# Conference on Q2 FY2023
## (April 1 to September 30, 2023)
# Financial Results

Hiroshi Nomura, President and CEO

Sumitomo Pharma Co., Ltd.

October 31, 2023

Sumitomo Pharma
Innovation today, healthier tomorrows

# 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, 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 medical devices (including those under development) contained herein is not intended as advertising or as medical advice.

# Financial Results for Q2 FY2023

# Financial Results for Q2 FY2023 (Core Basis)

**The forecasts are not revised**

Billions of yen

| | Q2YTD FY2022 Results | Q2YTD FY2023 Results | Change | | | FY2023 | |
|---|---|---|---|---|---|---|---|
| | | | Value | FX impact | % | May 15 forecasts | % |
| **Revenue** | 319.3 | **152.6** | (166.6) | 3.8 | (52.2) | 362.0 | 42.2 |
| Cost of sales | 92.8 | **60.3** | (32.5) | (7.6) | (35.0) | 132.0 | 45.7 |
| Gross profit | 226.4 | **92.3** | (134.1) | 11.4 | (59.2) | 230.0 | 40.1 |
| SG&A expenses | 152.3 | **118.8** | (33.5) | 4.2 | (22.0) | 220.0 | 54.0 |
| R&D expenses | 49.4 | **45.3** | (4.1) | 1.5 | (8.3) | 84.0 | 53.9 |
| Other operating income/expenses | 0.0 | **5.9** | 5.9 | — | — | 12.0 | 48.9 |
| **Core operating profit** | 24.8 | **(65.8)** | (90.7) | 5.7 | — | (62.0) | 106.2 |
| Non-recurring items (negative number indicates net loss) | (53.8) | **(20.6)** | 33.1 | | | (16.0) | |
| **Operating profit** | (28.9) | **(86.5)** | (57.6) | | — | (78.0) | 110.9 |
| Finance income/costs | 49.9 | **30.4** | (19.6) | | | (3.0) | |
| Profit before taxes | 21.0 | **(56.1)** | (77.2) | | — | (81.0) | |
| Income tax expenses | 36.3 | **11.6** | (24.7) | | | (1.0) | |
| Net profit | (15.2) | **(67.7)** | (52.5) | | — | (80.0) | 84.7 |
| **Net profit attributable to owners of the parent** | (7.3) | **(67.7)** | (60.5) | | — | (80.0) | 84.7 |

- Revenue decreased significantly due to LATUDA®'s loss of exclusivity in the U.S.
- Share transfer of Sumitomo Pharma Animal Health Co., Ltd. included in Other operating income/ expenses
- Business structure improvement expenses in North America recognized as Non-recurring items

Average rates:
Q2 FY2022 Results : 1US$ = ¥134.05, 1RMB = ¥19.89
Q2 FY2023 Results : 1US$ = ¥141.07, 1RMB = ¥19.75
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

Period end rates:
As of the end of March 2023 : 1US$ = ¥133.54, 1RMB = ¥19.42
As of the end of September 2023 : 1US$ = ¥149.58, 1RMB = ¥20.50

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# Financial Results for Q2 FY2023 (Core Basis) - vs. Q2 YTD FY2023 Plans

Billions of yen

| | Q2YTD FY2023 Plans | **Q2YTD FY2023 Results** | Change | | | |
|---|---|---|---|---|---|---|
| | | | Value | % | FX impact | % (w/o FX) |
| **Revenue** | 166.2 | **152.6** | (13.6) | 91.8 | 6.3 | 88.0 |
| Cost of sales | 60.6 | **60.3** | (0.2) | 99.6 | 2.2 | 96.0 |
| Gross profit | 105.7 | **92.3** | (13.3) | 87.4 | 4.1 | 83.5 |
| SG&A expenses | 116.1 | **118.8** | 2.6 | 102.3 | 6.8 | 96.4 |
| R&D expenses | 44.3 | **45.3** | 1.0 | 102.3 | 2.3 | 97.0 |
| Other operating income/expenses | 7.0 | **5.9** | (1.1) | 84.4 | — | 84.4 |
| **Core operating profit** | (47.8) | **(65.8)** | (18.1) | — | (5.0) | — |

Average rates:
Q2 FY2023 Results : 1US$ = ¥141.07, 1RMB = ¥19.75
FY2023 forecasts : 1US$ = ¥130.00, 1RMB = ¥19.50

