borrowings
  - The repayment deadline for the bridge loan: Extended to the end of Dec. 2024
  - Discussing with financial institutions and Sumitomo Chemical regarding necessary refinancing

* non-consolidated, full-time employees

# Financial Results for Q2 FY2024 (Core Basis)

**The forecasts are not revised**

Billions of JPY

| | Q2YTD FY2023 Results | Q2YTD FY2024 Results | Change | | | FY2024 | |
|---|---|---|---|---|---|---|---|
| | | | Value | FX impact | % | May 14 forecasts | Progress % |
| **Revenue** | 152.6 | **180.7** | 28.1 | 9.6 | 18.4 | 338.0 | 53.5 |
| Cost of sales | 60.3 | **72.3** | 11.9 | 3.0 | 19.8 | 138.0 | 52.4 |
| Gross profit | 92.3 | **108.5** | 16.2 | 6.6 | 17.5 | 200.0 | 54.2 |
| SG&A expenses | 118.8 | **83.4** | (35.3) | 4.6 | (29.8) | 169.0 | 49.4 |
| R&D expenses | 45.3 | **25.1** | (20.2) | 0.8 | (44.6) | 50.0 | 50.2 |
| Other operating income/expenses | 5.9 | **(0.0)** | (5.9) | — | | 20.0 | |
| **Core operating profit** | (65.8) | **(0.0)** | 65.8 | 1.1 | — | 1.0 | — |
| Non-recurring items (negative number indicates net loss) | (20.6) | **(8.1)** | 12.5 | | | (1.0) | |
| **Operating profit** | (86.5) | **(8.2)** | 78.3 | | — | 0.0 | — |
| Finance income/costs | 30.4 | **(24.2)** | (54.6) | | | (18.0) | |
| Profit before taxes | (56.1) | **(32.4)** | 23.7 | | — | (18.0) | |
| Income tax expenses | 11.6 | **(0.2)** | (11.8) | | | (2.0) | |
| Net profit | (67.7) | **(32.2)** | 35.5 | | — | (16.0) | — |
| **Net profit attributable to owners of the parent** | (67.7) | **(32.2)** | 35.5 | | — | (16.0) | — |

Average rates:
Q2 FY2023 Results : 1US$ = ¥141.07, 1RMB = ¥19.75
Q2 FY2024 Results : 1US$ = ¥152.78, 1RMB = ¥21.17
FY2024 forecasts : 1US$ = ¥145.00, 1RMB = ¥20.00

Period end rates:
As of the end of March 2024 : 1US$ = ¥151.33, 1RMB = ¥20.84
As of the end of September 2024 : 1US$ = ¥142.82, 1RMB = ¥20.48

- Revenue increased primarily due to the growth of three key products
- In addition to the effects of business structure improvements, Group-wide streamlining, such as reductions through selection and concentration of R&D investments, has led to a significant reduction in SG&A expenses and R&D expenses
- Core operating profit improved significantly
- Non-recurring items:
  - Q2 FY2024: Business structure improvement expenses in Japan and North America
  - Q2 FY2023: Business structure improvement expenses in North America

# Revenue of Major Products in North America

| North America | Q2YTD FY2023 Results | Q2YTD FY2024 Results | Change | Q2YTD FY2023 Results | Q2YTD FY2024 Results | Change | | | FY2024 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Value | FX impact | % | May 14 forecasts | | JPY-basis Progress % |
| | Millions of USD | | | Billions of JPY | | | | | Millions of USD | Billions of JPY | |
| ORGOVYX® | 138 | **232** | 95 | 19.4 | **35.5** | 16.1 | 2.7 | 83.0 | 400 | 57.9 | 61.3 |
| MYFEMBREE® | 29 | **40** | 10 | 4.2 | **6.0** | 1.9 | 0.5 | 45.4 | 124 | 17.9 | 33.8 |
| GEMTESA® | 112 | **165** | 53 | 15.8 | **25.2** | 9.4 | 1.9 | 59.6 | 380 | 55.0 | 45.9 |
| APTIOM® | 114 | **131** | 16 | 16.1 | **19.9** | 3.8 | 1.5 | 23.6 | 201 | 29.1 | 68.6 |
| RETHYMIC® | 22 | **19** | (3) | 3.1 | **2.9** | (0.1) | 0.2 | (4.4) | 49 | 7.2 | 40.9 |
| Others | 37 | **28** | (9) | 5.2 | **4.3** | (0.9) | 0.3 | (18.1) | 216 | 31.6 | 45.9 |
| Export products/ One-time revenue, etc. * | 67 | **67** | (0) | 9.4 | **10.2** | 0.8 | 0.8 | 8.2 | | | |
| Total | 519 | **682** | 163 | 73.3 | **104.2** | 30.9 | 8.0 | 42.2 | 1,370 | 198.7 | 52.4 |

(Ref.) Achievement rate against Q2 YTD plans for three key products

Million $

| Plans | Results | % |
|---|---|---|
| 184 | 232 | 126.3 |
| 52 | 40 | 75.5 |
| 151 | 165 | 109.5 |

- Revenue growth of three key products in total exceeded the plan
- Sales of APTIOM® increased primarily due to price factor

Average rates:
Q2 FY2023 Results : 1US$ = ¥141.07
Q2 FY2024 Results : 1US$ = ¥152.78
FY2024 forecasts : 1US$ = ¥145.00

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# Revenue of Major Products in Japan & Asia

Billions of JPY

| | Q2YTD FY2023 Results | Q2YTD FY2024 Results | Change | | FY2024 | |
|---|---|---|---|---|---|---|
| | | | Value | % | May 14 forecasts | Progress % |
| **Japan** | | | | | | |
| Equa®/EquMet® | 15.8 | **14.2** | (1.6) | (10.4) | 26.3 | 53.8 |
| LATUDA® | 5.7 | **6.7** | 0.9 | 16.2 | 13.0 | 51.2 |
| TWYMEEG® | 2.6 | **3.6** | 0.9 | 34.7 | 11.3 | 31.5 |
| METGLUCO® | 3.7 | **3.8** | 0.0 | 1.2 | 7.4 | 50.9 |
| LONASEN® Tape | 1.8 | **2.3** | 0.4 | 24.1 | 4.4 | 51.7 |
| TRERIEF® | 8.5 | **2.4** | (6.2) | (72.1) | 2.1 | 113.7 |
| AG products | 4.6 | **5.6** | 1.0 | 20.9 | 11.1 | 50.1 |
| Others | 12.2 | **10.4** | (1.8) | (14.5) | 24.7 | 58.6 |
| Export products/ One-time revenue, etc. | 3.5 | **4.1** | 0.6 | 15.7 | | |
| Total | 58.5 | **52.8** | (5.7) | (9.8) | 100.3 | 52.7 |
| **Asia** | | | | | | |
| MEROPEN® （China） | 10.2 | **13.5** | 3.2 | 31.4 | 21.2 | 63.5 |
| Others | 10.6 | **10.3** | (0.3) | (2.8) | 17.8 | 57.7 |
| Total | 20.8 | **23.7** | 2.9 | 14.0 | 39.0 | 60.9 |

