



# **Conference on Q2 FY2025 (April 1, 2025 to September 30, 2025) Financial Results**

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**Sumitomo Pharma Co., Ltd.**

**October 31, 2025**

## ■ Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, goals, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of disclosure of such statements and involve both known and unknown risks and uncertainties.

Accordingly, due to various subsequent factors, forecasts, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals and other products (including those under development) contained herein is not intended as advertising or as medical advice.



# Financial Results for Q2 FY2025

## Financial Results for Q2 FY2025

# Financial Results for Q2 FY2025 (Core Basis)

The forecasts for FY2025 were revised  
(See P.8)

Billions of JPY

|                                                             | Q2YTD<br>FY2024<br>Results | Q2YTD<br>FY2025<br>Results | Change |           |        | FY2025                  |       |
|-------------------------------------------------------------|----------------------------|----------------------------|--------|-----------|--------|-------------------------|-------|
|                                                             |                            |                            | Value  | FX impact | %      | July 31 1H<br>Forecasts | %     |
| <b>Revenue</b>                                              | 180.7                      | <b>227.1</b>               | 46.4   | (8.2)     | 25.7   | 207.0                   | 109.7 |
| Cost of sales                                               | 72.3                       | <b>89.7</b>                | 17.4   | (3.0)     | 24.1   | 81.5                    | 110.1 |
| Gross profit                                                | 108.5                      | <b>137.4</b>               | 28.9   | (5.2)     | 26.7   | 125.5                   | 109.5 |
| SG&A expenses                                               | 83.4                       | <b>74.0</b>                | (9.5)  | (2.5)     | (11.3) | 78.0                    | 94.8  |
| R&D expenses                                                | 25.1                       | <b>17.5</b>                | (7.6)  | (0.6)     | (30.4) | 22.0                    | 79.4  |
| Others (core basis)                                         | (0.0)                      | <b>50.1</b>                | 50.1   |           |        | 44.5                    | 112.6 |
| <b>Core operating profit</b>                                | (0.0)                      | <b>96.1</b>                | 96.1   | (2.1)     | —      | 70.0                    | 137.3 |
| Adjustment items<br>(negative number indicates net expense) | (8.1)                      | <b>0.1</b>                 | 8.2    |           |        |                         |       |
| <b>Operating profit</b>                                     | (8.2)                      | <b>96.2</b>                | 104.3  |           | —      | 69.0                    | 139.4 |
| Finance income/costs                                        | (24.2)                     | <b>(3.4)</b>               | 20.9   |           |        |                         |       |
| Profit before taxes                                         | (32.4)                     | <b>92.8</b>                | 125.2  |           | —      |                         |       |
| Income tax expenses                                         | (0.2)                      | <b>(6.1)</b>               | (5.9)  |           |        |                         |       |
| <b>Net profit attributable to owners<br/>of the parent</b>  | (32.2)                     | <b>98.9</b>                | 131.1  |           | —      | 56.0                    | 176.5 |

- Revenue increased primarily due to the growth of ORGOVYX® and GEMTESA® and sales milestone revenue from ORGOVYX®
- SG&A expenses and R&D expenses decreased due to business structure improvements and realignment of the regenerative medicine and cell therapy business
- Others (core basis)  
FY2025: Gain on partial transfer of the Asian business +¥49.0B
- Adjustment items:  
FY2024: Business structure improvement expenses in Japan and North America

### Average rates:

Q2 FY2024 Results : 1US\$ = ¥152.78, 1RMB = ¥21.77  
Q2 FY2025 Results : 1US\$ = ¥146.03, 1RMB = ¥20.12  
FY2025 forecasts : 1US\$ = ¥145.00, 1RMB = ¥20.00

### Period end rates:

As of the end of March 2025 : 1US\$ = ¥149.53, 1RMB = ¥20.59  
As of the end of September 2025 : 1US\$ = ¥148.81, 1RMB = ¥20.74

## Financial Results for Q2 FY2025

# Revenue of Major Products in North America

|                                             | Q2YTD<br>FY2024<br>Results | Q2YTD<br>FY2025<br>Results | Change | Q2YTD<br>FY2024<br>Results | Q2YTD<br>FY2025<br>Results | Change |              |        | FY2025             |                    |                         |
|---------------------------------------------|----------------------------|----------------------------|--------|----------------------------|----------------------------|--------|--------------|--------|--------------------|--------------------|-------------------------|
|                                             |                            |                            |        |                            |                            | Value  | FX<br>impact | %      | May 13 forecasts   |                    | JPY-basis<br>Progress % |
| North America                               | Millions of USD            |                            |        | Billions of JPY            |                            |        |              |        | Millions<br>of USD | Billions<br>of JPY |                         |
| ORGOVYX®                                    | 232                        | 473                        | 241    | 35.5                       | 69.1                       | 33.6   | (3.2)        | 94.7   | 710                | 103.0              | 67.1                    |
| MYFEMBREE®                                  | 40                         | 43                         | 4      | 6.0                        | 6.3                        | 0.3    | (0.3)        | 4.9    | 85                 | 12.3               | 51.6                    |
| GEMTESA®                                    | 165                        | 297                        | 132    | 25.2                       | 43.4                       | 18.1   | (2.0)        | 71.9   | 572                | 82.9               | 52.3                    |
| RETHYMIC®                                   | 19                         | 22                         | 3      | 2.9                        | 3.3                        | 0.4    | (0.1)        | 12.0   | 45                 | 6.5                | 50.7                    |
| APTIOM®                                     | 131                        | 73                         | (57)   | 19.9                       | 10.7                       | (9.3)  | (0.5)        | (46.5) | 33                 | 4.8                | 222.5                   |
| Others                                      | 28                         | 25                         | (4)    | 4.3                        | 3.6                        | (0.7)  | (0.2)        | (16.6) | 267                | 38.7               | 77.9                    |
| Export products/<br>One-time revenue, etc.* | 67                         | 179                        | 112    | 10.2                       | 26.6                       | 16.3   | (1.0)        | 160.0  |                    |                    |                         |
| Total                                       | 682                        | 1,113                      | 432    | 104.2                      | 163.0                      | 58.8   | (7.3)        | 56.4   | 1,712              | 248.2              | 65.7                    |

\* Major items included in Export products/One-time revenue, etc.

|                             |                                                                 |                             |                                                                                                                       |
|-----------------------------|-----------------------------------------------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Q2YTD<br>FY 2024<br>Results | Deferred revenue from<br>the collaboration with Pfizer<br>\$59M | Q2YTD<br>FY 2025<br>Results | Deferred revenue from<br>the collaboration with Pfizer<br>Sales milestone revenue from<br>ORGOVYX®<br>\$44M<br>\$100M |
|-----------------------------|-----------------------------------------------------------------|-----------------------------|-----------------------------------------------------------------------------------------------------------------------|

- ORGOVYX® and GEMTESA® revenue increased significantly year-on-year
- APTIOM® revenue decreased due to loss of exclusivity
- Sales milestone revenue from ORGOVYX® has been recognized

Average rates:  
Q2 FY2024 Results : 1US\$ = ¥152.78  
Q2 FY2025 Results : 1US\$ = ¥146.03  
FY2025 forecasts : 1US\$ = ¥145.00