# Revenue of Major Products in North America

| | Q2YTD FY2022 Results | Q2YTD FY2023 Results | Change | Q2YTD FY2022 Results | Q2YTD FY2023 Results | Change | | | FY2023 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Value | FX impact | % | May 15 forecasts | | Yen-basis % |
| **North America** | Million $ | | | Billions of yen | | | | | Million $ | Billions of yen | |
| ORGOVYX® | 79 | **138** | 58 | 10.6 | **19.4** | 8.8 | 1.0 | 82.4 | 396 | 51.5 | 37.7 |
| MYFEMBREE® | 10 | **29** | 19 | 1.4 | **4.2** | 2.8 | 0.2 | 198.5 | 192 | 24.9 | 16.7 |
| GEMTESA® | 71 | **112** | 42 | 9.5 | **15.8** | 6.4 | 0.8 | 67.2 | 362 | 47.0 | 33.6 |
| APTIOM® | 129 | **114** | (15) | 17.4 | **16.1** | (1.2) | 0.8 | (7.0) | 273 | 35.5 | 45.5 |
| RETHYMIC® | 19 | **22** | 3 | 2.6 | **3.1** | 0.5 | 0.2 | 20.3 | 54 | 7.0 | 44.0 |
| LATUDA® | 952 | **29** | (923) | 127.6 | **4.0** | (123.6) | 0.2 | (96.8) | 161 | 20.9 | 19.3 |
| Others | 60 | **9** | (51) | 8.0 | **1.2** | (6.8) | 0.1 | (84.9) | 167 | 22.0 | 48.4 |
| Export products/ Lump-sum revenue, etc.* | 137 | **67** | (70) | 18.3 | **9.4** | (8.9) | 0.5 | (48.4) | | | |
| Total | 1,457 | **519** | (938) | 195.3 | **73.3** | (122.1) | 3.6 | (62.5) | 1,605 | 208.8 | 35.1 |

* Major items included in Export products/Lump-sum revenue, etc.

| | | | |
|---|---|---|---|
| Q2YTD FY2022 | Deferred revenue from the collaboration with Pfizer of $80M | Q2YTD FY2023 | Deferred revenue from the collaboration with Pfizer of $59M |
| | Revenue from the license agreement for ORGOVYX® in EU of $50M | | |

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

Million $

| Plans | Results | % |
|---|---|---|
| 155 | 138 | 88.7 |
| 60 | 29 | 49.3 |
| 156 | 112 | 72.0 |

- Of the “Export products/Lump-sum revenue, etc.” in Q2 FY2022, the lump-sum revenue under the license agreement for ORGOVYX® in EU was $50M. (See the breakdown below the table)

Average rates:
Q2 FY2022 Results : 1US$ = ¥134.05
Q2 FY2023 Results : 1US$ = ¥141.07
FY2023 forecasts : 1US$ = ¥130.00

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# Marketing Status of ORGOVYX®

| Plan for Q2 YTD FY2023 | Actual for Q2 YTD FY2023 | Achievement rate against plan for Q2 YTD FY2023 | Volume and price of influence against actual for Q2 YTD FY2023, $138M | |
|---|---|---|---|---|
| **$155M** | **$138M** | **89%** | Volume | Unfavorable. approx. ($23M) |
| | | | Price | Favorable. approx. $6M |

- ORGOVYX® continues to show strong growth – H1 FY2023 revenue increased approx. 75% compared to H1 FY2022 and provides important treatment advantages, as the first oral GnRH antagonist in the U.S., for advanced prostate cancer
- Forecasted volume was not achieved due to slower than anticipated market share while price was favorable vs. forecast due to lower prior quarter adjustments tied to coverage gap liability in Medicare Part D

| | FY2023 Strategies and Outlook |
|---|---|
| Volume | ✓ Urology in-office-dispensing clinics (approx. 19% of ADT Market*1): Utilizing analysis of Advanced Analytics team*2 to inform appropriate promotional messaging and improve timing of sales reps visit a prescribing physician in June<br>✓ Academic/Integrated Delivery Network (approx. 50% of ADT Market): Introduced Strategic Account Manager team in July focused on supporting adoption of ORGOVYX® in hospital setting<br>✓ Changes in Medicare Part D benefit design will improve ORGOVYX® affordability for patients as of Jan. 2024 by eliminating out of pocket following catastrophic phase and increasing the low income subsidy threshold |
| Price | ✓ Gross to net expected to be consistent with current trends |

