

## Analysts Meeting of Financial Results for FY2021

|                      |  |  |
|----------------------|--|--|
| [Date]               | May 16, 2022 10:30 – 11:30   |  |
| [Location]           | Live stream and Dial-in (Total: 60 minutes, Presentation: 25 minutes, Q&A: 35 minutes) |  |
| [Number of Speakers] | 4  |  |
|                      | Hiroshi Nomura   | Representative Director, President and CEO           |
|                      | Toru Kimura  | Representative Director, Executive Vice President    |
|                      | Yoshiharu Ikeda  | Member, Board of Directors, Senior Executive Officer |
|                      | Miwako Harada  | Senior Director, Corporate Communications            |

### Disclaimer:

This is a summary of the FY2021 call and clarifies certain information provided. Myovant Sciences Ltd. (“Myovant”) is listed on the New York Stock Exchange, and the Sumitomo Pharma Group holds approximately 53% of the outstanding shares of Myovant. ORGOVYX® (relugolix), MYFEMBREE® /RYEQO® (relugolix combination tablet) are owned by Myovant. This material contains information about Myovant, which is based on information disclosed by Myovant. For more information on Myovant, please visit <https://www.myovant.com>.

## Presentation

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**Harada:** We will now begin the presentation of Sumitomo Pharma Co., Ltd.'s FY2021 financial results. Thank you very much for taking time out of your busy schedule to join us today.

We would like to proceed with this briefing remotely via live webcast and conference call. As a friendly reminder, you can find today's presentation on our website. The live video is not synchronized with the materials, so please turn the pages for yourself.

We will have a question-and-answer session after the presentation. Please note that we may not be able to answer all questions due to the time restrictions. Please note that this briefing will be recorded and available on our website at a later date.

I would like to introduce today's speakers. Nomura, President, Representative Director, and CEO; Kimura, Representative Director and Executive Vice President; and Ikeda, Member of the Board of Directors and Senior Executive Officer. I am Miwako Harada from Corporate Communications and am serving as the moderator. Thank you.

President and CEO Hiroshi Nomura would like to explain the financial results for FY2021. Mr. Nomura, please go ahead.

**Nomura:** Good morning, everyone. Thank for taking time out of your busy schedule to participate in our financial results briefing today. Thank you very much for your continued interest in our company's management.

As you have already seen in the materials, FY2022 is the final year of the current Mid-term Business Plan, and we have fallen short of the Mid-term Business Plan targets announced last year, which I will explain.

LOE for LATUDA® will be a challenge for us in the future, and we will face that challenge as a Group, and I would like to ask for your continued support and confidence.

Financial Results for FY2021

**Major Topics in FY2021**

**Revenue increased y-o-y due to lump-sum alliance revenue, profit decreased mainly due to incremental costs related to Sumitovant**

|                      |   |
|----------------------|---|
| <b>Japan</b>         | Despite LATUDA® increase, revenue decreased largely due to NHI price revision impact on Equa® /EquMet®<br>Profit decreased y-o-y due to incremental sales costs   |
| <b>North America</b> | Despite LATUDA® and BROVANA® decreases, revenue increased due to lump-sum alliance revenue, and sales of ORGOVYX®, MYFEMBREE®, GEMTESA®<br>Profit decreased due to incremental costs related to Sumitovant  |
| <b>China/ Other</b>  | In China, revenue increased mainly due to sales growth of MEROPEN®<br>In Other Regions, lower profit due to decrease in export  |
| <b>R&amp;D</b>       | Success in three pipeline approvals<br><ul style="list-style-type: none"> <li>· MYFEMBREE®/ RYEQO® (relugolix combination tablet) in the U.S./ Europe: uterine fibroids</li> <li>· RETHYMIC® in the U.S.: pediatric congenital athymia</li> <li>· TWYMEEG® in Japan: type 2 diabetes</li> </ul> Three submissions for approval achieved:<br>Iefamulin in China (bacterial community-acquired pneumonia), MYFEMBREE® in the U.S. (endometriosis), METGLUCO® in Japan (public knowledge-based application for infertility treatment-related indications)<br>Entered into collaboration agreement for joint development and commercialization with Otsuka Pharmaceutical for four candidate compounds including ulotaront and SEP-4199<br>Started Phase 3 studies: SEP-4199 in the U.S. and Japan (bipolar I depression)<br>Initiated clinical studies: DSP-5336, DSP-0187, KSP-1007, DSP-3456 |

I would like to provide an explanation based on the materials.

Page three shows topics in FY2021.

As you can see at the top of the page, although revenue increased YoY owing to lump-sum alliance revenue, profit decreased due to an increase in marketing expenses related to Sumitovant.

Here is a description by segment.

Financial Results for FY2021

**Financial Results for FY2021 (Core Basis)**

|  | FY2020<br>Results | FY2021<br>Results | Change |           |        | FY2021<br>Jan. 31<br>forecasts |
|--|-------------------|-------------------|--------|-----------|--------|--------------------------------|
|  |                   |                   | Value  | FX impact | %      |                                |
| <b>Revenue</b>   | 516.0             | <b>560.0</b>      | 44.1   | 21.9      | 8.5    | 554.0                          |
| Cost of sales  | 137.5             | <b>157.1</b>      | 19.6   | 10.0      | 14.3   | 154.0                          |
| Gross profit   | 378.5             | <b>402.9</b>      | 24.5   | 11.9      | 6.5    | 400.0                          |
| SG&A expenses  | 211.8             | <b>251.6</b>      | 39.8   | 11.0      | 18.8   | 252.0                          |
| R&D expenses   | 97.1              | <b>94.0</b>       | (3.1)  | 3.7       | (3.2)  | 92.0                           |
| Other operating income/expenses  | (0.0)             | <b>1.2</b>        | 1.2    | —         | —      | 1.0                            |
| <b>Core operating profit</b>   | 69.6              | <b>58.5</b>       | (11.1) | (2.8)     | (15.9) | 57.0                           |
| Changes in fair value of contingent consideration (negative number indicates loss) | ① 22.5            | ① <b>3.3</b>      | (19.2) |           |        | (1.0)                          |
| Other non-recurring items (negative number indicates loss)                         | ②③ (20.8)         | ③ <b>(1.6)</b>    | 19.3   |           |        | (1.0)                          |
| <b>Operating profit</b>  | 71.2              | <b>60.2</b>       | (11.0) |           | (15.4) | 55.0                           |
| Profit before taxes  | 77.9              | <b>83.0</b>       | 5.1    |           | 6.6    |                                |
| Income tax expenses  | 41.0              | <b>42.4</b>       | 1.3    |           |        |                                |
| Net profit   | 36.8              | <b>40.6</b>       | 3.8    |           | 10.2   |                                |
| <b>Net profit attributable to owners of the parent</b>                             | 56.2              | <b>56.4</b>       | 0.2    |           | 0.3    | 37.0                           |