## Financial Results for Q2 FY2025

# Revenue of Major Products in Japan

Billions of JPY

|                                            | Q2YTD<br>FY2024<br>Results | Q2YTD<br>FY2025<br>Results | Change |        | FY2025              |               |
|--------------------------------------------|----------------------------|----------------------------|--------|--------|---------------------|---------------|
|                                            |                            |                            | Value  | %      | May 13<br>forecasts | Progress<br>% |
| Japan                                      |                            |                            |        |        |                     |               |
| LATUDA®                                    | 6.7                        | 6.9                        | 0.2    | 3.6    | 13.5                | 51.1          |
| TWYMEEG®                                   | 3.6                        | 5.0                        | 1.4    | 40.3   | 11.2                | 44.5          |
| METGLUCO®                                  | 3.8                        | 3.7                        | (0.1)  | (1.9)  | 7.6                 | 48.6          |
| Equa®/EquMet®                              | 14.2                       | 7.5                        | (6.7)  | (47.0) | 7.0                 | 107.1         |
| LONASEN® Tape                              | 2.3                        | 2.5                        | 0.2    | 9.3    | 5.2                 | 47.8          |
| AG products                                | 5.6                        | 6.1                        | 0.5    | 9.1    | 11.6                | 52.3          |
| Others                                     | 12.8                       | 11.2                       | (1.6)  | (12.6) | 29.6                | 51.5          |
| Export products/<br>One-time revenue, etc. | 4.1                        | 4.0                        | (0.0)  | (0.4)  |                     |               |
| Total                                      | 52.8                       | 46.9                       | (6.0)  | (11.3) | 85.7                | 54.7          |

- TWYMEEG® revenue continued to grow
- Equa®/EquMet® revenue decreased due to loss of exclusivity
- Total impact of NHI drug price revision (¥0.5B)

Note: Sales of each product are shown by invoice price

## Financial Results for Q2 FY2025

### Segment Information (Core Basis)

Billions of JPY

|                 |                       | Japan | North America | Asia | Total |
|-----------------|-----------------------|-------|---------------|------|-------|
| Q2YTD<br>FY2025 | Revenue               | 46.9  | 163.0         | 17.3 | 227.1 |
|                 | Cost of sales         | 24.5  | 61.2          | 4.1  | 89.7  |
|                 | Gross profit          | 22.4  | 101.8         | 13.2 | 137.4 |
|                 | SG&A expenses         | 14.5  | 55.2          | 4.2  | 74.0  |
|                 | Core segment profit   | 7.9   | 46.6          | 9.0  | 63.5  |
|                 | R&D expenses          |       |               |      | 17.5  |
|                 | Core operating profit |       |               |      | 96.1  |

|                 |                       |      |       |      |       |
|-----------------|-----------------------|------|-------|------|-------|
| Q2YTD<br>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) |

|        |                       |       |       |       |       |
|--------|-----------------------|-------|-------|-------|-------|
| Change | Revenue               | (6.0) | 58.8  | (6.4) | 46.4  |
|        | SG&A expenses         | (5.1) | (2.2) | (2.2) | (9.5) |
|        | Core segment profit   | 1.7   | 39.1  | (2.4) | 38.4  |
|        | R&D expenses          |       |       |       | (7.6) |
|        | Core operating profit |       |       |       | 96.1  |

#### Japan

- Despite the decline of gross profit due to lower revenue, core segment profit increased due to SG&A expense reduction

#### North America

- In addition to increase in gross profit resulting from revenue growth, core segment profit increased significantly due to SG&A expenses reduction

#### Asia

- Core segment profit decreased due to the partial transfer of the Asian business



# Financial Forecasts for FY2025

## Financial Forecasts for FY2025

# Financial Forecasts for FY2025 (Core Basis)

Billions of JPY

|                                                      | FY2025<br>May 13<br>Forecasts | FY2025<br>Revised<br>Forecasts | Change from Previous<br>forecasts |       |
|------------------------------------------------------|-------------------------------|--------------------------------|-----------------------------------|-------|
|                                                      |                               |                                | Value                             | %     |
| Revenue                                              | 355.0                         | <b>429.0</b>                   | 74.0                              | 20.8  |
| Cost of sales                                        | 146.0                         | <b>186.5</b>                   | 40.5                              | 27.7  |
| Gross profit                                         | 209.0                         | <b>242.5</b>                   | 33.5                              | 16.0  |
| SG&A expenses                                        | 153.5                         | <b>152.0</b>                   | (1.5)                             | (1.0) |
| R&D expenses                                         | 44.0                          | <b>44.0</b>                    | —                                 | —     |
| Others (core basis)                                  | 44.5                          | <b>50.5</b>                    | 6.0                               |       |
| Core operating profit                                | 56.0                          | <b>97.0</b>                    | 41.0                              | 73.2  |
| Adjustment items<br>(negative number indicates loss) | (2.0)                         | <b>1.0</b>                     | 3.0                               |       |
| Operating profit                                     | 54.0                          | <b>98.0</b>                    | 44.0                              | 81.5  |
| Finance income/costs                                 | (14.0)                        | <b>(12.0)</b>                  | 2.0                               |       |
| Income tax expenses                                  | 0.0                           | <b>(6.0)</b>                   | (6.0)                             |       |
| Net profit                                           | 40.0                          | <b>92.0</b>                    | 52.0                              | 130.0 |
| Net profit attributable to owners of the parent      | 40.0                          | <b>92.0</b>                    | 52.0                              | 130.0 |
| R O E                                                | 21.1%                         | <b>43.0%</b>                   |                                   |       |
| R O I C                                              | 11.8%                         | <b>20.7%</b>                   |                                   |       |

### FX rates:

FY2025

Previous Forecasts : 1US\$ = ¥145.00, 1RMB = ¥20.00

Revised Forecasts : 1US\$ = ¥145.00, 1RMB = ¥20.12

- **Revenue:** Revised upward by ¥74.0B  
Japan +¥6.8B : EquMet® revised up  
North America +¥65.4B : ORGOVYX® revised up  
China +¥1.8B : MEROPEN® (China) revised up
- **SG&A and R&D expenses:**  
In line with previous forecasts
- **Others (core basis):**  
Gain on partial transfer of the Asian business  
+¥49.0B
- **Income tax expenses :**  
Gain on reversal of deferred tax liabilities  
due to assignment of intangible assets within  
our group

## Financial Forecasts for FY2025

# Revenue of Major Products in North America

|                                            | FY2025<br>May 13<br>Forecasts | FY2025<br>Revised<br>Forecasts | Change | FY2025<br>May 13<br>Forecasts | FY2025<br>Revised<br>Forecasts | Change |       |
|--------------------------------------------|-------------------------------|--------------------------------|--------|-------------------------------|--------------------------------|--------|-------|
|                                            |                               |                                |        |                               |                                | Value  | %     |
| North America                              | Millions of USD               |                                |        | Billions of JPY               |                                |        |       |
| ORGOVYX®                                   | 710                           | 1,020                          | 310    | 103.0                         | 147.9                          | 44.9   | 43.6  |
| MYFEMBREE®                                 | 85                            | 85                             | —      | 12.3                          | 12.3                           | —      | —     |
| GEMTESA®                                   | 572                           | 588                            | 16     | 82.9                          | 85.3                           | 2.4    | 2.9   |
| RETHYMIC®                                  | 45                            | 45                             | —      | 6.5                           | 6.5                            | —      | —     |
| APTiom®                                    | 33                            | 85                             | 52     | 4.8                           | 12.3                           | 7.5    | 156.3 |
| Others                                     | 267                           | 340                            | 73     | 38.7                          | 49.3                           | 10.6   | 27.4  |
| Export products/<br>One-time revenue, etc. |                               |                                |        |                               |                                |        |       |
| Total                                      | 1,712                         | 2,163                          | 451    | 248.2                         | 313.6                          | 65.4   | 26.3  |