*1 Androgen Deprivation Therapy market where ORGOVYX® is prescribed
*2 SMPA's Advanced Analytics Computational Technology & Research (AACTR), which leverages SMPA's digital infrastructure, including DrugOME and Digital Innovation

Financial Results for Q2 FY2023

# Marketing Status of MYFEMBREE®

| Plan for Q2 YTD FY2023 | Actual for Q2 YTD FY2023 | Achievement rate against plan for Q2 YTD FY2023 | Volume and price of influence against actual for Q2 YTD FY2023, $29M | |
|---|---|---|---|---|
| **$60M** | **$29M** | **49%** | Volume | Unfavorable. approx. ($24M) |
| | | | Price | Unfavorable. approx. ($7M) |

- MYFEMBREE® continues to grow – H1 FY2023 revenue has increased approx. 190% increase compared to H1 FY2022.
- TRx and NBRx share* in uterine fibroids (UF) and endometriosis (EM) of GnRH antagonists market are 37% and 46% in Sep. 2023 (30% and 40% in March 2023)
- Volume of forecast was not achieved due to slower than anticipated market share especially in endometriosis and price of forecast was not achieved due to higher proportion of Medicaid volume and Co-pay cards assistance

| | FY2023 Strategies and Outlook |
|---|---|
| Volume | ✓ Position MYFEMBREE® as the standard of care for women with UF or EM:<br>☐ UF: Establish MYFEMBREE® as GnRH therapy use earlier in the treatment journey by positioning GnRH antagonists as treatment of choice after first oral contraceptive failure<br>☐ EM: Establish MYFEMBREE® as GnRH of choice by differentiating MYFEMBREE® on effectively treating pain<br>✓ Continuous field force targeting optimization in collaboration with the Advanced Analytics team and Pfizer Inc.<br>✓ Leveraging Advanced Analytics team to improve DTC effectiveness/efficiency and partnering with Pfizer Inc. to launch new DTC |
| Price | ✓ Monitoring usage and reinforcing proper use of Co-pay cards |

*Source: Symphony METYS – Data through September 2023, IDV®

# Marketing Status of GEMTESA®

| Plan for Q2 YTD FY2023 | Actual for Q2 YTD FY2023 | Achievement rate against plan for Q2 YTD FY2023 | Volume and price of influence against actual for Q2 YTD FY2023, $112M | |
|---|---|---|---|---|
| **$156M** | **$112M** | **72%** | Volume | Unfavorable. approx. ($14M) |
| | | | Price | Unfavorable. approx. ($30M) |

- GEMTESA® continues to grow – H1 FY2023 revenue has increased approx. 58% increase compared to H1 FY2022
- TRx and NBRx Share* in Beta3 are 21% and 32% in Sep. 2023 (16% and 28% in March 2023)
- Volume of forecast was not achieved due to lower than assumed Beta3 market share and price of forecast was not achieved due to higher proportion of Medicare Part D volume and lower proportion of non-contracted volume

| | FY2023 Strategies and Outlook |
|---|---|
| Volume | ✓ Focus on increasing awareness (currently approx. 30%) and prescription uptake in primary care and long-term care, which account for approx. 45% of total prescriptions for over active bladder<br>✓ Plan to conduct a satellite media tour during Bladder Health Awareness Month in Nov. to raise awareness, in addition to the digital advertising currently being conducted on the web and in clinic waiting rooms |
| Price | ✓ Price is expected to be improved in Q4 FY2023 because pharmaceutical companies' burden of the Coverage Gap in Medicare Part D will be lower in Q4 FY2023 than in other quarters |