Billions of yen

| (Ref.) Earnings related to Sumitovant                  | Billions of yen |               |
|--|-----------------|---------------|
|  | FY20            | FY21          |
| <b>Revenue</b>   | <b>7.8</b>      | <b>35.7</b>   |
| SG&A expenses *  | 46.5            | 90.3          |
| R&D expenses   | 24.6            | 24.3          |
| <b>Core operating profit</b>                           | <b>(63.6)</b>   | <b>(86.9)</b> |
| <b>Operating profit</b>                                | <b>(63.6)</b>   | <b>(86.5)</b> |
| Net profit   | (63.6)          | (87.4)        |
| <b>Net profit attributable to owners of the parent</b> | <b>(44.3)</b>   | <b>(71.6)</b> |

The figures include intra-group transaction  
\* Include amortization of patent rights

FX rates:  
FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7  
FY21 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5  
FY21 Forecasts : 1US\$ = ¥110.0, 1RMB = ¥17.0



- ① Revised business plans of oncology pipelines
- ② Gain on sale of former Ibaraki plant
- ③ Impairment losses on oncology pipelines

Next, page four.

Revenue was JPY560 billion, core operating profit was JPY58.5 billion, operating profit was JPY60.2 billion, and net profit attributable to owners of the parent was JPY56.4 billion.

The forecast figures are shown on the far right. The results were not much different from these figures. Changes in fair value of contingent consideration and other non-recurring items were revalued at the end of the fiscal year, so there is a slight difference.

The largest difference, which cannot be seen in the table, is the nearly JPY25 billion foreign exchange gain on financial income and expenses owing to the difference in exchange rates on March 31, the end of the fiscal year, which resulted in a large difference from the original forecast. The result is that, in terms of net profit attributable to owners of the parent company, the figure is almost the same as last year.

As you can see here, SG&A expenses in particular increased by JPY43.8 billion. As you can see on the far right these are expenses related to Sumitovant, although to some extent this is within core operating profit as expected. SG&A expenses decreased in Sunovion and other areas, resulting in an overall increase of JPY39.8 billion. In any case, the current situation is characterized by the large impact of the exchange rate.

Financial Results for FY2021

## Revenue of Major Products in Japan

Billions of yen

|               | FY2020<br>Results | FY2021<br>Results | Change       |              |
|---------------|-------------------|-------------------|--------------|--------------|
|               |                   |                   | Value        | %            |
| Equa®/EquMet® | 40.1              | <b>37.5</b>       | (2.6)        | (6.5)        |
| Trulicity®*   | 33.9              | <b>33.6</b>       | (0.3)        | (0.8)        |
| TRERIEF®      | 16.2              | <b>16.4</b>       | 0.2          | 1.1          |
| REPLAGAL®     | 13.8              | <b>12.4</b>       | (1.4)        | (10.4)       |
| METGLUCO®     | 9.1               | <b>8.1</b>        | (1.0)        | (10.9)       |
| LATUDA®       | 2.4               | <b>6.9</b>        | 4.5          | 188.1        |
| LONASEN® Tape | 1.3               | <b>2.1</b>        | 0.8          | 61.6         |
| AMLODIN®      | 6.5               | <b>5.7</b>        | (0.9)        | (13.5)       |
| AG products   | 8.0               | <b>9.7</b>        | 1.7          | 20.8         |
| Others        | 21.1              | <b>17.7</b>       | (3.5)        | (16.5)       |
| <b>Total</b>  | <b>152.5</b>      | <b>149.9</b>      | <b>(2.6)</b> | <b>(1.7)</b> |

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

- Decrease in Equa®/EquMet® is attributed to NHI price revision
- Sale of REPLAGAL® was terminated in February 2022
- LATUDA® showing steady growth
- “Others” include TWYMEEG® launched in September 2021
- NHI price revision affected (¥7.4B) on Japan segment total

Domestic sales.

As indicated at the bottom of the right-hand side of the page, the impact of the NHI price revision was JPY7.4 billion. Considering this, sales decreased year over year by JPY2.6 billion, although we managed to make up for this in volume.

Financial Results for FY2021

**Revenue of Major Products in North America & China**

|                       | FY2020 Results | FY2021 Results | Change     | FY2020 Results  | FY2021 Results | Change      |             |             |
|-----------------------|----------------|----------------|------------|-----------------|----------------|-------------|-------------|-------------|
|                       |                |                |            |                 |                | Value       | FX impact   | %           |
| <b>North America</b>  | Million \$     |                |            | Billions of yen |                |             |             |             |
| LATUDA®               | 1,946          | 1,816          | (130)      | 206.5           | 204.1          | (2.3)       | 11.4        | (1.1)       |
| APTIOM®               | 242            | 241            | (1)        | 25.7            | 27.1           | 1.4         | 1.5         | 5.4         |
| BROVANA®              | 278            | 129            | (149)      | 29.4            | 14.5           | (15.0)      | 0.8         | (50.8)      |
| KYNMOBI®              | 2              | 5              | 4          | 0.2             | 0.6            | 0.4         | 0.0         | 204.0       |
| ORGOVYX®              | 4              | 83             | 79         | 0.4             | 9.3            | 8.9         | 0.5         | 2,321.5     |
| MYFEMBREE®/<br>RYEQO® | —              | 11             | 11         | —               | 1.3            | 1.3         | 0.1         | —           |
| GEMTESA®              | —              | 63             | 63         | —               | 7.1            | 7.1         | 0.4         | —           |
| Others                | 182            | 496            | 314        | 19.3            | 55.7           | 36.5        | 3.1         | 189.2       |
| <b>Total</b>          | <b>2,653</b>   | <b>2,845</b>   | <b>192</b> | <b>281.5</b>    | <b>319.8</b>   | <b>38.3</b> | <b>17.9</b> | <b>13.6</b> |
| <b>China</b>          | Million RMB    |                |            | Billions of yen |                |             |             |             |
| MEROPEN®              | 1,435          | 1,708          | 273        | 22.5            | 29.9           | 7.4         | 3.1         | 33.0        |
| Others                | 340            | 478            | 138        | 5.3             | 8.4            | 3.0         | 0.9         | 57.1        |
| <b>Total</b>          | <b>1,775</b>   | <b>2,186</b>   | <b>411</b> | <b>27.8</b>     | <b>38.3</b>    | <b>10.5</b> | <b>4.0</b>  | <b>37.6</b> |

- **North America segment**  
Revenue increased due to the alliance revenue, new products of Sumitovant and impact of fluctuations in FX rates
- LATUDA® decreased due largely to down-stream inventory destocking and lower price
- BROVANA® decreased due to generic products erosion
  
- Revenue from the alliance with Otsuka \$270M (¥30.3B) is recorded in "Others"
  
- **China segment**  
Increased sales by recovering from the effect of COVID-19 in previous year

FX rates:  
FY2020 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7  
FY2021 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5



In North America and China, especially North America, LATUDA® decreased by about USD130 million. This, of course, was partly due to the down-stream inventory, but in the end, due to lower average prices. So, the year over year revenue decreased.