Note: Sales of each product in Japan are shown by invoice price

**Japan**

- Sales of LATUDA®, TWYMEEG®, and LONASEN® Tape continue to grow
- Sales of TRERIEF® decreased due to loss of exclusivity
- Total impact of NHI drug price revision (¥3.1B)

**Asia**

- MEROPEN® (China) revenue increased despite the impact of Volume-Based Procurement application

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# Segment Information (Core Basis)

Billions of JPY

| | | Japan | North America | Asia | Total |
|---|---|---|---|---|---|
| Q2YTD FY2024 | Revenue | 52.8 | 104.2 | 23.7 | 180.7 |
| | Cost of sales | 27.0 | 39.4 | 5.9 | 72.3 |
| | Gross profit | 25.9 | 64.8 | 17.8 | 108.5 |
| | SG&A expenses | 19.6 | 57.4 | 6.4 | 83.4 |
| | Core segment profit | 6.3 | 7.4 | 11.4 | 25.1 |
| | R&D expenses | | | | 25.1 |
| | Core operating profit | | | | (0.0) |
| Q2YTD FY2023 | Revenue | 58.5 | 73.3 | 20.8 | 152.6 |
| | Cost of sales | 28.0 | 27.0 | 5.3 | 60.3 |
| | Gross profit | 30.6 | 46.3 | 15.5 | 92.3 |
| | SG&A expenses | 24.7 | 88.4 | 5.6 | 118.8 |
| | Core segment profit | 5.9 | (42.2) | 9.9 | (26.4) |
| | R&D expenses | | | | 45.3 |
| | Core operating profit | | | | (65.8) |
| Change | Revenue | (5.7) | 30.9 | 2.9 | 28.1 |
| | SG&A expenses | (5.1) | (31.1) | 0.8 | (35.3) |
| | Core segment profit | 0.4 | 49.6 | 1.5 | 51.5 |
| | R&D expenses | | | | (20.2) |
| | Core operating profit | | | | 65.8 |

**Japan**

- Despite a decrease in gross profit due to decline in revenue, core segment profit increased due to reduced SG&A expenses

**North America**

- In addition to increase in gross profit as a result of revenue growth, core segment profit increased significantly due to reduced SG&A expenses

**Asia**

- Core segment profit increased due to increased gross profit as a result of revenue growth

# Financial Forecasts for FY2024

**The initial financial forecasts remains unchanged at this point as there are uncertain factors**

- Revenue
  - In the second half of the fiscal year, revenue is expected to grow due to the three key products, and second half results should exceed first half results
    There is a slight downside risk due to factors such as headcount reduction following the implementation of early retirement program in Japan
- Costs
  - In the second half of the fiscal year, the outlook for SG&A expenses as well as R&D expenses is expected to be roughly in line with the Q2 financial results

⇒As a result of the above, the outlook for the core operating profit (loss) excluding other operating income/expenses is expected to be roughly in line with the Q2 financial results

- Other operating income/expenses (Core basis)
  - The success and scale of the multiple asset divestiture plans currently under negotiation could significantly impact earnings (In the initial financial forecasts: 20.0 billion JPY)
- Non-recurring items, Finance income/costs
  - The recording of business structure improvement expenses associated with the implementation of early retirement program in Japan will be a factor contributing to the cost of non-recurring items
  - The exchange rate at the end of the period will have an impact on final results, with a weak yen leading to a positive impact and a strong yen leading to a negative impact (assumption in the initial financial forecasts: 1US$=145)

# Initiatives towards the Reconstruction

# Strategic Scenarios for Regrowth

- By achieving profitability through short-term intensive measures and realizing the launch of development pipelines, the Company will return to a growth trajectory
  Create new value through R&D activities in the area of Oncology, Psychiatry & Neurology, and regenerative medicine and cell therapy business to establish a position as a "Global Specialized Player" by 2033

## Laying the foundation for regrowth

**Complete implementation of measures for regrowth**
**On track to return to achieve positive FCF***

**～FY2025**

**Achievement targets (business)**

- Focusing on business operations centered around three key products in the U.S.
- Changing organization size in line with revenue scale
- Selecting and Concentrating the R&D programs
- Completing of measures to streamline the organization

**Achievement targets (financial)**

- Turning core operating profit positive in FY2024
- Turning bottom line profit positive in FY2025

## Acquiring the next generation revenue base

**Ensure commercialization of priority investment pipeline**
**Continue to nurture in-house developed products**

**FY2026～2032**

- Launching and expanding of two oncology compounds (enzomenib/DSP-5336, nuvisertib/TP-3654)
- Fully launching the regenerative medicine and cell therapy business
- Nurturing early-stage development compounds in the areas of Oncology and Psychiatry & Neurology while maintaining financial discipline

- Eliminating excessive debt
- Turning FCF positive from FY2027 onward (excluding transient)

## Achieving a qualitative transformation in business structure

**Evolve to a business structure centered around innovations of its own origin**

**FY2033～**

- Restructuring of sustained business portfolio (Oncology and Psychiatry & Neurology, etc.)
- Establishing a unique global position through expansion of regenerative medicine and cell therapy business

* FCF: Free Cash Flow

# The Current Strategy for Business Reconstruction

## Implement a fundamental business structural reform through intensive short-term efforts and achieve a V-shaped recovery

Achieve early positive core operating profit and bottom line profit

- Expanding revenue (maximizing the value of the three key products early)
- Strengthening cost management
  - Implement personnel optimization and organizational restructuring to operate with a lean organization in line with revenue scale
  - Balancing continuous R&D and R&D expenses reduction through the selection and concentration of pipelines
    - ✓ Focus on the areas of Oncology, Psychiatry & Neurology, and the regenerative medicine and cell therapy business, while prioritizing early market launch

Strengthening financial position (repayment of borrowings)