* Source IQVIA NPA

# Revenue of Major Products in Japan & Asia

Billions of yen

| | Q2YTD FY2022 Results | Q2YTD FY2023 Results | Change | | FY2023 | |
|---|---|---|---|---|---|---|
| | | | Value | % | May 15 forecasts | % |
| **Japan** | | | | | | |
| Equa®/EquMet® | 17.3 | **15.8** | (1.5) | (8.7) | 32.4 | 48.7 |
| TRERIEF® | 8.6 | **8.5** | (0.0) | (0.5) | 15.0 | 57.0 |
| LATUDA® | 4.6 | **5.7** | 1.1 | 23.3 | 12.5 | 45.8 |
| METGLUCO® | 4.0 | **3.7** | (0.2) | (5.8) | 7.5 | 49.6 |
| TWYMEEG® | 0.5 | **2.6** | 2.1 | 420.7 | 4.2 | 62.9 |
| LONASEN® Tape | 1.4 | **1.8** | 0.4 | 31.7 | 3.3 | 55.5 |
| AG products | 4.6 | **4.6** | (0.0) | (0.7) | 8.6 | 53.5 |
| Trulicity® * | 16.7 | **—** | (16.7) | — | — | — |
| Others | 8.7 | **10.9** | 2.1 | 24.5 | 30.6 | 51.3 |
| Export products/ Lump-sum revenue, etc. | 9.6 | **3.5** | (6.1) | (63.6) | | |
| Non-pharmaceutical operations | 22.1 | **1.3** | (20.8) | (94.1) | | |
| Total | 98.1 | **58.5** | (39.5) | (40.3) | 114.1 | 51.3 |
| **Asia** | | | | | | |
| MEROPEN® （China) | 18.7 | **10.2** | (8.5) | (45.3) | 18.7 | 54.8 |
| Others | 7.1 | **10.6** | 3.4 | 48.4 | 20.4 | 51.8 |
| Total | 25.9 | **20.8** | (5.0) | (19.5) | 39.1 | 53.2 |

**Japan**

- Progress is fundamentally on track in total
- Sales of TWYMEEG®, LATUDA®, and LONASEN® Tape continue to grow
- Of the “Export products/Lump- sum revenue, etc." in Q2 FY2022, the lump-sum revenue under the license agreement for DSP-0187 was ¥6.1B
- NHI drug price revision effect (¥2.0B) in total

**Asia**

- MEROPEN® (China) revenue decreased due to Volume-Based Procurement application

Note: Sales of each product are shown by invoice price (* Trulicity® is shown by NHI drug price)

# Segment Information (Core Basis)

Billions of yen

| | | Japan | North America | Asia | Total |
|---|---|---|---|---|---|
| Q2 YTD FY2023 Results | 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) |
| Q2 YTD FY2022 Results | Revenue | 98.1 | 195.3 | 25.9 | 319.3 |
| | Cost of sales | 56.0 | 31.2 | 5.7 | 92.8 |
| | Gross profit | 42.1 | 164.2 | 20.2 | 226.4 |
| | SG&A expenses | 29.2 | 116.9 | 6.1 | 152.3 |
| | Core segment profit | 12.9 | 47.3 | 14.0 | 74.2 |
| | R&D expenses | | | | 49.4 |
| | Core operating profit | | | | 24.8 |
| Change | Revenue | (39.5) | (122.1) | (5.0) | (166.6) |
| | SG&A expenses | (4.5) | (28.5) | (0.5) | (33.5) |
| | Core segment profit | (7.1) | (89.4) | (4.2) | (100.6) |
| | R&D expenses | | | | (4.1) |
| | Core operating profit | | | | (90.7) |

- **Japan:** Core segment profit decreased owing to a decrease in gross profit due to revenue decline
- **North America:** Core segment profit decreased owing to the significant decrease in gross profit due to revenue decline, despite the reduction in selling, general and administrative expenses
- **Asia:** Core segment profit decreased owing to a decrease in gross profit due to revenue decline