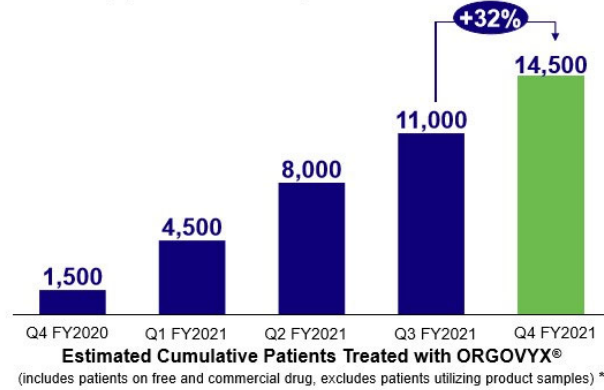
Then, for ORGOVYX®, MYFEMBREE®/RYEQO®, and GEMTESA®, the results are listed. Year over year the Others segment increased by USD314 million, which was based on the lump-sum payment from Otsuka Pharmaceutical.

In China, MEROPEN® and the Others segment are still increasing.

Financial Results for FY2021

**Marketing Status of ORGOVYX®**

- Obtained approx. 3,500 new patient starts in FY2021 Q4 with wide range of patients (32% growth vs. Q3)



**Obtained prescriptions of wide range of patients**



- 60% ADT naïve / 40% ADT transition patients
- 55% with localized PC
- 32% with metastatic PC
- 20% receiving combination therapy

**Established broad payer coverage**

- Commercial – 82% of lives
- Medicare Part D – 99% of lives (March 2022)

- Achieved 18% commercial demand volume growth in FY2021 Q4 vs. Q3 (Prescribed approx. 80% of the total at Dispensing Clinics, Academic, etc.)
- Led to high prescriber satisfaction by no testosterone surge, profound/sustained testosterone suppression and one-pill, once-a-day (ORGOVYX® prescriber satisfaction is 73% in April 2022)



\* Source : Presentation of Fourth Fiscal Quarter 2021 Earnings Conference Call of Myovant Sciences Ltd.

This is a summary of data already published by Myovant.

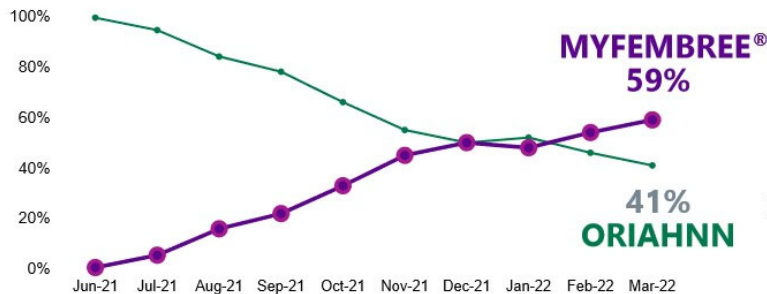
ORGOVYX® was launched in January 2021, and you can see that the number of patients has been gradually and steadily increasing since then, and the number of patients in Q4 FY2021 increase by more than 30% from Q3.

The payer coverage on the middle of the page shows 82% of commercial insurance and nearly 100% of Medicare Part D. I think we are almost at the point where we have enough coverage.

The characteristics of ORGOVYX®, as shown in the bottom square mark, have been highly evaluated by prescribing physicians, with 73% of prescribers satisfied with the product.

## Marketing Status of MYFEMBREE®

- Obtained 59% NBRx share among GnRH antagonists therapies for uterine fibroids in March 2022 as market leader



### Established broad payer coverage

- Commercial – 93% of lives (April 2022)

NBRx share among GnRH antagonists therapies for uterine fibroids\*1

- Achieved 2.4 times class growth in TRx for GnRH antagonists therapies for uterine fibroids since MYFEMBREE® launch\*2
- Achieved 87% intent to prescribe in important targets by substantial/sustained MBL reduction, anemia improvement, one-pill, once-a-day, etc. in March 2022



\*1 Source : Presentation of Fourth Fiscal Quarter 2021 Earnings Conference Call of Myovant Sciences Ltd.

\*2 As of end of March 2022

This slide for MYFEMBREE® is also a summary of what Myovant has published.

The market share of new prescriptions for GnRH antagonists for the treatment of uterine fibroids in March 2022 is shown in the chart, but since the only competitor is ORIAHNN, this is a comparison to that, but at the end of March, MYFEMBREE® accounted for 59% of new patients, which means that it has surpassed the existing drug. MYFEMBREE®'s coverage of uterine fibroids is also very high, at 93% with private insurance.

At the bottom of the list -- we were talking about doctor satisfaction with ORGOVYX® earlier, and this is 87% of obstetrician-gynecologists' intention to prescribe the product. We understand that MYFEMBREE® is also a very highly appreciated.



### Marketing Status of GEMTESA®

- GEMTESA® was prescribed 26,145 TRx in March 2022 and ahead of our FY2021 forecast

|                     | GEMTESA®  |            |
|---------------------|-----------|------------|
|                     | Dec. 2021 | March 2022 |
| TRx Share in Beta 3 | 4.7%      | 6.4%       |
| Monthly TRx numbers | 18,933    | 26,145     |



- Coverage continues to expand and plans to secure most of peak coverage during FY2022

|  | GEMTESA®  |                   |
|--|-----------|-------------------|
|  | Jan. 2022 | End of March 2022 |
| All of commercial lives (Approx. 178 million)    | 34%       | 56%               |
| All of Medicare Part D lives (Approx. 46million) | 24%       | 31%               |

- Sales reps calls in person, promote building a strong presence at major Urology and Long Term Care conferences
- Focus on online video distribution for disease awareness and product recognition for patients, including potential patients

This is the marketing status of GEMTESA®.

The table on top shows the number of prescriptions in December, its share, and then the share and number of prescriptions at the end of March, where the prescription share is gradually increasing. This 6.4% was at the end of March, for example, and the rest of share is where Mirabegron is being prescribed, so we will try to increase our share as much as possible.

The second table shows the coverage for private insurance, which was 34% in January and 56% at the end of March. Medicare Part D was 24% in January and 31% at the end of March, which is slower progress than ORGOVYX® and MYFEMBREE® mentioned earlier, but this is because Mirabegron is the giant in the market and increasing coverage while Mirabegron is in place will lead to a large discount being demanded. We are trying to balance the situation as we increase the coverage.