**FX rates:** Not changed

FY2025 Forecasts : 1US\$ = ¥145.00

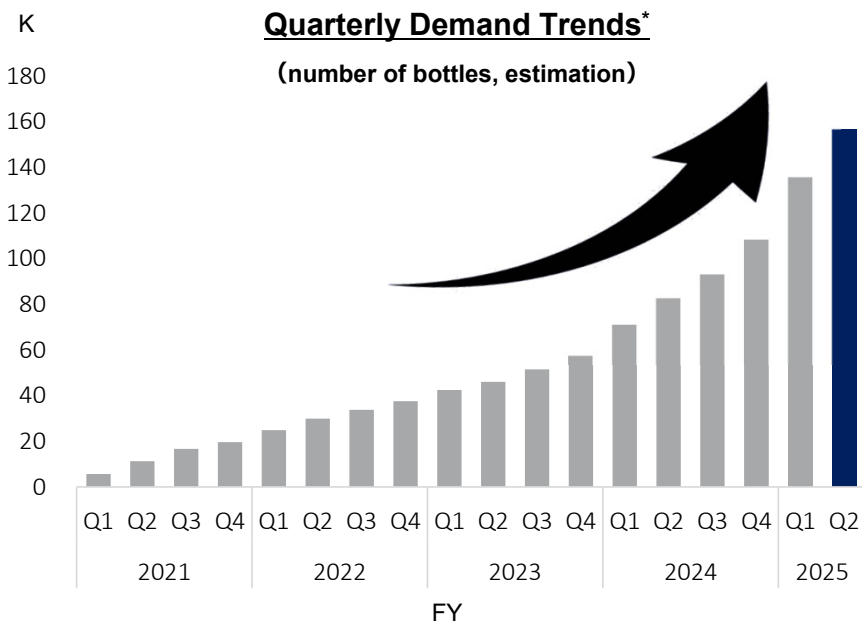
- Sales of ORGOVYX® and GEMTESA® revised upward with strong sales
- ORGOVYX® expected to exceed \$1B
- Sales of APTiom® revised upward due to slower decline than expected after loss of exclusivity
- Others increased due to bulk exports of three key products to the EU and other regions

## Financial Forecasts of FY2025

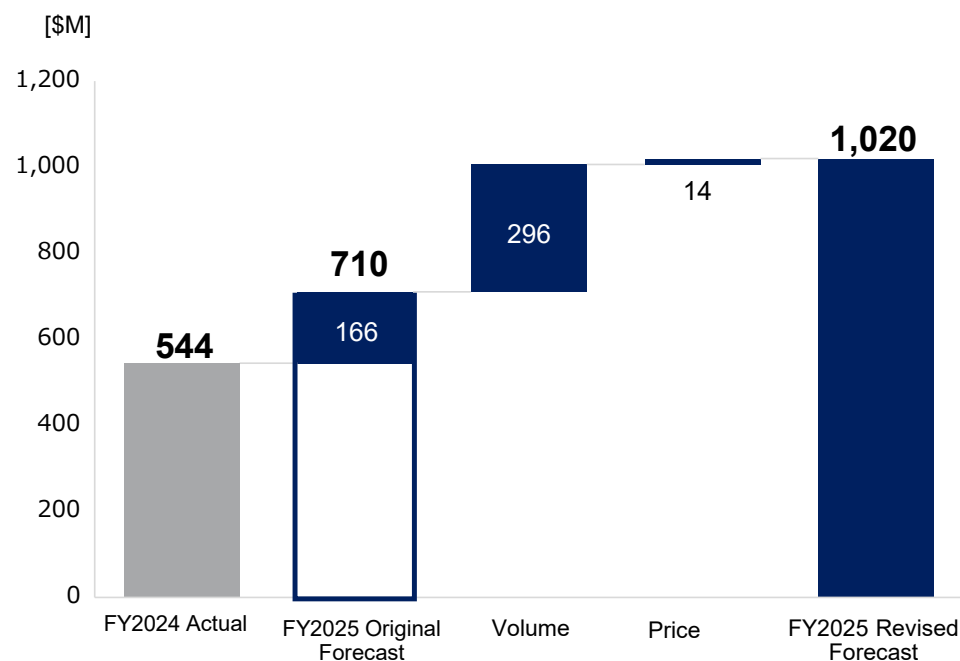


- Q2 YTD: Achieved 133% of net sales versus original forecast primarily driven by solid patient growth from Jan. 2025  
Revised annual sales forecast upward to **\$1,020M (+\$310M)**

| Plan for Q2<br>YTD FY2025 | Actual for Q2<br>YTD FY2025          | Year-over-year<br>comparison |
|---------------------------|--------------------------------------|------------------------------|
| <b>\$355M</b>             | <b>\$473M</b><br>(Achievement: 133%) | <b>204%</b>                  |



### Variance Analysis Between Original and Revised FY2025 Forecasts



Reference: YoY Growth: \$476M (+87%) — FY2025 (\$1,020M) vs. FY2024

## Financial Forecasts of FY2025

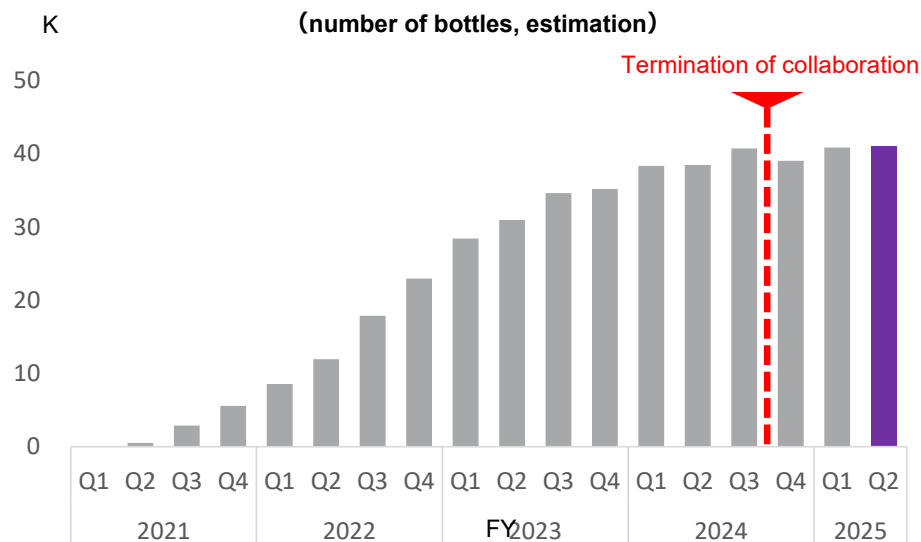
### MYFEMBREE®

- Q2 YTD: Achieved 103% of net sales versus original forecast primarily driven by stable volume even after the termination of collaboration. Annual forecast remains at **\$85M**
- **Achieved profitable product contribution** through optimization of SG&A investments (excluding R&D expenses)

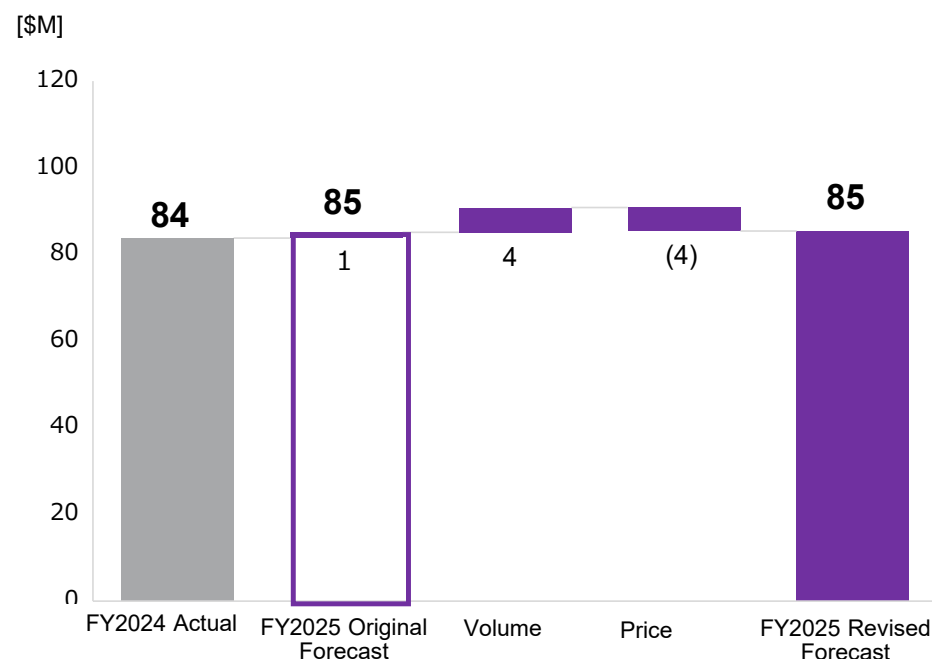
| Plan for Q2<br>YTD FY2025 | Actual for Q2<br>YTD FY2025         | Year-over-year<br>comparison |
|---------------------------|-------------------------------------|------------------------------|
| <b>\$42M</b>              | <b>\$43M</b><br>(Achievement: 103%) | <b>110%</b>                  |