# Research and Development

Research and Development

# Development Pipeline (as of October 31, 2023)

: Psychiatry & Neurology : Oncology : Others

| Area | Phase 1 | | Phase 2 | Phase 3 | NDA submitted |
|---|---|---|---|---|---|
| Japan | **DSP-9632P** (Levodopa-induced dyskinesia in Parkinson's disease)<br>**DSP-0187** (Narcolepsy)<br>**DSP-0378** (Dravet syndrome, Lennox–Gastaut syndrome) | **TP-3654** (Myelofibrosis)<br>**DSP-5336** (Acute leukemia)<br>**DSP-0390** (Glioblastoma) | **EPI-589** (ALS/Investigator-initiated study)<br>**Allo iPS cell-derived products** (Parkinson's disease/ Investigator-initiated study)<br>**Allo iPS cell-derived products** (Retinal pigment epithelium tear) | **ulotaront (SEP-363856)** (Schizophrenia)*<br>**ulotaront (SEP-363856)** (Generalized anxiety disorder)* | |
| U.S. | **SEP-378614** (To be determined)<br>**SEP-380135** (To be determined)<br>**DSP-0038** (Alzheimer's disease psychosis)<br>**DSP-3456** (Treatment resistant depression)<br>**DSP-2342** (To be determined) | **TP-3654** (Myelofibrosis)<br>**DSP-5336** (Acute leukemia)<br>**DSP-0390** (Glioblastoma)<br>**TP-1287** (Solid tumors)<br>**TP-1454** (Solid tumors)<br>**KSP-1007** (Complicated urinary tract infections, Complicated intra-abdominal infections)<br>**SP-101** (cystic fibrosis) | **EPI-589** (Parkinson's disease/ALS)<br>**ulotaront (SEP-363856)** (Parkinson's disease psychosis) | **ulotaront (SEP-363856)** (Schizophrenia)<br>**ulotaront (SEP-363856)** (Adjunctive major depressive disorder)*<br>**ulotaront (SEP-363856)** (Generalized anxiety disorder)*<br>**GEMTESA® (vibegron)** (New indication: OAB in men with BPH) | |
| China | | | | **ulotaront (SEP-363856)** (Schizophrenia)*<br>**vibegron** (Overactive bladder) | **lefamulin** (Bacterial community-acquired pneumonia) |

*Phase 2/3 study

# Clinical Development Status (Major Changes since July 31, 2023)

- **ORGOVYX® (relugolix)**
  Canada: Approved for advanced prostate cancer in October 2023 and planning to launch in Q4 FY2023

- **MYFEMBREE® (relugolix combination tablet)**
  Canada: Approved for uterine fibroids and endometriosis in September 2023 and October 2023, respectively, and planning to launch in Q4 FY2023

- **GEMTESA® (vibegron)**
  U.S.: OAB in men with BPH
  - As a result of Phase 3 study, the co-primary endpoints reached statistical significance, sNDA submission is anticipated in Q4 FY2023

- **Development strategy and future plan on schizophrenia for ulotaront in the U.S.**
  - Detailed analysis of the results of DIAMOND 1 and 2 studies is currently underway, including the reason why the placebo effect was large
  - Plan to reach an agreement with Otsuka in Q4 FY2023 based on a re-evaluation of business feasibility
  - In a case of developing ulotaront for schizophrenia, need to conduct an additional pivotal study

- **SEP-4199**
  Japan, U.S.: Decided to discontinue Phase 3 study for bipolar I depression due to significant delay in recruiting progress
  Development strategy under consideration with Otsuka

- **DSP-3905**
  U.S.: Neuropathic pain (Phase 1 study)
  - Deleted from the Development Pipeline due to out-licensing to AlphaNavi Pharma

# Oncology Area: Clinical Development Status of TP-3654, DSP-5336

## TP-3654 (PIM1 kinase inhibitor)

- Conducting the Phase 1/2 monotherapy study in Japan, U.S., and Australia. Conducting clinical studies have been approved by EU and UK regulatory agencies and clinical studies are being expanded to other regions
- Interim results of the ongoing clinical study were presented orally at The Japanese Society of Hematology (October 2023) Accepted for oral presentation at ASH 2023 (December 2023) and the latest interim results will be presented
- Including patients who did not respond to JAK inhibitors, reduction in spleen volume and improvement in systemic symptom scores have been observed with monotherapy, with few hematologic toxicities such as thrombocytopenia. A combination study with JAK inhibitors to be initiated in FY2024
- Aiming for potential approval (U.S.: myelofibrosis) in FY2027

## DSP-5336 (Menin-MLL interaction inhibitor)

- Conducting the Phase 1/2 monotherapy study in Japan, U.S., and Canada. Conducting clinical studies have been approved by Singapore, Korea, Taiwan, and EU regulatory agencies and clinical studies are being expanded to other regions
- Interim results of the ongoing clinical study to be presented for the first time in a poster presentation at ASH 2023 (December 2023)
- Considering conducting a combination study with standard treatment
- Very limited treatment options in difficult-to-treat relapsed and refractory acute myeloid leukemia, and approval is expected in a monotherapy pivotal study without a control treatment
  A monotherapy pivotal study will begin after discussion with regulatory agencies in the first half of FY2024, aiming for potential approval (U.S.: acute myeloid leukemia*) in FY2026 and potential approval (Japan: acute myeloid leukemia) in FY2027