## Financial Results for FY2021

### Segment Information (Core Basis)

Billions of yen

|                       | Pharmaceuticals Business     |               |        |               |          | Other Business | Total  |
|-----------------------|------------------------------|---------------|--------|---------------|----------|----------------|--------|
|                       | Japan                        | North America | China  | Other Regions | Subtotal |                |        |
| <b>FY2021 Results</b> | Revenue (Sales to customers) | 149.9         | 319.8  | 38.3          | 12.2     | 520.2          | 560.0  |
|                       | Cost of sales                | 78.7          | 33.6   | 7.4           | 6.6      | 126.3          | 157.1  |
|                       | Gross profit                 | 71.3          | 286.2  | 30.9          | 5.5      | 393.9          | 402.9  |
|                       | SG&A expenses                | 51.7          | 180.8  | 11.3          | 2.3      | 246.1          | 251.6  |
|                       | Core segment profit          | 19.6          | 105.4  | 19.6          | 3.3      | 147.8          | 151.4  |
|                       | R&D expenses                 |               |        |               |          | 93.2           | 94.0   |
| Core operating profit |                              |               |        |               | 55.8     | 58.5           |        |
| <b>FY2020 Results</b> | Revenue (Sales to customers) | 152.5         | 281.5  | 27.8          | 17.2     | 479.1          | 516.0  |
|                       | Cost of sales                | 77.5          | 20.8   | 5.4           | 5.7      | 109.4          | 137.5  |
|                       | Gross profit                 | 75.1          | 260.7  | 22.5          | 11.5     | 369.8          | 378.5  |
|                       | SG&A expenses                | 50.8          | 143.8  | 9.2           | 2.8      | 206.7          | 211.8  |
|                       | Core segment profit          | 24.3          | 116.9  | 13.2          | 8.7      | 163.1          | 166.7  |
|                       | R&D expenses                 |               |        |               |          | 96.2           | 97.1   |
| Core operating profit |                              |               |        |               | 66.9     | 69.6           |        |
| <b>Change</b>         | Revenue (Sales to customers) | (2.6)         | 38.3   | 10.5          | (5.1)    | 41.1           | 44.1   |
|                       | SG&A expenses                | 0.9           | 37.0   | 2.1           | (0.5)    | 39.4           | 39.8   |
|                       | Core segment profit          | (4.7)         | (11.5) | 6.4           | (5.4)    | (15.3)         | (15.3) |
|                       | R&D expenses                 |               |        |               |          | (3.0)          | (3.1)  |
| Core operating profit |                              |               |        |               | (11.1)   | (11.1)         |        |

- **Japan:** Lower profit due to declined gross profit and increased expenses resulting from the launch of TWYMEEG®
- **North America:** Lower profit mainly due to incremental costs related to Sumitovant despite higher sales from the alliance revenue and new products sales
- **China:** Profit increased mainly due to higher revenue
- **Other Regions:** Lower profit due to decrease in export

This is a comparison by segment between the previous year and the current year. You can see the details here.

## Financial Forecasts for FY2022

### Financial Forecasts for FY2022 (Core Basis)

|  | FY2021<br>Results | FY2022<br>Forecasts | Change        |            |               |
|--|-------------------|---------------------|---------------|------------|---------------|
|  |                   |                     | Value         | FX         | %             |
| Revenue  | 560.0             | 550.0               | (10.0)        | 37.5       | (1.8)         |
| Cost of sales  | 157.1             | 164.5               | 7.4           | 7.5        | 4.7           |
| Gross profit   | 402.9             | 385.5               | (17.4)        | 30.0       | (4.3)         |
| SG&A expenses  | 251.6             | 283.5               | 31.9          | 21.7       | 12.7          |
| R&D expenses   | 94.0              | 93.0                | (1.0)         | 6.5        | (1.1)         |
| Other operating income and expenses<br>(Core basis)                    | 1.2               | 21.0                | 19.8          | 2.1        | —             |
| <b>Core operating profit</b>   | <b>58.5</b>       | <b>30.0</b>         | <b>(28.5)</b> | <b>3.9</b> | <b>(48.7)</b> |
| Changes in fair value of contingent<br>consideration (negative number) | 3.3               | (0.5)               | (3.8)         |            |               |
| Other non-recurring item<br>(negative number indicates)                | (1.6)             | (5.5)               | (3.9)         |            |               |
| <b>Operating profit</b>  | <b>60.2</b>       | <b>24.0</b>         | <b>(36.2)</b> |            | <b>(60.2)</b> |
| <b>Net profit attributable to owners of<br/>the parent</b>             | <b>56.4</b>       | <b>22.0</b>         | <b>(34.4)</b> |            | <b>(61.0)</b> |
| R O E (%)  | 9.5               | 3.6                 |               |            |               |
| R O I C (%)  | 1.7               | 0.7                 |               |            |               |

#### Expect both revenue and profit down for FY2022

- **Revenue:** Japan (¥19.9B), North America ¥14.5B, China (¥10.7B)
  - Japan will be affected by termination of sale of REPLAGAL®, NHI price revision
  - North America will decrease on USD basis because the alliance revenue ¥30.3B was recorded in FY2021, while ORGOVYX®, MYFEMBREE®, GEMTESA® will grow
  - China is expected price down by VBP application to MEROPEN®
- **SG&A and R&D expenses:**
  - SG&A will increase mainly due to impact of FX
  - R&D will decrease despite FX impact
- **Other operating income and expenses (Core basis):**
  - Sale of priority review voucher will be assumed

(Ref.) Expenses related to Sumitovant (¥B)

|   | 2021 | 2022  | Change |
|---|------|-------|--------|
| SG&A expenses                             | 90.3 | 117.9 | 27.6   |
| Amortization of patent<br>rights in above | 17.4 | 20.8  | 3.4    |
| R&D expenses                              | 24.3 | 25.8  | 1.5    |

The figures are before intra-group elimination



FX rates:  
 FY2021 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5  
 FY2022 Forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

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## Forecasts.

Revenue is JPY550 billion, core operating profit is JPY30 billion, and net income attributable to owners of the parent is JPY22 billion. Compared with the final year of the Mid-term Business Plan announced last year, this represents a significant decrease from JPY600 billion in revenue and JPY60 billion in core operating profit. We will address the differences later.

Compared to the previous year, the revenue decreases by JPY10 billion here. In Japan, as you will see later, we would like to manage to increase the volume in spite of the termination of REPLAGAL® sales and the effects of the NHI price revision.

In North America, foreign exchange gains are positive JPY24.5 billion, although negative in the dollar. In China, we expect VBP application to MEROPEN® and then LATUDA®, starting around August, so we can see such an impact.