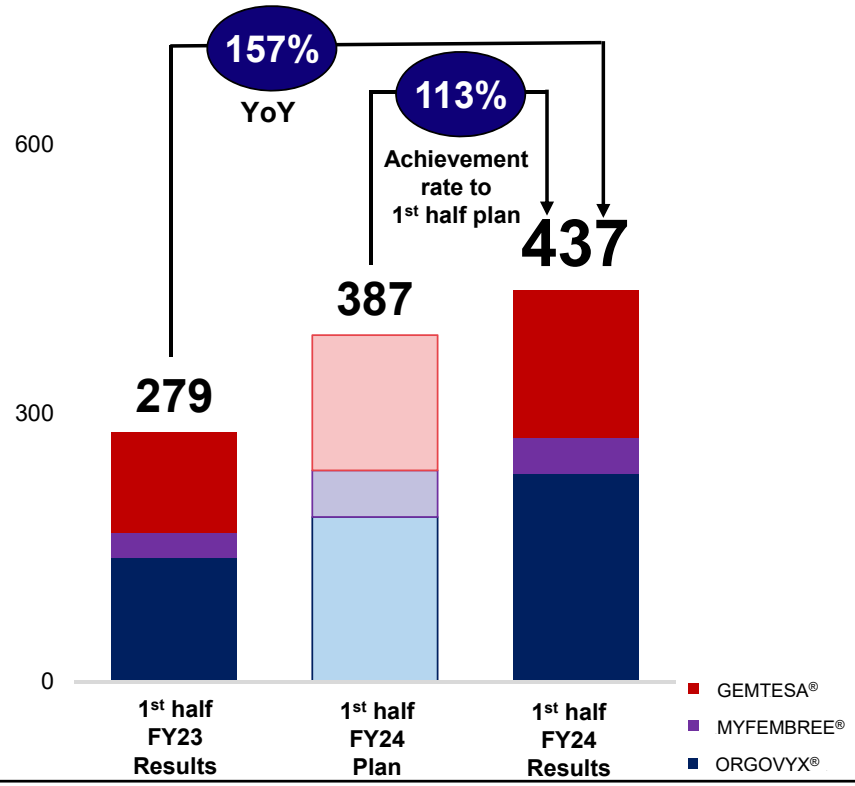
- Improving Free Cash Flow
- Streamlining of assets (selection and concentration of business areas, and sale of non-essential and non-urgent assets)

# Progress in Initiatives to Address the Challenges towards Reconstruction

## Expanding revenue

ORGOVYX® is making favorable progress in the U.S. and leading sales expansion of three key products

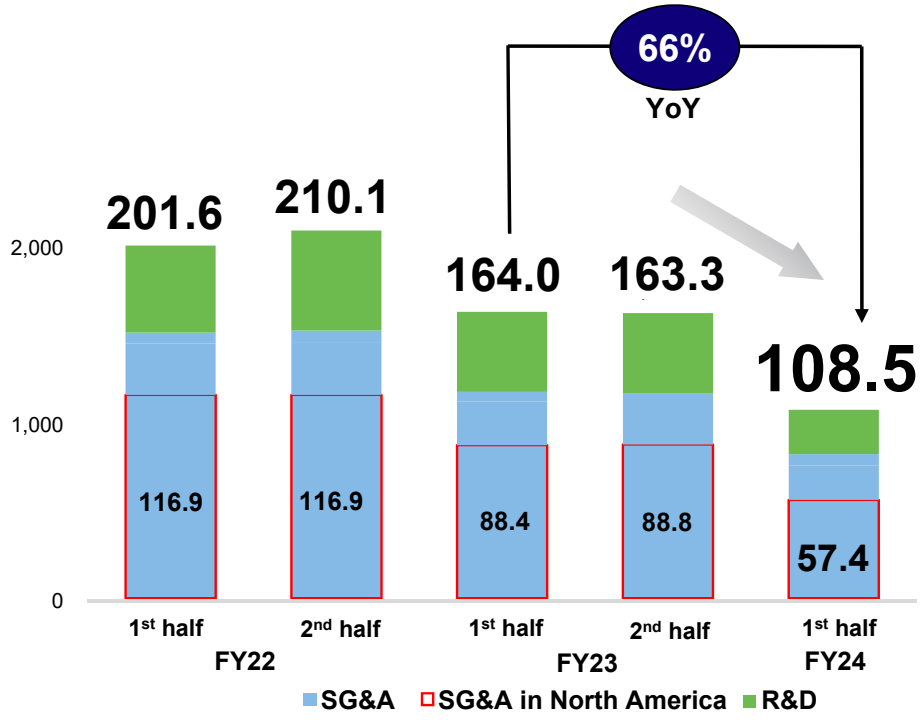
**Revenue of three key products (M$)**




## Reducing costs

The Group is focusing on increasing efficiency in organizational operations and trimming costs to the minimum. Achieved significant cost reductions, primarily in North America

**Trends in SG&A and R&D expenses (core basis, billions of JPY)**



# Initiatives towards the Reconstruction

## ORGOVYX®

| Plan for Q2 YTD FY2024 | Actual for Q2 YTD FY2024 | YoY comparison | Breakdown of actual volume and price difference from plan | |
|---|---|---|---|---|
| **$184M** | **$232M (126% to plan)** | **Approx. 69% increase** | Volume | $37M |
| | | | Price | $12M |

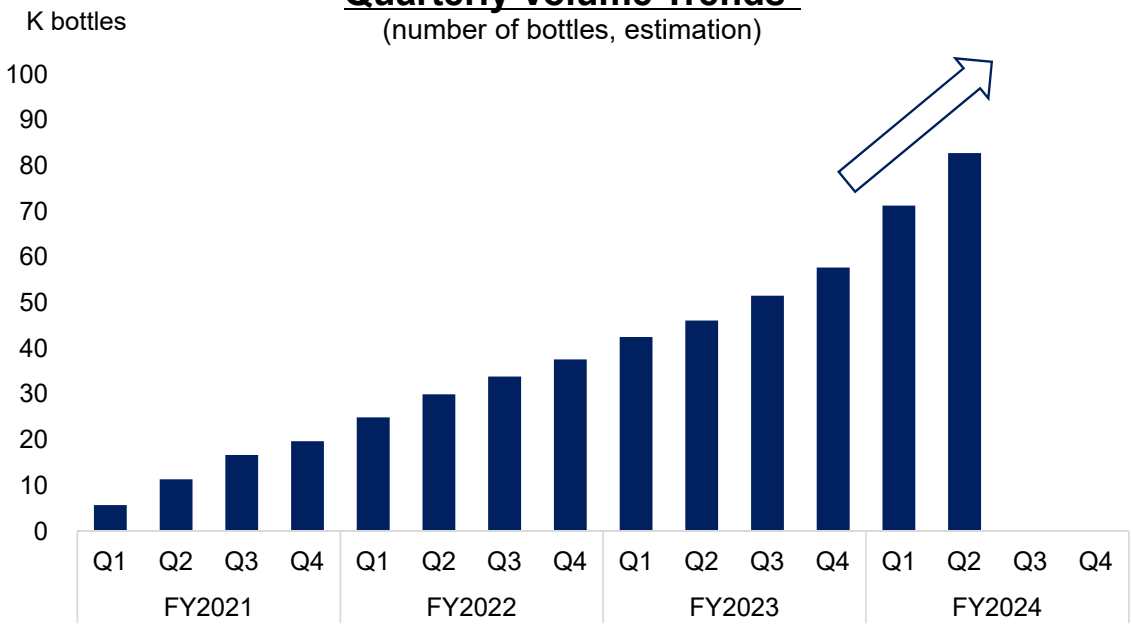
- Volume grew more than expected due to the changes in the medication benefit design for Medicare Part D
- Price was higher than expected due to the lower-than-anticipated returns and coverage gap