### Quarterly Demand Trends\*

(number of bottles, estimation)



### Variance Analysis Between Original and Revised FY2025 Forecasts



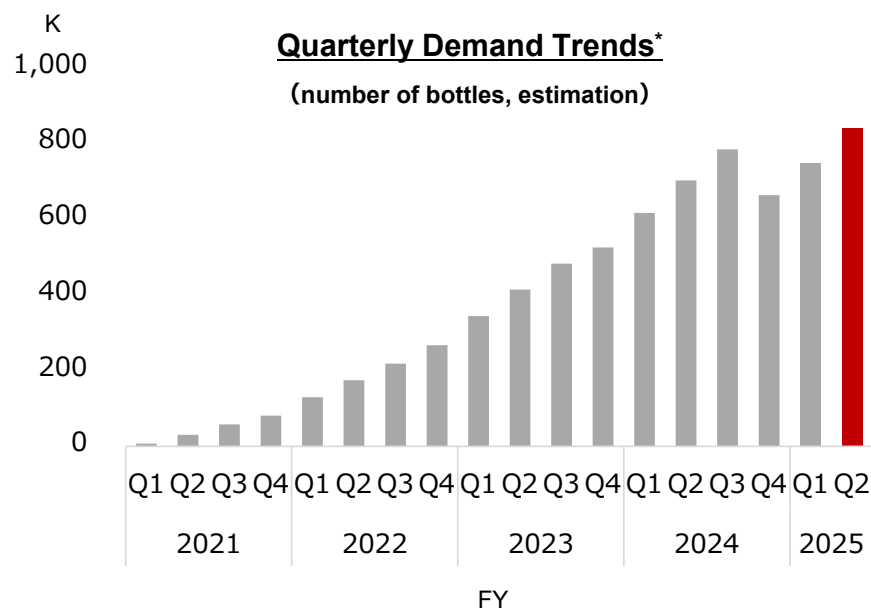
Reference: YoY Growth: \$1.6M (+1.9%) — FY2025 (\$85M) vs. FY2024

## Financial Forecasts of FY2025

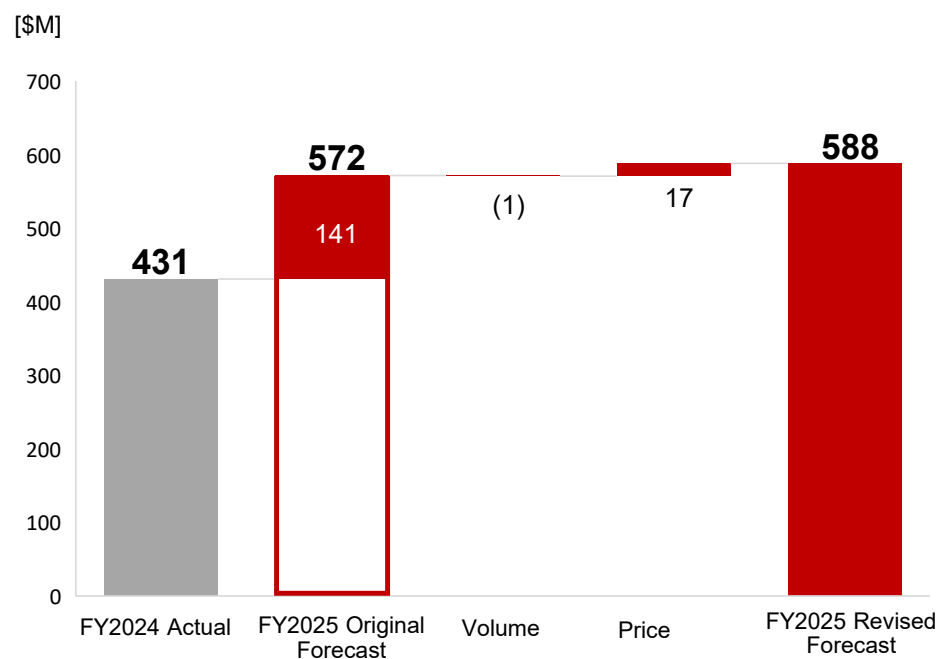


- Q2 YTD: Achieved 109% of net sales versus original forecast primarily driven by increased volume since March 2025  
Revised annual sales forecast upward to **\$588M (+\$16M)**

| Plan for Q2<br>YTD FY2025 | Actual for Q2<br>YTD FY2025          | Year-over-year<br>comparison |
|---------------------------|--------------------------------------|------------------------------|
| <b>\$271M</b>             | <b>\$297M</b><br>(Achievement: 109%) | <b>180%</b>                  |



### Variance Analysis Between Original and Revised FY2025 Forecasts



Reference: YoY Growth: \$157M (+37%) — FY2025 (\$588M) vs. FY2024

## Financial Forecasts for FY2025

### Segment Information (Core Basis)

Billions of JPY

|                          |                       | Japan | North America | Asia | Total |
|--------------------------|-----------------------|-------|---------------|------|-------|
| FY2025 Revised Forecasts | Revenue               | 92.5  | 313.6         | 22.9 | 429.0 |
|                          | Cost of sales         | 48.8  | 128.9         | 8.8  | 186.5 |
|                          | Gross profit          | 43.7  | 184.7         | 14.1 | 242.5 |
|                          | SG&A expenses         | 31.5  | 115.8         | 4.7  | 152.0 |
|                          | Core segment profit   | 12.2  | 68.9          | 9.4  | 90.5  |
|                          | R&D expenses          |       |               |      | 44.0  |
|                          | Core operating profit |       |               |      | 97.0  |

|                         |                       |      |       |      |       |
|-------------------------|-----------------------|------|-------|------|-------|
| FY2025 May 13 Forecasts | Revenue               | 85.7 | 248.2 | 21.1 | 355.0 |
|                         | Cost of sales         | 46.0 | 92.1  | 7.9  | 146.0 |
|                         | Gross profit          | 39.7 | 156.1 | 13.2 | 209.0 |
|                         | SG&A expenses         | 32.2 | 115.8 | 5.5  | 153.5 |
|                         | Core segment profit   | 7.5  | 40.3  | 7.7  | 55.5  |
|                         | R&D expenses          |      |       |      | 44.0  |
|                         | Core operating profit |      |       |      | 56.0  |

|        |                       |       |      |       |       |
|--------|-----------------------|-------|------|-------|-------|
| Change | Revenue               | 6.8   | 65.4 | 1.8   | 74.0  |
|        | SG&A expenses         | (0.7) | 0.0  | (0.8) | (1.5) |
|        | Core segment profit   | 4.7   | 28.6 | 1.7   | 35.0  |
|        | R&D expenses          |       |      |       | 0.0   |
|        | Core operating profit |       |      |       | 41.0  |