SG&A expenses. Excluding foreign exchange, the increase is about JPY10 billion, but as you can see in the lower right-hand corner, the increase is mainly related to Sumitovant.

In particular, there is JPY21 billion in other income and expenses here, and some of you may wonder what this is. We received a priority review voucher for pediatric congenital athymia, and we recognized about JPY10 billion by selling it. In addition, we will take measures to improve profit and loss, and we are hoping to bring the total to JPY21 billion. In that sense, core operating profit is JPY30 billion.

Other non-recurring items include a negative JPY5.5 billion. As you all know, LATUDA® will reach its LOE in February 2023, and we are planning to reorganize our sales structure, so this is factored in.

Just to mention a word about LATUDA®'s sales structure, by having sales reps promoting for as long as possible, it is positive from a sales and profit perspective. Since LATUDA® is a detail-sensitive agent, we have conducted a simulation that shows that we can maximize profits by detailing the product as much as possible. We will work on this in this fiscal year.

Financial Forecasts for FY2022

**Variance with FY2022 Target of Revised MTBP (1)**

|                       | Financial Forecasts for FY2022 | Mid-term Business Plan 2022<br>(Revised in May 2021) |
|-----------------------|--------------------------------|--|
| Revenue               | ¥550.0B                        | ¥600.0B  |
| SG&A expenses         | ¥283.5B                        | ¥262.0B  |
| R&D expenses          | ¥93.0B                         | ¥93.0B   |
| Core operating profit | ¥30.0B                         | ¥60.0B   |
| ROIC                  | 0.7 %                          | 3 %  |
| ROE                   | 3.6 %                          | 3 %  |
| FX rate               | 1US\$ = ¥125.0                 | 1US\$ = ¥110.0                                       |

**Revenue :**

- Downward adjustment of ¥90.0B except for increased revenue by weaker yen, due to taking much time for market penetration of new products than assumption in revised MTBP because of effects of COVID-19

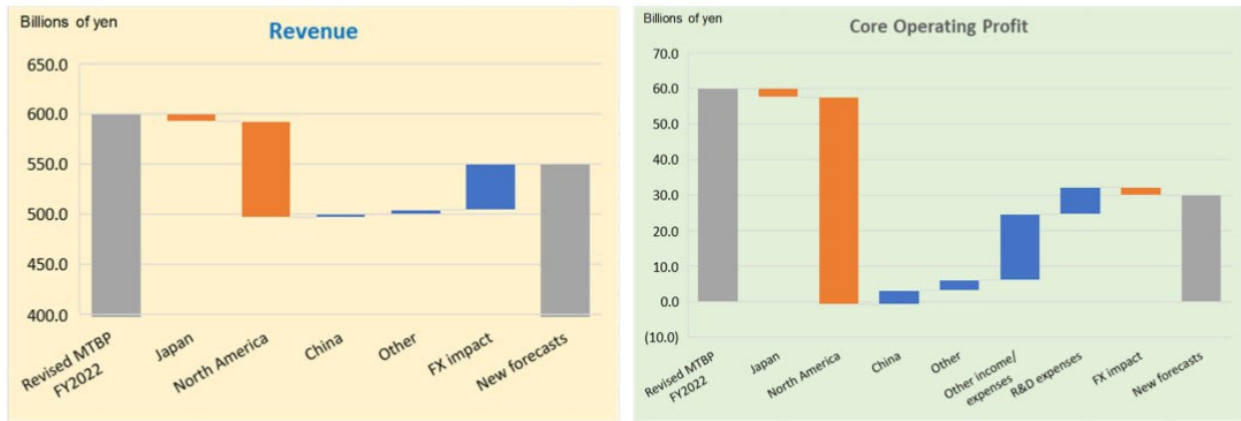
**Core operating profit :**

- Downward adjustment of ¥30.0B due to decrease in revenue and gross profit

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As I have mentioned many times, this is a revised part of the management objectives of the Mid-term Business Plan announced last May.

## Variance with FY2022 Target of Revised MTBP (2)



I cannot go into too much detail because there are listed companies, but sales revenue in North America, shown in orange, is significantly lower than we had expected, partly due to COVID-19.

The core operating profit on the right is also where North America has a large impact in terms of profit. We try to secure core operating profit of JPY30 billion by adding up these costs with other income and expenses, such as the sale of the voucher mentioned earlier, other profit improvement measures, and a slight decrease in research and development expenses.

Financial Forecasts for FY2022

**Segment Information (Core Basis)**

Billions of yen

|                         | Pharmaceuticals Business     |               |        |               |          | Other Business | Total  |        |
|-------------------------|------------------------------|---------------|--------|---------------|----------|----------------|--------|--------|
|                         | Japan                        | North America | China  | Other Regions | Subtotal |                |        |        |
| <b>FY2022 Forecasts</b> | Revenue (Sales to customers) | 130.0         | 334.3  | 27.6          | 16.1     | 508.0          | 42.0   | 550.0  |
|                         | Cost of sales                | 67.6          | 53.6   | 5.6           | 5.2      | 132.0          | 32.5   | 164.5  |
|                         | Gross profit                 | 62.4          | 280.7  | 22.0          | 10.9     | 376.0          | 9.5    | 385.5  |
|                         | SG&A expenses                | 53.0          | 211.0  | 11.6          | 1.6      | 277.2          | 6.3    | 283.5  |
|                         | Core segment profit          | 9.4           | 69.7   | 10.4          | 9.3      | 98.8           | 3.2    | 102.0  |
|                         | R&D expenses                 |               |        |               |          | 90.5           | 2.5    | 93.0   |
|                         |                              |               |        |               | 29.3     | 0.7            | 30.0   |        |
| <b>FY2021 Results</b>   | Revenue (Sales to customers) | 149.9         | 319.8  | 38.3          | 12.2     | 520.2          | 39.9   | 560.0  |
|                         | Cost of sales                | 78.7          | 33.6   | 7.4           | 6.6      | 126.3          | 30.8   | 157.1  |
|                         | Gross profit                 | 71.3          | 286.2  | 30.9          | 5.5      | 393.9          | 9.0    | 402.9  |
|                         | SG&A expenses                | 51.7          | 180.8  | 11.3          | 2.3      | 246.1          | 5.5    | 251.6  |
|                         | Core segment profit          | 19.6          | 105.4  | 19.6          | 3.3      | 147.8          | 3.5    | 151.4  |
|                         | R&D expenses                 |               |        |               |          | 93.2           | 0.8    | 94.0   |
|                         |                              |               |        |               | 55.8     | 2.7            | 58.5   |        |
| <b>Change</b>           | Revenue (Sales to customers) | (19.9)        | 14.5   | (10.7)        | 3.9      | (12.2)         | 2.1    | (10.0) |
|                         | SG&A expenses                | 1.3           | 30.2   | 0.3           | (0.7)    | 31.1           | 0.8    | 31.9   |
|                         | Core segment profit          | (10.2)        | (35.7) | (9.2)         | 6.0      | (49.0)         | (0.3)  | (49.4) |
|                         | R&D expenses                 |               |        |               |          | (2.7)          | 1.7    | (1.0)  |
|                         |                              |               |        |               | (26.5)   | (2.0)          | (28.5) |        |