*Premise of accelerated approval

# Appendix

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Appendix (Financial Results for Q2 FY2023)

# Financial Results for Q2 FY2023 (Full Basis)

Billions of yen

| | Q2YTD FY2022 Results | Q2YTD FY2023 Results | Change | |
|---|---|---|---|---|
| | | | Value | % |
| Revenue | 319.3 | 152.6 | (166.6) | (52.2) |
| Cost of sales | 92.8 | 60.3 | (32.5) | (35.0) |
| Gross profit | 226.4 | 92.3 | (134.1) | (59.2) |
| SG&A expenses | 207.9 | 134.0 | (73.9) | (35.5) |
| R&D expenses | 50.0 | 50.4 | 0.4 | 0.8 |
| Other operating income and expenses | 2.5 | 5.6 | 3.1 | |
| Operating profit | (28.9) | (86.5) | (57.6) | — |
| Finance income and costs | 49.9 | 30.4 | (19.6) | |
| Profit before taxes | 21.0 | (56.1) | (77.2) | — |
| Income tax expenses | 36.3 | 11.6 | (24.7) | |
| Net profit | (15.2) | (67.7) | (52.5) | — |
| Net profit attributable to owners of the parent | (7.3) | (67.7) | (60.5) | — |

# Financial Position and Cash Flow

Billions of yen

| B / S | As of March 2023 | As of Sep. 2023 | Change |
|---|---|---|---|
| Assets | 1,134.7 | 1,148.9 | 14.1 |
| Goodwill / Intangible assets | 538.7 | 591.1 | 52.4 |
| Other financial assets (Non-current) | 134.0 | 182.9 | 48.9 |
| Cash and deposit / Short-term loan receivable | 153.5 | 60.4 | (93.1) |
| Liabilities | 728.0 | 736.8 | 8.9 |
| Bonds and borrowings | 334.7 | 383.8 | 49.1 |
| Provisions | 119.1 | 92.5 | (26.6) |
| Other current liabilities | 78.0 | 54.4 | (23.6) |
| Equity | 406.8 | 412.0 | 5.3 |
| Attributable to owners of the parent | 406.7 | 412.0 | 5.3 |
| (Ratio of equity attributable to owners of the parent to total assets) | 35.8% | 35.9% | |

| C / F | Q2YTD FY2022 | **Q2YTD FY2023** | Change |
|---|---|---|---|
| Operating CF | 29.5 | (174.5) | (204.0) |
| Investment CF | 7.1 | 32.7 | 25.6 |
| Financial CF | (26.7) | 44.8 | 71.4 |
| Cash and cash equivalents | 250.6 | 60.4 | (190.2) |
| (Operating funds) | 271.3 | 62.1 | (209.3) |

- Increase due to FX rate impact
- Increase due to changes in valuation of securities
- Increase in short-term borrowings
- Decrease in LATUDA® sales rebates provision
- Decrease in accrued bonuses due to the combination of group companies in the U.S.
- In addition to the net loss, there was a decrease in provisions and an increase in corporate income tax payments
- Proceeds from sales of investment securities and transfer of shares of Sumitomo Pharma Animal Health Co., Ltd.
- Proceeds from increase in short-term borrowings, etc.

Appendix (Research and Development)