#### Japan

- Profit expected to increase due to increase of gross profit and reduction in SG&A expenses

#### North America

- Profit expected to increase significantly due to the impact of the upward revision of revenue

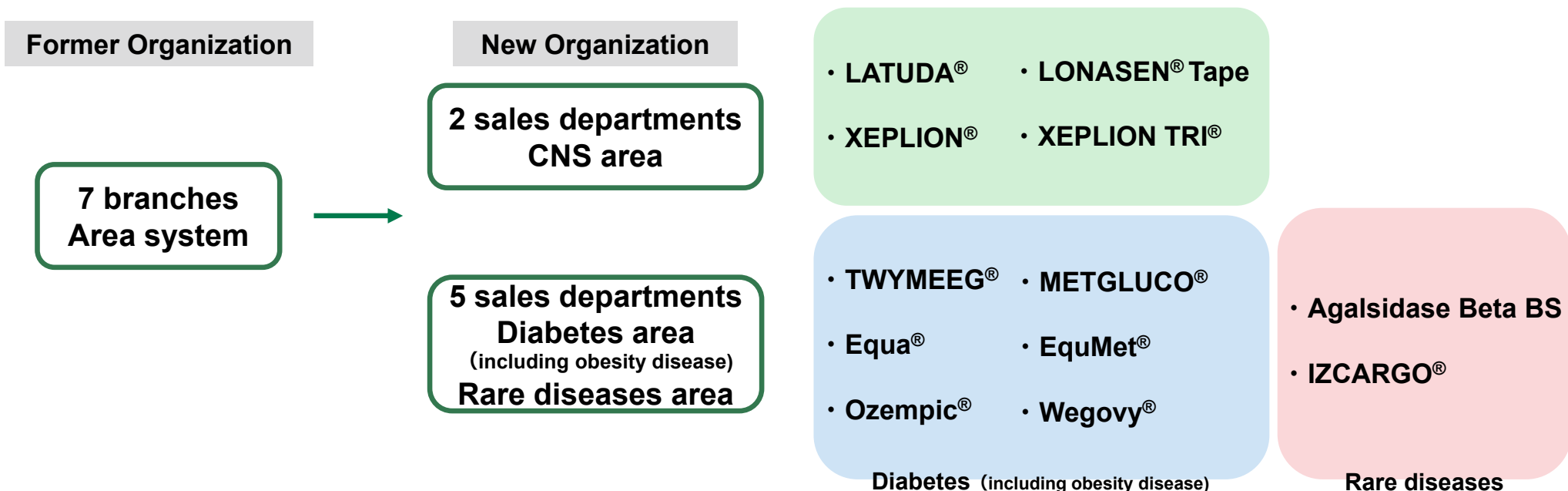
#### Asia

- Profit expected to increase due to increase of gross profit and reduction in SG&A expenses

## Marketing and Sales in Japan

### ■ Transition to a Sales Structure Specialized on Priority Therapeutic Areas (from Oct. 2025)

- ✓ Transitioned from a regional-based structure to a therapeutic-area-based structure to drive more strategic and agile sales activities in our focus areas—CNS, diabetes (including obesity disease), and rare diseases
- ✓ This reorganization aims to maximize product value through effective allocation of sales resources and utilization of sales infrastructure and relationships



### ■ Co-Promotion Agreement with Novo Nordisk Pharma for the Obesity Disease Treatment “Wegovy® Subcutaneous Injection” (in Oct. 2025)

**Wegovy®**

- ✓ Starting co-promotion activities in Nov. 2025
- ✓ Building upon the strong collaborative relationship both companies have established, we aim to contribute to the treatment of obesity disease



# Research and Development

## Research and Development

# Development Pipeline (as of October 31, 2025)

Revisions since the announcement in July 2025 are shown in red

| Area                   | Generic name/Product code   | Mechanism of action, etc.                                                                          | Planned indication(s)                                                                          | Development stage            |
|------------------------|-----------------------------|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|------------------------------|
| Psychiatry & Neurology | DSP-0038                    | Serotonin 5-HT <sub>2A</sub> receptor antagonist and serotonin 5-HT <sub>1A</sub> receptor agonist | Alzheimer's disease psychosis                                                                  | Phase 1                      |
|                        | DSP-0187 *                  | Selective orexin 2 receptor agonist                                                                | Narcolepsy                                                                                     | Phase 1                      |
|                        | DSP-3456                    | Metabotropic glutamate receptor 2/3 negative allosteric modulator (mGluR2/3 NAM)                   | Treatment resistant depression                                                                 | Phase 1                      |
|                        | DSP-0378                    | Gamma-aminobutyric acid (GABA) A receptor positive allosteric modulator                            | Progressive Myoclonic Epilepsy<br>Developmental Epileptic Encephalopathy                       | Phase 1                      |
|                        | DSP-2342                    | Serotonin 5-HT <sub>2A</sub> and 5-HT <sub>7</sub> receptor antagonist                             | To be determined                                                                               | Phase 1                      |
|                        | CT1-DAP001/DSP-1083 (Japan) | Allogeneic iPS [induced pluripotent stem] cell-derived dopaminergic neural progenitor cells        | Parkinson's disease/Investigator-initiated study                                               | MAA submitted in August 2025 |
|                        | CT1-DAP001/DSP-1083 (U.S.)  | Allogeneic iPS cell-derived dopaminergic neural progenitor cells                                   | Parkinson's disease/Investigator-initiated study, Company-sponsored clinical study             | Phase 1/2                    |
|                        | HLCR011(Japan)              | Allogeneic iPS cell-derived retinal pigment epithelial cells                                       | Retinal pigment epithelium tear                                                                | Phase 1/2                    |
|                        | DSP-3077(U.S.)              | Allogeneic iPS cell-derived retinal sheet                                                          | Retinitis pigmentosa                                                                           | Phase 1/2                    |
| Oncology               | enzomenib/DSP-5336          | Menin and KMT2A inhibitor                                                                          | Acute leukemia                                                                                 | Phase 2                      |
|                        | nuvisertib/TP-3654          | PIM1 kinases inhibitor                                                                             | Myelofibrosis                                                                                  | Phase 1/2                    |
|                        | SMP-3124                    | CHK1 inhibitor                                                                                     | Solid tumors                                                                                   | Phase 1/2                    |
|                        | DSP-0390                    | EBP inhibitor                                                                                      | Glioblastoma                                                                                   | Phase 1                      |
| Others                 | KSP-1007                    | β-lactamases inhibitor                                                                             | Complicated urinary tract and intraabdominal infections, Hospital-acquired bacterial pneumonia | Phase 1                      |
|                        | fH1/DSP-0546LP              | Split, Adjuvanted vaccine                                                                          | Influenza virus prophylaxis                                                                    | Phase 1                      |

\* Development rights: Japan, China, and certain Asian countries

## Major Topics in Clinical Development

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

#### ■ Allogeneic iPS cell-derived dopaminergic neural progenitor cells (U.S., Japan) (collaboration with RACTHERA)

- Parkinson's disease

MAA submitted in Japan in August 2025 based on data from the investigator-initiated study by Kyoto University

Aiming to obtain approval within FY2025

### ● Oncology

#### ■ enzomenib (DSP-5336) (U.S., Japan)

- Initiated dosing in the portion of the global monotherapy Phase 2 positioned as a confirmatory trial
- Agreed with PMDA on the study design of the portion of the monotherapy Phase 2 positioned as a confirmatory trial in Japan
- Presented Japanese patient data orally at the Japanese Society of Hematology Annual Meeting in October 2025 (For details, see page 18)

#### ■ nuvisertib (TP-3654) (U.S., Japan)

- Encore presentation of EHA2025 data at the Japanese Society of Hematology Annual Meeting in October 2025