- **Japan segment:** Profit will decrease largely because of revenue decrease
- **North America segment:** Revenue will increase by FX, but decrease on USD basis  
Gross profit will decrease due to changes in component such as decrease of alliance revenue  
SG&A expenses will be the same as FY2021 except for FX impact  
Core segment profit will decrease due to decrease in Gross profit
- **China segment:** Profit will decrease largely because revenue decrease
- **Other Regions segment:** Lump-sum payment (\$50M) based on the license out contract for DSP-0187 is included
- **Other Business:** Revenue and expenses in the frontier business will be expected

Page 15. Here is a comparison by segment between FY2021 and FY2022.

This year we will start selling a neurorehabilitation device under the Frontier Business, which is included in Others. I would like to add that the small amount is included in the sales.

Financial Forecasts for FY2022

## Revenue of Major Products in Japan

Billions of yen

|               | FY2021<br>Results | FY2022<br>Forecasts | Change        |               |
|---------------|-------------------|---------------------|---------------|---------------|
|               |                   |                     | Value         | %             |
| Equa®/EquMet® | 37.5              | <b>34.9</b>         | (2.6)         | (6.9)         |
| Trulicity®*   | 33.6              | <b>31.0</b>         | (2.6)         | (7.8)         |
| TRERIEF®      | 16.4              | <b>17.3</b>         | 0.9           | 5.7           |
| LATUDA®       | 6.9               | <b>9.9</b>          | 3.0           | 44.0          |
| METGLUCO®     | 8.1               | <b>7.8</b>          | (0.3)         | (4.3)         |
| LONASEN® Tape | 2.1               | <b>2.7</b>          | 0.6           | 31.2          |
| TWYMEEG®      | 0.2               | <b>1.5</b>          | 1.3           | 752.2         |
| REPLAGAL®     | 12.4              | —                   | (12.4)        | —             |
| AG products   | 9.7               | <b>9.7</b>          | 0.0           | 0.4           |
| Others        | 23.1              | <b>15.2</b>         | (7.9)         | (34.3)        |
| <b>Total</b>  | <b>149.9</b>      | <b>130.0</b>        | <b>(19.9)</b> | <b>(13.3)</b> |

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



- Revenue will decrease ¥19.9B on Japan segment total
- Decrease in Equa®/EquMet® and Trulicity® are attributed to NHI price revision
- Sales of LATUDA®, LONASEN® Tape and TWYMEEG® will increase
- Sale of REPLAGAL® was terminated in February 2022
- Revenue of Agalsidase Beta BS which promotion started in April 2022 is included in "Others"
- NHI price revision impact in FY2022 (¥12.0B)

This shows revenue of major products in Japan.

REPLAGAL® has been transferred to Takeda Pharmaceutical and it is zero. The impact of the NHI price revision will be JPY12 billion, so although the volume increases, revenues of Trulicity® and Equa®-EquMet® are negative compared to the previous year. As for LATUDA®, I would say that it is growing steadily.

Financial Forecasts for FY2022

**Revenue of Major Products in North America & China**

|                       | FY2021<br>Results | FY2022<br>Forecasts | Change       | FY2021<br>Results | FY2022<br>Forecasts | Change        |             |               |
|-----------------------|-------------------|---------------------|--------------|-------------------|---------------------|---------------|-------------|---------------|
|                       |                   |                     |              |                   |                     | Value         | FX impact   | %             |
| <b>North America</b>  | Million \$        |                     |              | Billions of yen   |                     |               |             |               |
| LATUDA®               | 1,816             | 1,726               | (90)         | 204.1             | 215.8               | 11.7          | 21.7        | 5.7           |
| APTIOM®               | 241               | 255                 | 14           | 27.1              | 31.8                | 4.7           | 3.2         | 17.3          |
| RETHYMIC®             | 3                 | 48                  | 45           | 0.3               | 6.0                 | 5.7           | 0.6         | 1,854.4       |
| BROVANA®              | 129               | 26                  | (103)        | 14.5              | 3.2                 | (11.3)        | 0.3         | (77.9)        |
| KYNMOBI®              | 5                 | 18                  | 13           | 0.6               | 2.3                 | 1.7           | 0.2         | 273.4         |
| ORGOVYX®              | 83                | 601                 | (50)         | 9.3               | 75.2                | 2.1           | 7.7         | 2.8           |
| MYFEMBREE®/<br>RYEQO® | 11                |                     |              | 1.3               |                     |               |             |               |
| GEMTESA®              | 63                |                     |              | 7.1               |                     |               |             |               |
| Others                | 493               |                     |              | 55.4              |                     |               |             |               |
| <b>Total</b>          | <b>2,845</b>      | <b>2,674</b>        | <b>(171)</b> | <b>319.8</b>      | <b>334.3</b>        | <b>14.5</b>   | <b>33.7</b> | <b>4.5</b>    |
| <b>China</b>          | Million RMB       |                     |              | Billions of yen   |                     |               |             |               |
| MEROPEN®              | 1,708             | 863                 | (845)        | 29.9              | 16.8                | (13.1)        | 1.7         | (43.8)        |
| Others                | 478               | 553                 | 75           | 8.4               | 10.8                | 2.4           | 1.1         | 28.9          |
| <b>Total</b>          | <b>2,186</b>      | <b>1,416</b>        | <b>(770)</b> | <b>38.3</b>       | <b>27.6</b>         | <b>(10.7)</b> | <b>2.8</b>  | <b>(27.9)</b> |

\* Even though the United States Patent and Trademark Office (USPTO) has made decision that there is no patentability of LATUDA patent for use, we are seeking the withdrawal of this decision, we consider there is no impact for the loss of exclusivity in February 2023.

FX rates:  
FY2021 Results : 1US\$ = ¥112.4, 1RMB = ¥17.5  
FY2022 Forecasts : 1US\$ = ¥125.0, 1RMB = ¥19.5

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- **North America segment**  
Revenue will increase on JPY basis due to ¥33.7B of FX impact despite decrease on the USD basis
- LATUDA® will reach loss of exclusivity in February 2023  
Considering the effect of competing products, we focus on promotion until December 2022
- BROVANA® decreased due to generic products of BROVANA® launched in June 2021
- Revenue from the alliance with Otsuka \$270M (¥30.3B) included in "Others" will decrease, deferred revenue from the alliance for relugolix will be \$100M / ¥12.5B (FY2021: \$105M / ¥11.8B)
- **China segment**  
MEROPEN® will decrease due to expected price down by VBP

North America and China.