## Sales Forecasts and Marketing Topics

- Volume trend has accelerated since January 2024
- The further reduction in the patient's out-of-pocket cost cap scheduled for January 2025 is also expected to provide a tailwind, and revenue for this fiscal year is projected to exceed the initial plan

- New patient starts have continued to increase
- Strong demand growth continued in all account segments, with significant growth in Urology and Oncology Clinics with in-office dispensing as well as Academic Centers/Integrated Delivery Networks

**Quarterly Volume Trends***
(number of bottles, estimation)




* Internal calculation

Initiatives towards the Reconstruction

# MYFEMBREE®

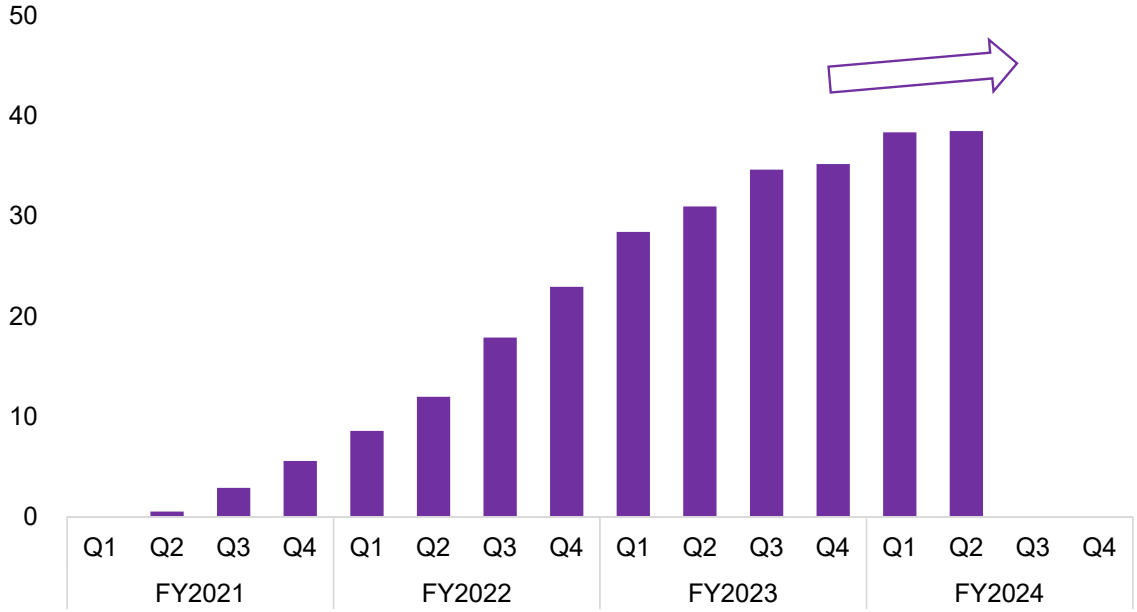
Myfembree® (relugolix, estradiol, and norethindrone acetate) tablets 40 mg, 1 mg, 0.5 mg

| Plan for Q2 YTD FY2024 | Actual for Q2 YTD FY2024 | YoY comparison | Breakdown of actual volume and price difference from plan | |
|---|---|---|---|---|
| **$52M** | **$40M (75% to plan)** | **Approx. 34% increase** | Volume | △$11M |
| | | | Price | △$2M |

- Volume grew less than expected due to the lower-than-expected market growth of GnRH antagonists and market share in EM*2
- Price was slightly lower than expected due to an increase in commercial rebates and allowance for sales returns

## Quarterly Volume Trends*1

(number of bottles, estimation)




## Sales Forecasts and Marketing Topics

While the volume has slightly grown, given the market trends of oral GnRH, achieving the initial plan for this fiscal year remains challenging

- Status by indication
  - UF*3: MYFEMBREE® has already captured over 80%*1 market share
  - EM: The market is shrinking, and share capture is less than expected
- Focus on field force execution to accelerate share growth in EM

*1 Source: *Symphony Health, an ICON plc Company, Metys®, April 1, 2021, to September 30, 2024.*, *2 endometriosis, *3 uterine fibroids