### ● Others

#### ■ fH1/DSP-0546LP

- Universal Influenza Vaccine

Progress update from interim analysis of the universal influenza vaccine based on post-treatment follow-up up to four weeks after the second dose (Evaluation of safety, tolerability, and immunogenicity; for details, see page 19)

**Oncology: enzomenib (DSP-5336) Acute leukemia (Oral presentations data at the Japanese Society of Hematology 2025 )**

- ✓ Efficacy in the Japanese population was similar to that of the overall population
- ✓ In both the overall population and the Japanese population, enzomenib was well tolerated, and no dose-limiting toxicities (DLTs) were reported. Differentiation syndrome was reported in 10.7% of patients in the overall population and 13.6% in the Japanese population; however, no fatal cases or treatment discontinuations due to enzomenib were reported

(Refer to the press release issued on [October 14, 2025](#))**KMT2A-rearrangements AML/ALL**

Unit: Values are percentages (%), figures in parentheses indicate the number of individuals

|                                                    | Japanese population |                      |                   | Overall population  |                       |                    |
|----------------------------------------------------|---------------------|----------------------|-------------------|---------------------|-----------------------|--------------------|
|                                                    | 200 mg BID<br>n = 2 | 300 mg BID*<br>n = 5 | Total<br>n = 7    | 200 mg BID<br>n = 8 | 300 mg BID*<br>n = 15 | Total<br>n = 23    |
| Objective Response Rate<br>(CR + CRh + CRi + MLFS) | 100                 | 60                   | 71.4 (5/7)        | 50                  | 73.3                  | 65.2 (15/23)       |
| Composite CR<br>(CR + CRh + CRi)                   | 100                 | 60                   | 71.4 (5/7)        | 37.5                | 60                    | 52.2 (12/23)       |
| <b>CR + CRh</b>                                    | <b>50</b>           | <b>40</b>            | <b>42.9 (3/7)</b> | <b>12.5</b>         | <b>40</b>             | <b>30.4 (7/23)</b> |

**NPM1-mutated AML**

|                                                    | Japanese population |                     |                 | Overall population   |                     |                    |
|----------------------------------------------------|---------------------|---------------------|-----------------|----------------------|---------------------|--------------------|
|                                                    | 200 mg BID<br>n = 3 | 300 mg BID<br>n = 2 | Total<br>n = 5  | 200 mg BID<br>n = 10 | 300 mg BID<br>n = 7 | Total<br>n = 17    |
| Objective Response Rate<br>(CR + CRh + CRi + MLFS) | 66.7                | 100                 | 80 (4/5)        | 60                   | 57.1                | 58.8 (10/17)       |
| Composite CR<br>(CR + CRh + CRi)                   | 33.3                | 50                  | 40 (2/5)        | 50                   | 42.9                | 47.1 (8/17)        |
| <b>CR + CRh</b>                                    | <b>33.3</b>         | <b>50</b>           | <b>40 (2/5)</b> | <b>50</b>            | <b>42.9</b>         | <b>47.1 (8/17)</b> |

\* The recommended dose for the confirmatory Phase 2 part in KMT2A-rearranged AML/ALL has been determined as 300 mg BID

CR: Complete Remission, CRh: Complete Remission with Partial Hematologic Recovery, CRi: Complete Remission with Incomplete Blood Count Recovery, MLFS: Morphologic Leukemia-Free State

## Research and Development

# Other areas: fH1/DSP-0546LP Influenza virus prophylaxis

### ● Europe Phase1 Study Overview

- Objective: Evaluation of safety, tolerability, and immunogenicity (antibody titers, antiviral activity, cross-reactivity)
- Subjects: 144 healthy adults (18–40 years)
- Design: Randomized, placebo-controlled, double-blind comparative study
- Dose Levels: fH1 (2 µg, 8 µg) / DSP-0546LP (2.5 µg, 5 µg, 10 µg)
- Administration: Intramuscular injection, 2 doses at 3-week intervals

### ● Interim Analysis: Follow-up Observations up to Four Weeks After Second Dose (Day 50)

#### Safety and Tolerability:

- ✓ No serious adverse events or deaths were observed
- ✓ Most frequently reported adverse events: injection site pain and headache

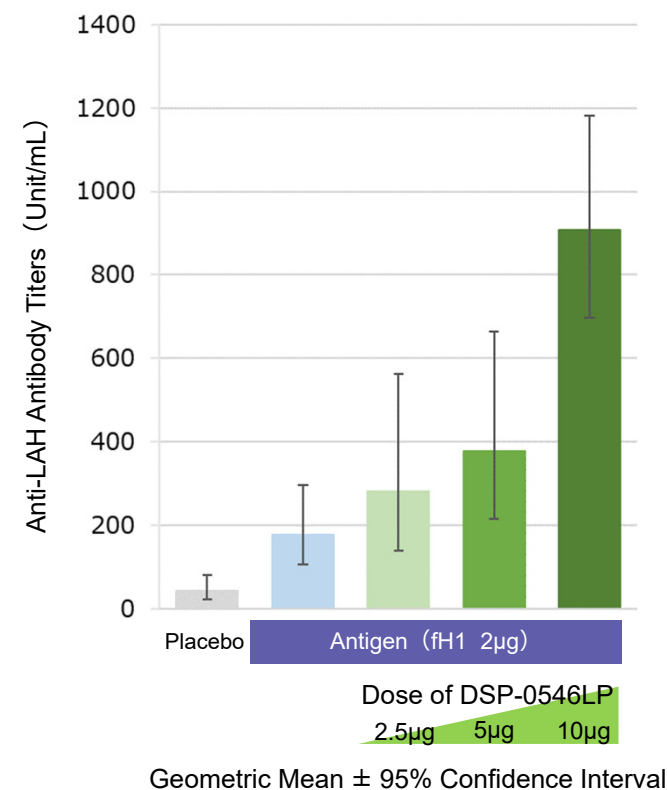
#### Immunogenicity:

- ✓ At all dose levels, GMT (Geometric Mean Titer) of anti-LAH antibodies on Day 50 was higher compared to the placebo group
- ✓ Geometric mean fold increase from Day 1 to Day 50 was higher compared to the placebo group
- ✓ Compared to antigen-alone groups, formulation groups with DSP-0546LP adjuvant showed higher GMT of anti-LAH antibodies

#### Next Steps:

- ✓ Follow-up observations for one year post-injection, evaluation of cross-reactivity and antibody-dependent cellular cytotoxicity

### Antibody Induction Against a Novel Epitope (LAH\*)



\*LAH (Long Alpha Helix): A conserved antigenic region shared across a wide range of influenza viruses

# Appendix

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## Appendix (Financial Results for Q2 FY2025)

# Financial Results for Q2 FY2025 (Full Basis)

Billions of JPY

|                                                 | Q2YTD<br>FY2024<br>Results | Q2YTD<br>FY2025<br>Results | Change |        |
|-------------------------------------------------|----------------------------|----------------------------|--------|--------|
|                                                 |                            |                            | Value  | %      |
| Revenue                                         | 180.7                      | 227.1                      | 46.4   | 25.7   |
| Cost of sales                                   | 72.3                       | 89.7                       | 17.4   | 24.0   |
| Gross profit                                    | 108.4                      | 137.4                      | 29.0   | 26.7   |
| SG&A expenses                                   | 90.0                       | 76.6                       | (13.4) | (14.9) |
| R&D expenses                                    | 26.3                       | 17.5                       | (8.7)  | (33.3) |
| Other operating income and expenses             | (0.3)                      | 52.8                       | 53.2   |        |
| Operating profit                                | (8.2)                      | 96.2                       | 104.3  | —      |
| Finance income and costs                        | (24.2)                     | (3.4)                      | 20.9   |        |
| Profit before taxes                             | (32.4)                     | 92.8                       | 125.2  | —      |
| Income tax expenses                             | (0.2)                      | (6.1)                      | (5.9)  |        |
| Net profit attributable to owners of the parent | (32.2)                     | 98.9                       | 131.1  | —      |