In North America, this fiscal year is the last year for LATUDA® in terms of market exclusivity in the U.S. Compared to the previous year, the revenue decreases by USD90 million, but if you look to the right, you will see an increase of JPY11.7 billion owing to the impact of foreign exchange.

Then here is RETHYMIC®. In the dollar, it is USD3 million and expect to be USD48 million in FY2022. We are expecting to be able to perform transplant surgeries on about 20 patients.

Then ORGOVYX®, MYFEMBREE®/RYEQO®, GEMTESA®, and others are collectively USD601 million, since the breakdown cannot be disclosed.

Although they decrease year over year by USD50 million, considering the lump-sum payment of USD270 million from Otsuka Pharmaceutical, please understand that the actual sales of these items are increasing.

As for MEROPEN® in China, sales decreases to JPY13.1 billion. VBP application will significantly reduce the price and volume of drugs. Generally speaking, it is said that generics will dominate about 70% of the market. Concerning antibacterial drugs, we see 60%. So, we are trying to maintain our presence in the rest of the market in China until lefamulin is released.



## Dividend Policy

- Performance-linked dividend hike will be considered in addition to consistent dividend payments
- Current MTBP 5-year (FY2018-2022) average payout ratio: 20% or higher (expected to be 28%)

|                                       | FY2020 actual | FY2021 plan | FY2022 plan |
|---------------------------------------|---------------|-------------|-------------|
| Dividend per share (yen)              | 28.00         | 28.00       | 28.00       |
| Payout ratio (%)                      | 19.8          | 19.7        | 50.6        |
| Return on Invested Capital (ROIC) (%) | 3.1           | 1.7         | 0.7         |
| Return on Equity (ROE) (%)            | 10.1          | 9.5         | 3.6         |

ROIC: (core operating profit – income taxes) / (total capital + interest-bearing liabilities)

Shareholder dividend policy and return policy.

We plan a dividend of JPY28 per year for FY2021, and the same dividend is planned for FY2022.

Research and Development

## Development Pipeline (as of May 13, 2022)

■ : Psychiatry & Neurology 
 ■ : Oncology 
 ■ : Regenerative medicine / Cell therapy 
 ■ : Others 
 ■ : Frontier business 
 Revisions since the announcement of January 2022 are shown in red

| Area  | Phase 1   | Phase 2   | Phase 3  | NDA submitted  |   |
|-------|---|---|--|--|---|
| Japan | DSP-9632P<br>(Levodopa-induced dyskinesia in Parkinson's disease) | DSP-0390<br>(Solid tumors)  | EPI-589<br>(ALS/Investigator-initiated study)  | ulotaront (SEP-363856)<br>(Schizophrenia)                    | METGLUCO® (metformin)<br>(New indication: infertility treatment)                        |
|       | DSP-0187<br>(Narcolepsy)  | TP-3654<br>(Hematologic malignancies)<br>DSP-5336<br>(Hematologic malignancies)<br>guretolimod (DSP-0509)<br>(Solid tumors) | Allo iPS cell-derived products<br>(Parkinson's disease/<br>Investigator-initiated study) | SEP-4199<br>(Bipolar I depression)                           |   |
| U.S.  | DSP-6745<br>(Parkinson's disease psychosis)                       | guretolimod (DSP-0509)<br>(Solid tumors)  | EPI-589<br>(Parkinson's disease/ALS)   | ulotaront (SEP-363856)<br>(Schizophrenia)                    | MYFEMBREE® (relugolix)<br>(New indication: Endometriosis)<br>PDUFA goal date: Aug. 2022 |
|       | SEP-378608<br>(Bipolar disorder)                                  | TP-1287<br>(Solid tumors)   | ulotaront (SEP-363856)<br>(Parkinson's disease psychosis)                                | SEP-4199<br>(Bipolar I depression)                           |   |
|       | DSP-3905<br>(Neuropathic pain)                                    | TP-3654<br>(Hematologic malignancies)   | dubermatinib (TP-0903)<br>(AML/Research group-initiated study)                           | GEMTESA® (vibegron)<br>(New indication: OAB in men with BPH) |   |
|       | SEP-378614<br>(To be determined)                                  | TP-1454<br>(Solid tumors)   | DSP-7888<br>(Solid tumors)   |  |   |
|       | SEP-380135<br>(To be determined)                                  | DSP-0390<br>(Solid tumors)  | rodatristat ethyl<br>(Pulmonary arterial hypertension)                                   |  |   |
|       | DSP-0038<br>(Alzheimer's disease psychosis)                       | DSP-5336<br>(Hematologic malignancies)  | URO-902<br>(Overactive bladder)  |  |   |
|       | DSP-3456<br>(Treatment resistant depression)                      | KSP-1007<br>(Complicated urinary tract infections,<br>Complicated intra-abdominal infections)                               |  |  |   |
| China |   |   | LATUDA®<br>(New indication: Bipolar I depression)  | Iefamulin<br>(Bacterial community-acquired pneumonia)        |   |
|       |   |   | ulotaront (SEP-363856)<br>(Schizophrenia)  |  |   |

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Research and Development.

The submission on the far right for MYFEMBREE® in the US has a PDUFA date of August this year for completion of the review.

Originally, the PDUFA date was May 6, but as I am sure you are all aware, we received a letter from the FDA in early April stating that there would be a deficiency. After that, we were asked to submit additional data, and when we did, we were told that it would take a bit of time to review the data. So, it resulted in a three-month delay.

## Clinical Development Status (Major Changes since January 31, 2022)

- **DSP-3456**  
U.S.: Started Phase 1 study for treatment resistant depression
- **Relugolix**  
Europe: Approved for prostate cancer in April 2022  
✓ In May 2022, Myovant entered into an exclusive license agreement with Accord Healthcare, Ltd. to commercialize ORGOVYX® for the treatment of prostate cancer in Europe  
Accord Healthcare is expected to launch ORGOVYX® in Europe in the second half of calendar year 2022
- **DSP-0509 (guretolimod)**  
Japan: Started Phase 1/2 study for solid tumors
- **TP-0184**  
U.S.: Discontinued development for anemia associated with myelodysplastic syndromes (Phase 1/2 study)
- **MYFEMBREE® (relugolix combination tablet)**  
U.S.: Extended PDUFA goal date of FDA (May 6, 2022→ August 6, 2022)
- **METGLUCO® (metformin)**  
Japan: Submitted additional indication for infertility treatment (“ovulation induction for patients with polycystic ovary syndrome” and “controlled ovarian stimulation in assisted reproductive technology for patients with polycystic ovary syndrome”) in March 2022

Research and Development progress.