# Initiatives towards the Reconstruction

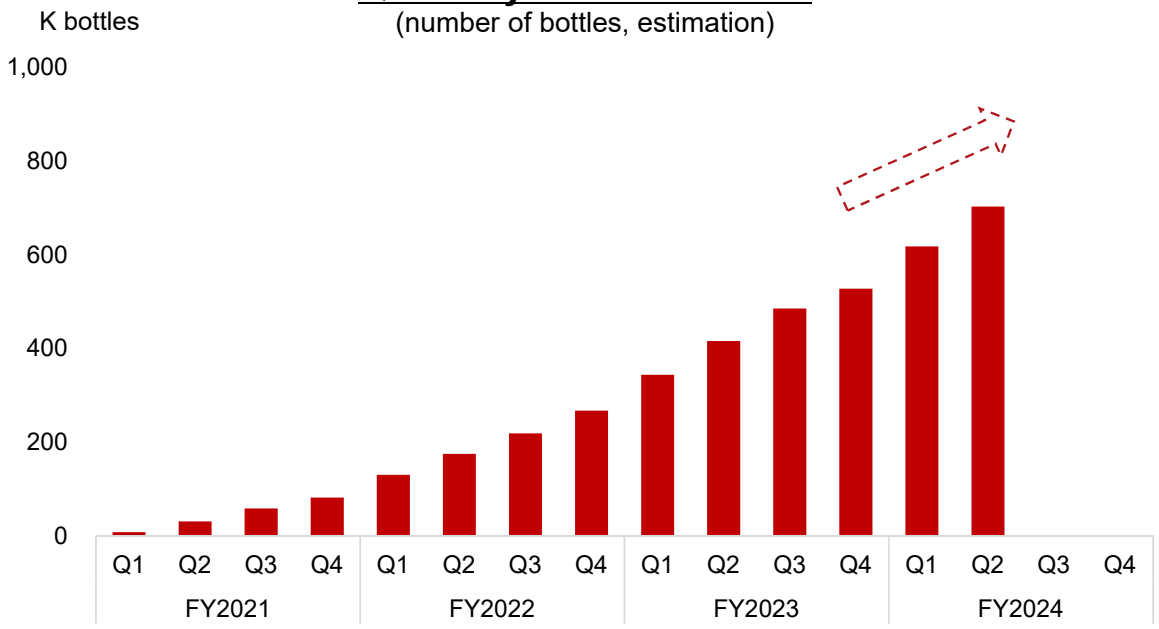
## GEMTESA®

| Plan for Q2 YTD FY2024 | Actual for Q2 YTD FY2024 | YoY comparison | Breakdown of actual volume and price difference from plan | |
|---|---|---|---|---|
| **$151M** | **$165M (109% to plan)** | **Approx. 47% increase** | Volume | △$4M |
| | | | Price | $19M |

- Volume grew slightly less than expected due to timing of downstream (retail) purchases
- Price was higher than expected due to several factors, including the lower-than-anticipated returns and coverage gap compared to the initial plan

### Quarterly Volume Trends*

(number of bottles, estimation)




### Sales Forecasts and Marketing Topics

- Volume has continued to grow despite the launch of generic mirabegron in April 2024
- Although the initial plan for this fiscal year is expected to be achieved, there are still uncertainties due to insurance resets after January 2025

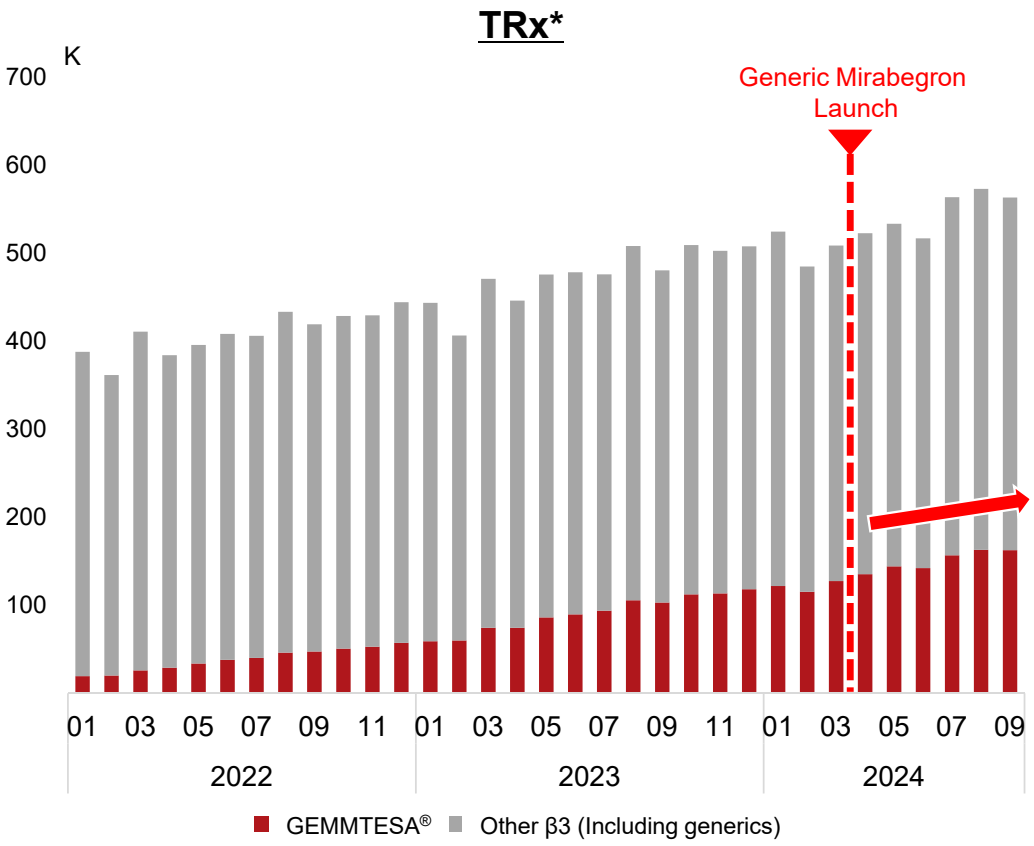
- Continue to promote the differentiated clinical profile of GEMTESA® including:
  - No blood pressure warning as approx. 60% of patients with overactive bladder also have hypertension
  - Low risk of interactions with other drugs
  - Efficacy on reducing urgency

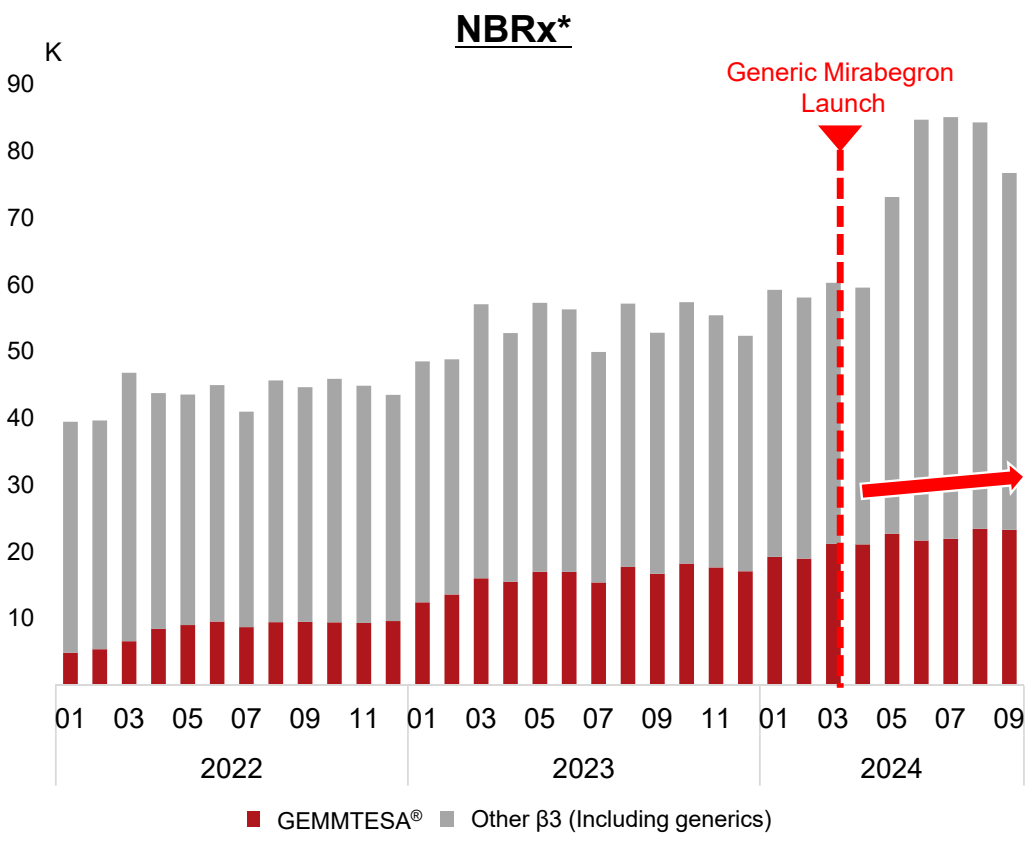
* Source: *Converted pill volume to number of bottles (30 tablets/bottle) based on information licensed from IQVIA: NPA for the period 4/1, 2021 to 9/30, 2024 reflecting estimates of real-world activity. All rights reserved.*