# Main Events / Targets for FY2023 (as of October 31, 2023)

Revisions since the announcement of July 2023 are shown in red

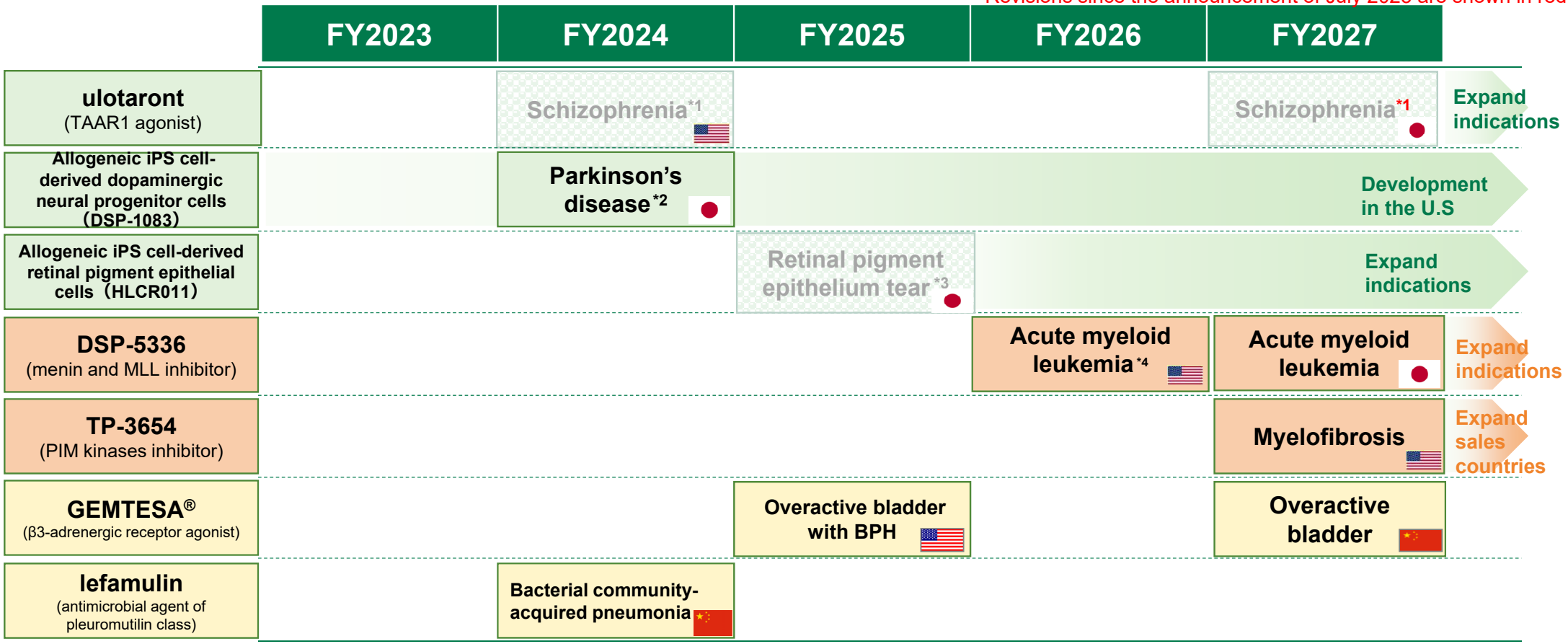
| | |
|---|---|
| **Psychiatry & Neurology** | ☐ ulotaront (SEP-363856) : ☑ Obtain results from two Phase 3 studies for schizophrenia〔☑ DIAMOND 1 ☑ DIAMOND 2〕<br>☐ Submit NDA for schizophrenia in the U.S.<br>☐ Advance Phase 2/3 study in Japan and China for schizophrenia<br>☐ Advance Phase 2/3 studies for two additional indications (aMDD, GAD)<br>~~☐ SEP-4199: Advance Phase 3 studies for Bipolar I depression~~<br>☑ Allogeneic iPS cell-derived products（Retinal pigment epithelium tear) : Start clinical study in Japan<br>☐ Allogeneic iPS cell-derived products（Parkinson's disease) : Start clinical study in the U.S.<br>☐ Complete manufacturing plant in the U.S. (for RETHYMIC® and allogeneic iPS cell-derived products) |
| **Oncology** | ☐ Advance early Phase studies |
| **Others** | ☐ relugolix: Obtain approval for endometriosis in Europe<br>☐ vibegron: Obtain results from Phase 3 study and submit sNDA for overactive bladder (OAB) with benign prostatic hyperplasia in the U.S.<br>☑ rodatristat ethyl: Obtain results from Phase 2 study for pulmonary arterial hypertension (PAH)<br>☐ universal influenza vaccine, malaria vaccines : Promote joint research and development projects |
| **Frontier** | ☐ Launch product: (Japan) Automated blood collection/stabilization device<br>☐ Promoting the current themes and generating evidence data for maximizing the value of the launched products |

Appendix (Research and Development)

# Product Launch Target (as of October 31, 2023)

Psychiatry & Neurology | Oncology | Others

Revisions since the announcement of July 2023 are shown in red




*1 To be revised for launch target based on development strategy for schizophrenia
*2 Launch schedule is based on our goal pending agreement with partner
*3 Under review for launch target based on clinical study status
*4 Premise to utilize an application of accelerated approval program (Plan to consult with the FDA)