## Appendix (Financial Results for Q2 FY2025)

# Financial Position and Cash Flow

Billions of JPY

| B / S                                                                     | As of March<br>2025 | As of Sep.<br>2025 | Change |
|---------------------------------------------------------------------------|---------------------|--------------------|--------|
| Assets                                                                    | 742.6               | 778.4              | 35.8   |
| Other non-current assets                                                  | 28.2                | 54.7               | 26.5   |
| Trade and other receivables                                               | 74.8                | 124.5              | 49.7   |
| Assets held for sale                                                      | 30.4                | 0.0                | (30.4) |
| Liabilities                                                               | 573.1               | 512.8              | (60.3) |
| Bonds and borrowings                                                      | 305.4               | 262.9              | (42.6) |
| Deferred tax liabilities                                                  | 26.6                | 14.2               | (12.4) |
| Other liabilities                                                         | 70.3                | 57.7               | (12.6) |
| Liabilities directly associated with assets held<br>for sale              | 3.5                 | 0.0                | (3.5)  |
| Equity                                                                    | 169.5               | 265.6              | 96.1   |
| Attributable to owners of the parent                                      | 169.5               | 265.6              | 96.1   |
| (Ratio of equity attributable to owners of the parent<br>to total assets) | 22.8%               | 34.1%              |        |

← Increase in investments accounted for using the equity method

← Increase in accounts receivable due to sales growth, etc.

← Repayment of short-term borrowings

← Reversal of deferred tax liabilities due to assignment of intangible assets within our group

| C / F                                          | Q2 FY2024 | Q2 FY2025 | Change |
|------------------------------------------------|-----------|-----------|--------|
| Operating CF                                   | 4.6       | 18.0      | 13.5   |
| Investment CF                                  | 97.5      | 27.6      | (69.8) |
| Financial CF                                   | (29.4)    | (44.0)    | (14.5) |
| Cash and cash equivalents at beginning of year | 29.0      | 23.1      | (5.9)  |
| Cash and cash equivalents at end of period     | 99.1      | 38.5      | (60.6) |

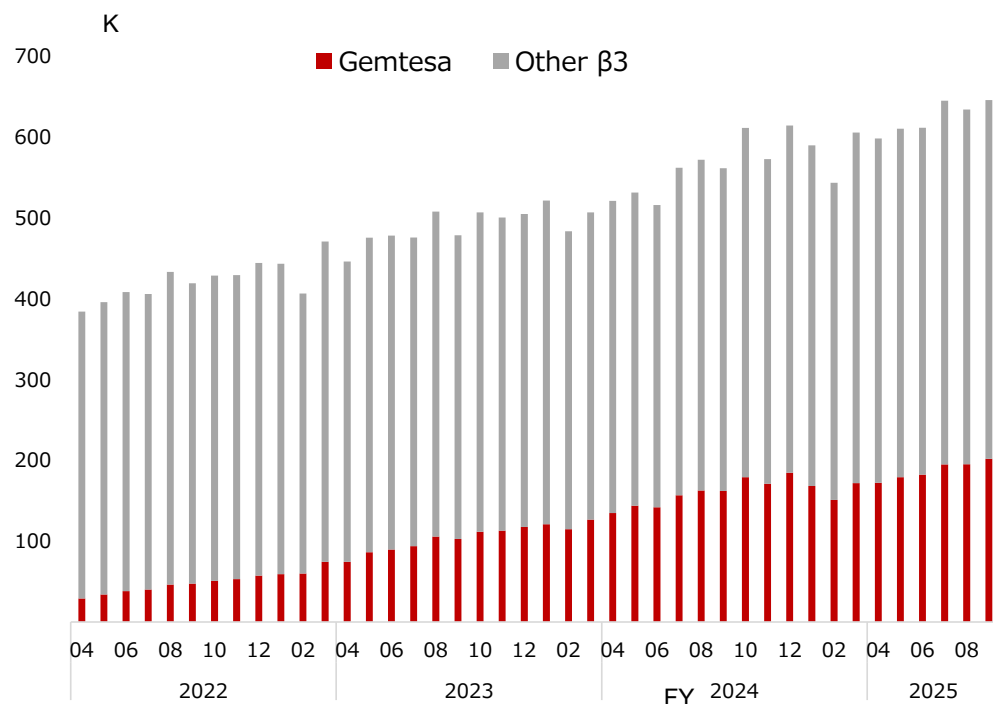
← FY24: Sales of investment securities  
FY25: Proceeds from loss of control of subsidiaries

← Repayment of short-term borrowings

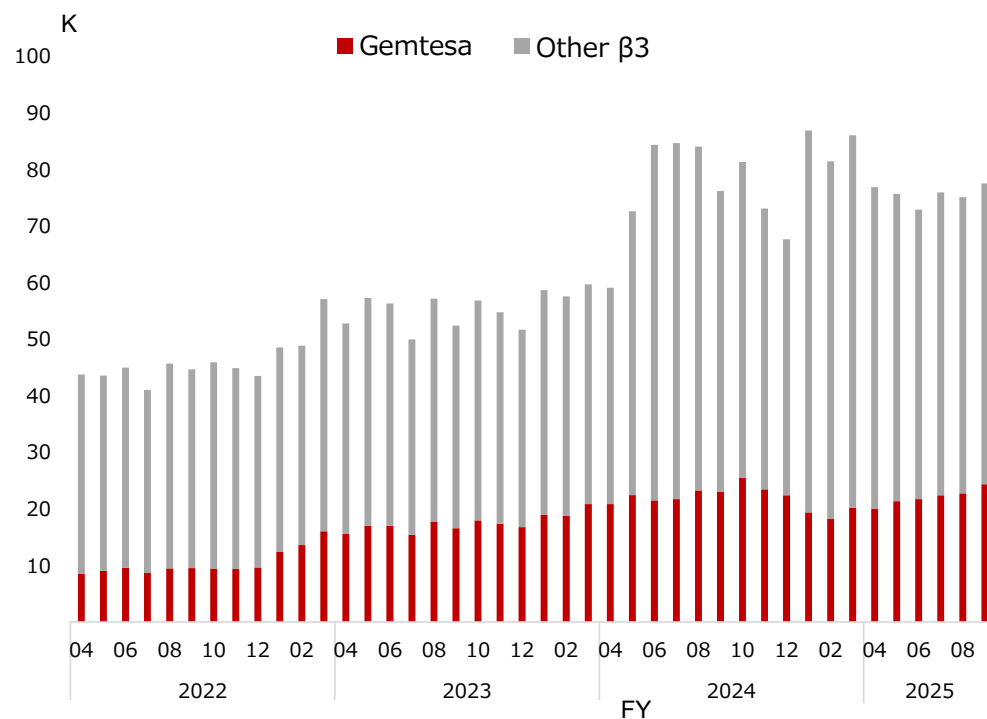
## Prescription Trends of GEMTESA®

- Despite the launch of Mirabegron generics in April 2024, the total number of GEMTESA® prescriptions and new prescriptions continued to increase. However, since Jan. 2025, there was a slight decline due to changes in Medicare Part D coverage and other factors. Following this temporary trend, prescriptions have started to grow again and have now reached an all-time high

### TRx in $\beta$ -3 Market



### NBRx in $\beta$ -3 Market



\* Source: Based on information licensed from IQVIA: NPA for the period 4/1, 2022 to 9/30, 2025 reflecting estimates of real-world activity. All rights reserved.