Initiatives towards the Reconstruction

## GEMTESA®

- GEMTESA® has continued to grow, even after the launch of generic Mirabegron since April 2024




* Source: *Based on information licensed from IQVIA: NPA for the period 1/1, 2022 to 9/30, 2024 reflecting estimates of real-world activity. All rights reserved.*

Initiatives towards the Reconstruction

# New Structure from December 2024

## Research and Development Division

### Build a structure that can conduct R&D activities efficiently and continuously

- Drug Research Division, Drug Development Division, and Technology Research & Development Division will be integrated to promote a unified R&D activities through a lean organization
- 3 Divisions 17 Departments→1 Division 15 Departments
  Approx. 560→ Approx. 440 employees

**R&D Strategy**

- Focus on development programs for the two oncology programs that are close to launch and regenerative medicine and cell therapy
- Promote small molecule development programs in the area of Oncology and Psychiatry & Neurology to support the 2030's

## Sales & Marketing Division

### Build a sales structure in Japan that can continuously secure profits

- Division's functions and branches will be reorganized for efficient organization and productivity improvement
- 19→10 Departments (including 12→7 branches)
  Approx. 1,050→ Approx. 620 employees (including MRs: approx. 770→450 employees)

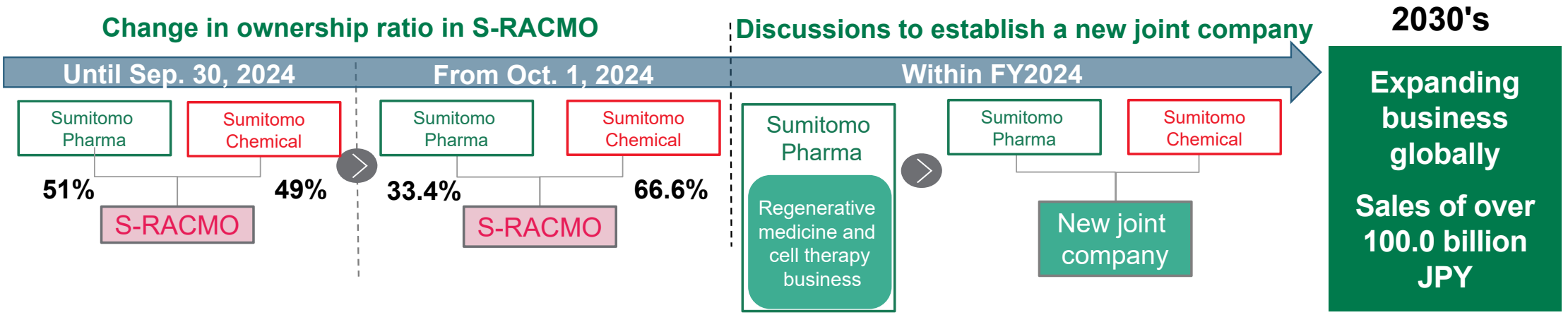
**Sales & Marketing Strategy**

- Shift the MR deployment from a disease area system to an area system
- Minimize the impact of headcount reduction by providing information that meets customer needs

■ Corporate Departments: Related functional departments will be integrated and reorganized into a lean and efficient organization (18→13 departments)

Initiatives towards the Reconstruction

# Changes in the Structure of the Regenerative Medicine and Cell Therapy Business




**Aim of Sumitomo Pharma**

The benefits of integrated operations with Sumitomo Chemical

- **Continue investing in R&D as well as production facilities**, enabling acceleration of commercialization
- Fully leverage **technologies and expertise as a front-runner** in the field of regenerative medicine and cell therapy
- **Maintain the infrastructure of the pharmaceutical functions**, while flexibly considering and determining the business structure, including the pharmaceutical business

# Research and Development

Research and Development

# Development Pipeline (as of October 30, 2024)

No revisions since the announcement in July 2024

| Area | Generic name/Product code | Mechanism of action, etc. | Proposed indication | Region | Development stage |
|---|---|---|---|---|---|
| Psychiatry & Neurology | DSP-0038 | Serotonin 5-$HT_{2A}$ receptor antagonist and serotonin 5-$HT_{1A}$ receptor agonist | Alzheimer's disease psychosis | U.S. | Phase 1 |
| | DSP-0187 | Selective orexin 2 receptor agonist | Narcolepsy | Japan | Phase 1 |
| | DSP-3456 | Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM) | Treatment resistant depression | U.S. | Phase 1 |
| | DSP-0378 | Gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator | Dravet syndrome, Lennox-Gastaut syndrom | Japan | Phase 1 |
| | DSP-2342 | Serotonin 5-$HT_{2A}$ and 5-$HT_7$ receptor antagonist | To be determined | U.S. | Phase 1 |
| | CT1-DAP001/DSP-1083 | Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells | Parkinson's disease/Investigator-initiated study | Japan | Under preparation for the NDA |
| | CT1-DAP001/DSP-1083 | Allogeneic iPS cell-derived dopaminergic neural progenitor cells | Parkinson's disease/Investigator-initiated study, Company-sponsored clinical study | U.S. | Phase 1/2 |
| | HLCR011 | Allogeneic iPS cell-derived retinal pigment epithelial cells | Retinal pigment epithelium tear | Japan | Phase 1/2 |
| Oncology | nuvisertib/TP-3654 | PIM1 kinases inhibitor | Myelofibrosis | U.S., Japan | Phase 1/2 |
| | enzomenib/DSP-5336 | Menin and MLL inhibitor | Acute myeloid leukemia | U.S., Japan | Phase 1/2 |
| | DSP-0390 | EBP inhibitor | Glioblastoma | U.S., Japan | Phase 1 |
| | SMP-3124 | CHK1 inhibitor | Solid tumors | U.S., Japan | Phase 1/2 |
| Others | vibegron (Brand name: GEMTESA®) | ß3 adrenergic receptor agonist | (New indication) Overactive bladder (OAB) in men with benign prostatic hyperplasia (BPH) | U.S. | sNDA submitted in February 2024 |
| | vibegron | ß3 adrenergic receptor agonist | Overactive bladder (OAB) | China | Phase 3 |
| | KSP-1007 | β-lactamases inhibitor | Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia | U.S., Japan | Phase 1 |
| | fH1/DSP-0546LP | Split, Adjuvanted vaccine | Influenza virus prophylaxis | Europe | Phase 1 |