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## Regenerative Medicine/Cell Therapy Launched Product and Development Pipeline (as of October 31, 2023)

| 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) DSP-1083 | Parkinson's disease | JP US | ● | | ●[1] | | | Launch Target* (FY2024) |
| Retinal pigment epithelial cells (Allo iPS cell-derived) HLCR011 | Retinal pigment epithelium tear | JP | | | ● | | | |
| Photoreceptor (3D) (Allo iPS cell-derived) DSP-3077 | Retinitis pigmentosa | JP US | ● | ●[2] | | | | |
| Neural progenitor cells (Allo iPS cell-derived) | Spinal cord injury | JP 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

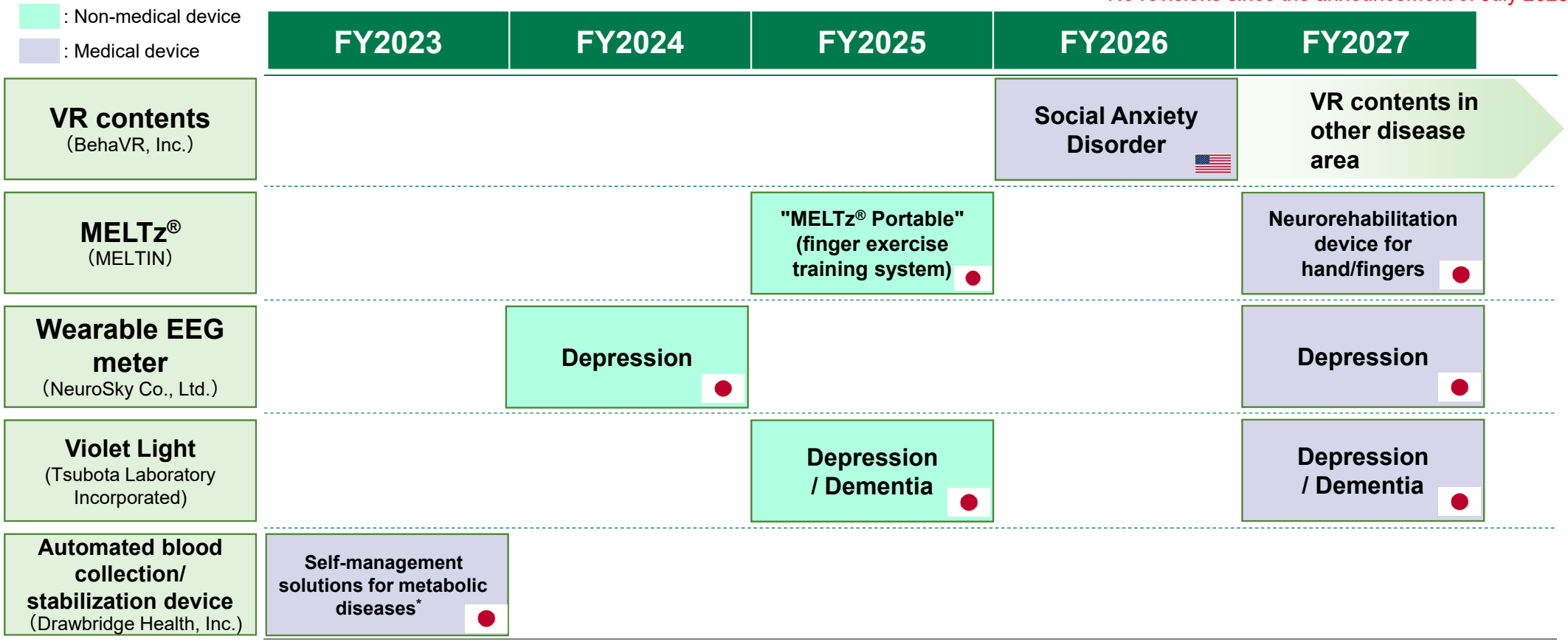
* Subject to conditional and time-limited approval

Appendix (Research and Development)

# Frontier Business Product Launch Target (as of October 31, 2023)

No revisions since the announcement of July 2023

: Non-medical device
: Medical device




* At the start of the business, we plan to provide management solutions for metabolic disease management
The details and rights regarding business rights in Japan are currently under discussion with Drawbridge Health, and they have not been agreed upon with the company

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