## Appendix (Financial Forecasts for FY2025)

# Revenue of Major Products in Japan

Billions of JPY

|                                            | FY2025<br>May 13<br>Forecasts | FY2025<br>Revised<br>Forecasts | Change |       |
|--------------------------------------------|-------------------------------|--------------------------------|--------|-------|
|                                            |                               |                                | Value  | %     |
| Japan                                      |                               |                                |        |       |
| LATUDA®                                    | 13.5                          | 13.5                           | —      | —     |
| TWYMEEG®                                   | 11.2                          | 11.2                           | —      | —     |
| METGLUCO®                                  | 7.6                           | 7.5                            | (0.1)  | (1.3) |
| Equa®/EquMet®                              | 7.0                           | 9.0                            | 2.0    | 28.6  |
| LONASEN® Tape                              | 5.2                           | 5.0                            | (0.2)  | (3.8) |
| AG products                                | 11.6                          | 11.6                           | —      | —     |
| Others                                     | 29.6                          | 34.7                           | 5.1    | 17.2  |
| Export products/<br>One-time revenue, etc. |                               |                                |        |       |
| Total                                      | 85.7                          | 92.5                           | 6.8    | 7.9   |

## Japan

- Sales of EquMet® revised upward due to change in its generics launch timing
- Ozempic® sales partnership begins
- Export business revised upward

## Appendix (Research and Development)

### ■ Main Events / Targets for FY2025 (as of October 31, 2025)

#### Psychiatry & Neurology

- ❑ Allogeneic iPS cell-derived products (Parkinson's disease): Obtain approval in Japan  
⇒ MAA submitted (Aug. 2025)
- ❑ Allogeneic iPS cell-derived products (Parkinson's disease): Advance Phase 1/2 study in the U.S.
- ❑ Allogeneic iPS cell-derived products (Retinal pigment epithelium tear): Start the randomized portion of the Phase 1/2 study in Japan
- ❑ Allogeneic iPS cell-derived products (Retinitis pigmentosa): Achieve clinical administration in the U.S.

#### Oncology

- ❑ enzomenib (DSP-5336): Completion of patient enrollment for Phase 2 study
- ❑ nuvisertib (TP-3654): Advance Phase 1/2 study (monotherapy or in combination with JAK inhibitors)
- ❑ SMP-3124: Advance Phase 1/2 study
- ❑ Advance early Phase studies of early stage compounds

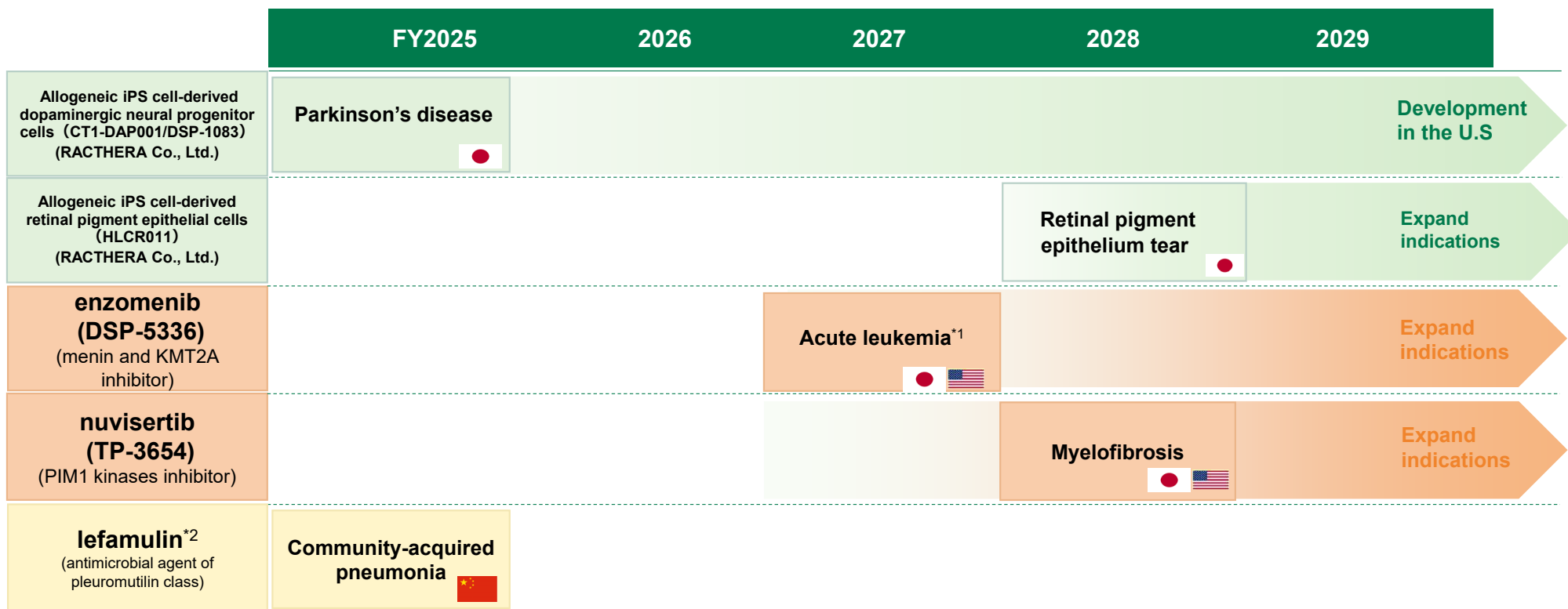
#### Others

- ❑ Advance Phase 1 studies of universal influenza vaccine
- ❑ Advance early Phase studies of early stage compounds

## Appendix (Research and Development)

### Product Launch Target (as of October 31, 2025)

■ Psychiatry & Neurology
 ■ Oncology
 ■ Others



\*1 Relapsed or refractory acute leukemia with KMT2A rearrangement or acute myeloid leukemia with NPM1 mutation

\*2 The IP rights have been transferred to the joint venture company with Marubeni Global Pharma Corporation

## Appendix (Research and Development)

### Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline(RACTHERA Co., Ltd.) (as of October 31, 2025)

Revisions since the announcement in July 2025 are shown in red

| Brand name/Cell type<br>Product code                                                      | Indications                        | JP/<br>US | Pre-clinical                                                                        | Clinical<br>research                                                                  | Phase 1/2                                                                                                                                                               | Phase 3 | Approval<br>application                                                                          | Approval→<br>Launch                                                                 |
|-------------------------------------------------------------------------------------------|------------------------------------|-----------|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| RETHYMIC®                                                                                 | Congenital athymia                 | US        |                                                                                     |                                                                                       |                                                                                                                                                                         |         |                                                                                                  |  |
| Dopaminergic neural<br>progenitor cells<br>(Allo iPS cell-derived)<br>CT1-DAP001/DSP-1083 | Parkinson's<br>disease             | JP<br>US  |                                                                                     |                                                                                       |   |         |  <sup>1</sup> | Aiming to obtain<br>approval in<br>Japan in FY<br>2025                              |
| Retinal pigment<br>epithelial cells<br>(Allo iPS cell-derived)<br>HLCR011                 | Retinal pigment<br>epithelium tear | JP        |                                                                                     |                                                                                       |                                                                                      |         |                                                                                                  |                                                                                     |
| Retinal sheet<br>(3D retinal tissue)<br>(Allo iPS cell-derived)<br>DSP-3077               | Retinitis pigmentosa               | JP<br>US  |                                                                                     |    |                                                                                      |         |                                                                                                  |                                                                                     |
| Neural progenitor cells<br>(Allo iPS cell-derived)                                        | Spinal cord injury                 | JP<br>US  |                                                                                     |  |                                                                                                                                                                         |         |                                                                                                  |                                                                                     |
| Nephron progenitor cells<br>(organ)<br>(Auto/ Allo iPS cell-based<br>induced)             | Kidney failure                     | JP/<br>US |  |                                                                                       |                                                                                                                                                                         |         |                                                                                                  |                                                                                     |