# Major Topics in Clinical Development

## Psychiatry & Neurology (Regenerative medicine/cell therapy)

**Allogeneic iPS cell-derived dopaminergic neural progenitor cells (Japan)**

- Preparing for NDA submission based on the data from the investigator-initiated study for Parkinson's disease by Kyoto University
  Had been aiming for NDA submission and obtaining approval by the end of FY2024, but at present reviewing the submission target based on discussions with the PMDA
- Release of the results of the investigator-initiated study by Kyoto University

**Allogeneic iPS cell-derived retinal pigment epithelial cells (Japan)**

- Conducted the first patient transplantation in the Phase 1/2 study for RPE tear

## Oncology

**enzomenib (DSP-5336) (U.S., Japan)**

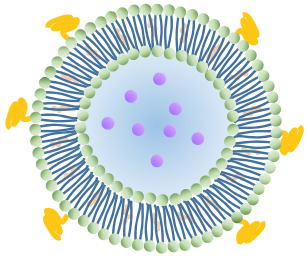
- Started the combination cohort study with other drugs in the Phase 1/2 study for acute myeloid leukemia in the U.S.
- Received Orphan Drug Designation from the Ministry of Health, Labour and Welfare Designation in Japan
- Plan to present new clinical data at the American Society of Hematology (ASH) 2024 in December 2024

**nuvisertib (TP-3654) (U.S., Japan)**

- Plan to present new clinical data at ASH 2024

**SMP-3124 (U.S., Japan)**

- Started the patient dosing in the Phase 1/2 study in the U.S. and Japan



SMP-3124: Nanomedicine, a CHK1 inhibitor encapsulated within liposome

## Others

**vibegron (China)**

- Based on results of the Phase 3 study in patients with overactive bladder (OAB), the bridging study was unsuccessful.
  The development strategy is under consideration

**XENLETA® (lefamulin) (China)**

- Submitted the local manufacturing applications for injectable formulations in May 2024 and tablet formulations in August 2024. Aim to launch in FY2025

# Appendix

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Appendix (Financial Results for Q2 FY2024)

# Financial Results for Q2 FY2024 (Full Basis)

Billions of JPY

| | Q2YTD FY2023 Results | Q2YTD FY2024 Results | Change | |
|---|---|---|---|---|
| | | | Value | % |
| Revenue | 152.6 | 180.7 | 28.1 | 18.4 |
| Cost of sales | 60.3 | 72.3 | 12.0 | 19.9 |
| Gross profit | 92.3 | 108.4 | 16.1 | 17.4 |
| SG&A expenses | 134.0 | 90.0 | (44.0) | (32.9) |
| R&D expenses | 50.4 | 26.3 | (24.1) | (47.8) |
| Other operating income and expenses | 5.6 | (0.3) | (5.9) | |
| Operating profit | (86.5) | (8.2) | 78.3 | — |
| Finance income and costs | 30.4 | (24.2) | (54.6) | |
| Profit before taxes | (56.1) | (32.4) | 23.7 | — |
| Income tax expenses | 11.6 | (0.2) | (11.8) | |
| Net profit | (67.7) | (32.2) | 35.5 | — |
| Net profit attributable to owners of the parent | (67.7) | (32.2) | 35.5 | — |

# Financial Position and Cash Flow

Billions of JPY

| B / S | As of March 2024 | As of Sep. 2024 | Change |
|---|---|---|---|
| Assets | 907.5 | 799.8 | (107.7) |
| Goodwill / Intangible assets | 395.4 | 368.5 | (26.9) |
| Other financial assets (Non-current) | 161.7 | 39.4 | (122.3) |
| Cash and deposit / Short-term loan receivable | 29.0 | 99.1 | 70.0 |
| Liabilities | 751.4 | 685.5 | (65.8) |
| Bonds and borrowings | 418.9 | 389.4 | (29.5) |
| Deferred tax liabilities | 38.2 | 14.1 | (24.1) |
| Income taxes payable | 1.3 | 18.6 | 17.3 |
| Equity | 156.1 | 114.2 | (41.9) |
| Attributable to owners of the parent | 156.1 | 114.2 | (41.9) |
| (Ratio of equity attributable to owners of the parent to total assets) | 17.2% | 14.3% | |

| C / F | Q2 FY2023 | Q2 FY2024 | Change |
|---|---|---|---|
| Operating CF | (174.5) | 4.6 | 179.0 |
| Investment CF | 32.7 | 97.5 | 64.8 |
| Financial CF | 44.8 | (29.4) | (74.2) |
| Cash and cash equivalents | 60.4 | 99.1 | 38.7 |
| (Operating funds) | 62.1 | 99.1 | 37.0 |

Decrease due to FX rate impact

Decrease due to sales of investment securities

Decrease in short-term borrowings

Decrease due to sales of investment securities

Increase due to sales of investment securities

Q2 FY2023: In addition to net loss, decrease in provisions and increase in corporate income tax payments
Q2 FY2024: In addition to improvement in net profit, increase in provisions and corporate income tax refunds

Q2 FY2023: Proceeds from sales of Sumitomo Pharma Animal Health Co., Ltd. shares
Q2 FY2024: Proceeds from sales of investment securities

Q2 FY2023: Increase in short-term borrowings
Q2 FY2024: Decrease in short-term borrowings

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Appendix (Research and Development)

# Main Events / Targets for FY2024 (as of October 30, 2024)

Revisions since the announcement in July 2024 are shown in red

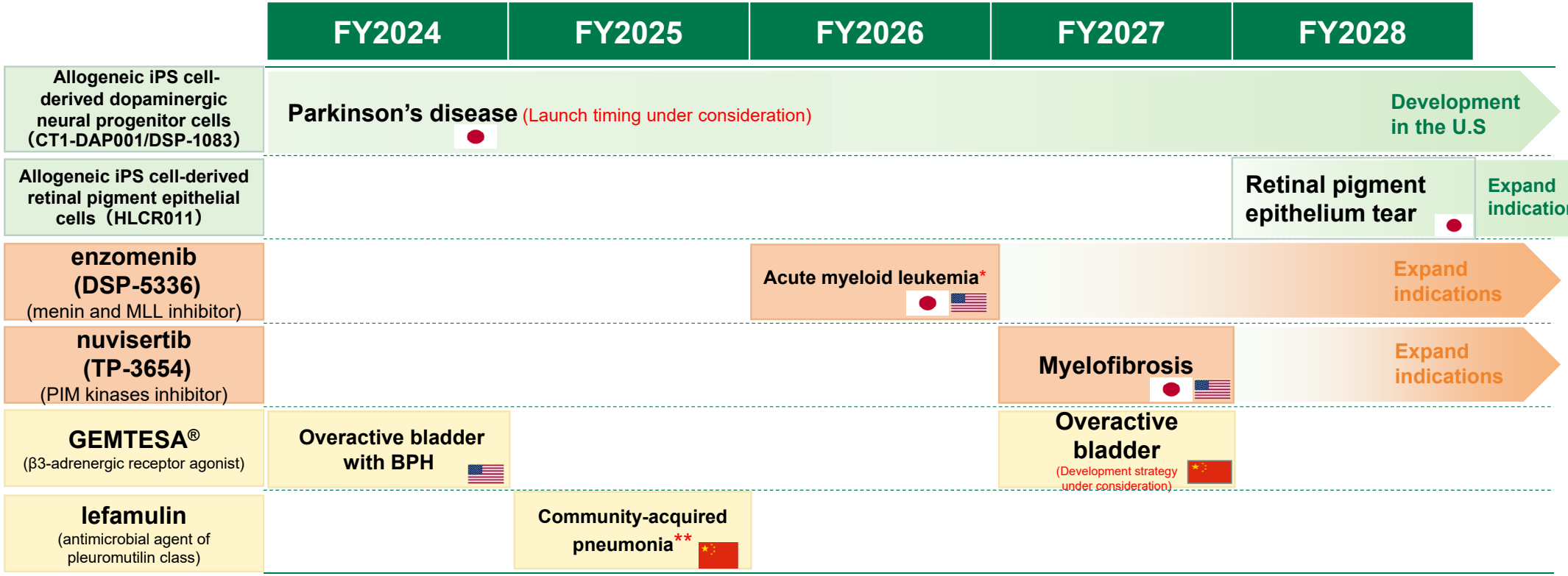
| | |
|---|---|
| **Psychiatry & Neurology** | ☐ Allogeneic iPS cell-derived products (Parkinson's disease): Submit NDA in Japan<br>→ Target submission date under consideration<br>☐ Allogeneic iPS cell-derived products (Parkinson's disease): Obtain approval in Japan<br>→ Target approval date under consideration<br>☐ Allogeneic iPS cell-derived products (Parkinson's disease): First patient implantation in the U.S.<br>☐ Allogeneic iPS cell-derived products (Retinal pigment epithelium tear): Start a randomized part of Phase 1/2 study in Japan<br>☐ Advance early Phase studies |
| **Oncology** | ☐ nuvisertib (TP-3654) ( ☐ Advance Phase 1/2 study ☑ Start the combination part of the study with a JAK inhibitor)<br>☐ enzomenib (DSP-5336) ( ☐ Advance Phase 1/2 study ☐ Start the Phase 2 part)<br>☐ SMP-3124 ( ☐ Advance Phase 1/2 study in the U.S. ☑ Start the same Phase 1/2 study in Japan) |
| **Others** | ☐ vibegron: Obtain approval for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S.<br>☐ Advance early Phase studies of universal influenza vaccine and others |
| **Frontier** | ☐ Promote the current themes and generate evidence data for maximizing the value of the launched products |

Appendix (Research and Development)

# Product Launch Target (as of October 30, 2024)

Psychiatry & Neurology | Oncology | Others

Revisions since the announcement in July 2024 are shown in red




* Relapsed or refractory acute myeloid leukemia with MLL rearrangement or NPM1 mutation

** Revised from "Under review for launch target" to "FY2025"

Appendix (Research and Development)

## Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of October 30, 2024)

Revisions since the announcement in July 2024 are shown in red

| Brand name/Cell type Product code | Indications | JP/ US | Pre-clinical | Clinical research | Phase 1/2 | Phase 3 | Approval application | Approval→ Launch |
|---|---|---|---|---|---|---|---|---|
| RETHYMIC® | Congenital athymia | US | | | | | | ● |
| Dopaminergic neural progenitor cells (Allo iPS cell-derived) CT1-DAP001/DSP-1083 | Parkinson's disease | JP<br>US | | | ●1<br>●4 ●5 | | | Launch timing under consideration |
| Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011 | Retinal pigment epithelium tear | JP | | | ●5 | | | |
| Photoreceptor (3D) (Allo iPS cell-derived) DSP-3077 | Retinitis pigmentosa | JP<br>US | ● | ●2 | | | | |
| Neural progenitor cells (Allo iPS cell-derived) | Spinal cord injury | JP<br>US | | ●3 | | | | |
| Nephron progenitor cells (organ) (Auto/ Allo iPS cell-based induced) | Kidney failure | JP/ US | ● | | | | | |

1. Kyoto University Hospital 2. Kobe City Eye Hospital 3. Keio University Hospital 4. University of California San Diego School of Medicine
5. Company-sponsored clinical study

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Appendix (Research and Development)

# Frontier Business Product Launch Target (as of October 30, 2024)

No revisions since the announcement in July 2024

: Non-medical device
: Medical device

| | FY2024 | FY2025 | FY2026 | FY2027 | FY2028 |
|---|---|---|---|---|---|
| **VR contents** (BehaVR, Inc.) | | | Social Anxiety Disorder | VR contents in other disease area | |
| **MELTz®** | | "MELTz® Portable" (finger exercise training system) | | | |
| **Wearable EEG meter** (NeuroSky Co., Ltd.) | | Depression | | Depression | |
| **Violet Light** (Tsubota Laboratory Incorporated) | | Depression / Dementia | | Depression / Dementia | |

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