The second on the slide, relugolix, was approved for prostate cancer in Europe in April. Then, we have licensed the European rights to Accord Healthcare. Accord Healthcare is primarily a generic company, but also offers about six brand-name products, and is also focused on oncology. Thus, this company was chosen.

TP-0184 is the third one from the bottom, but its development has been discontinued. In the results section I mentioned earlier, in terms of the fair value of contingent consideration, or below that, in terms of other non-recurring items, there was a positive impact in the fair value of the contingent consideration, and then below that, there was a negative impact of the impairment. It is not that large in value.

Regarding the second one from the bottom, MYFEMBREE®, I have already mentioned it.

## Progress of ulotaront and SEP-4199 (Co-Development with Otsuka Pharmaceutical)

### Progress of ulotaront

- ✓ First indication: schizophrenia (SZ)
  - Actively evaluating the impact of the situation in Russia and Ukraine on clinical study recruitment and implementing mitigation strategies
    - ⇒ New recruitment in Russia and Ukraine is on indefinite hold, and in the process of initiating new sites in other countries, including the U.S.
- ✓ Second indication: Adjunctive Major Depressive Disorder (aMDD)
  - Clinical program lead: Otsuka Pharmaceutical
  - Study design under review for finalization with IND planned in FY2022
- ✓ Third indication: Under consideration; mental health disorder synergistic with aMDD and SZ
  - Clinical program lead: Sunovion
  - Study design under consideration; disclosure of additional study details expected during FY2022

### Progress of SEP-4199

- ✓ Phase 3 study and its associated Open Label Extension (OLE) for bipolar I depression are ongoing
  - FPI for the both studies occurred at a U.S. site in Q4 FY2021

Page 22, ulotaront and SEP-4199, jointly developed by Otsuka Pharmaceutical.

Regarding ulotaront, as you all know, the situation in Russia and Ukraine has had a major impact on the recruitment of patients for clinical studies for schizophrenia, and we are currently discussing and formulating countermeasures with Otsuka Pharmaceutical. Currently, we have stopped recruiting new patients in Russia and Ukraine, and we are now working with Otsuka Pharmaceutical to conduct studies in other countries, mainly in the United States.

It has been decided that the second indication will be adjunctive therapy for major depressive disorder, adjunctive MDD. Otsuka Pharmaceutical will be in charge of conducting the studies. We have been told that the IND will be submitted this year.

We are currently in discussions with Otsuka Pharmaceutical regarding the third indication, but we have not yet reached a final decision. However, we will be able to determine with them during this fiscal year as to what indications we will be able to develop.

Then there is the ongoing work on SEP-4199.

Research and Development

**Main Events / Targets for FY2022 (as of May 13, 2022)**

|   |   |
|---|---|
| <b>Psychiatry &amp; Neurology</b>           | <input type="checkbox"/> ulotaront : <input type="checkbox"/> Start clinical studies for two new indications (SEP-363856) <input type="checkbox"/> Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia<br><input type="checkbox"/> SEP-4199: Advance Phase 3 studies for Bipolar I depression  |
| <b>Oncology</b>                             | <input checked="" type="checkbox"/> relugolix : (Europe) Obtain approval for prostate cancer<br><input type="checkbox"/> Advance early Phase studies  |
| <b>Regenerative medicine / Cell therapy</b> | <input type="checkbox"/> Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study<br><input type="checkbox"/> Allogeneic iPS cell-derived products (Parkinson's disease) : Start clinical study in the U.S.<br><input type="checkbox"/> Start construction of manufacturing plant in the U.S (for RETHYMIC® and allogeneic iPS cell-derived products)                          |
| <b>Infectious Diseases</b>                  | <input type="checkbox"/> Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines : Promote joint research and development projects  |
| <b>Others</b>                               | <input type="checkbox"/> relugolix : (U.S.) <input type="checkbox"/> Obtain approval for endometriosis (Europe) <input type="checkbox"/> Submit MAA for endometriosis   |
| <b>Frontier</b>                             | <input type="checkbox"/> Launch products: <input type="checkbox"/> (Japan) Neurorehabilitation device for hand/figures <input type="checkbox"/> (U.S.) VR contents for mental health<br><input type="checkbox"/> Generating evidence data for maximizing the value of the launched products: Digital device for relieving BPSD, etc.<br><input type="checkbox"/> Promote the current themes and development of new themes |

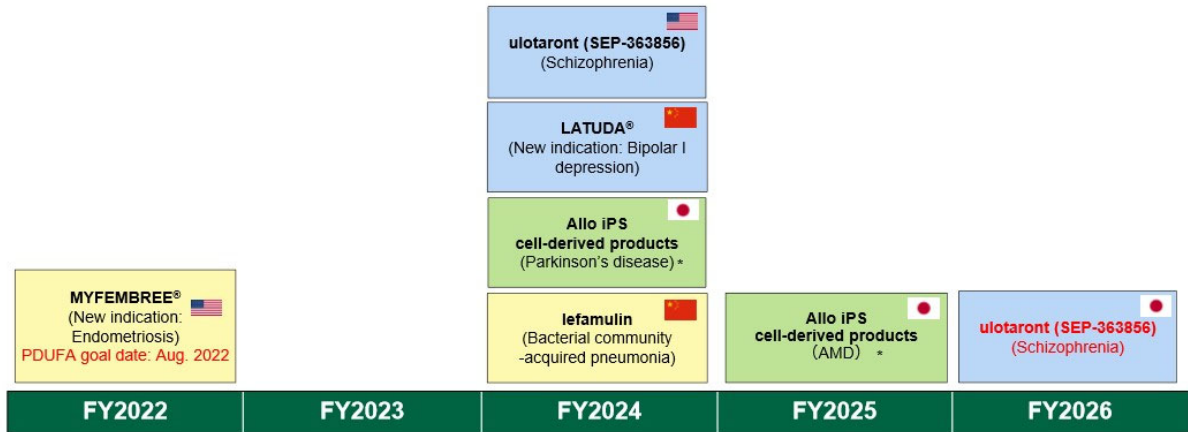
Here are major events and targets for FY2022.

There are many, but the second one from the top is that the approval of relugolix for prostate cancer in Europe has been achieved.

Research and Development

**Product Launch Target (as of May 13, 2022)**

Revisions since the announcement of January 2022 are shown in red



■ : Psychiatry & Neurology    ■ : Oncology  
■ : Regenerative medicine / cell therapy    ■ : Others

\* Launch schedule is based on our goal pending agreement with partners

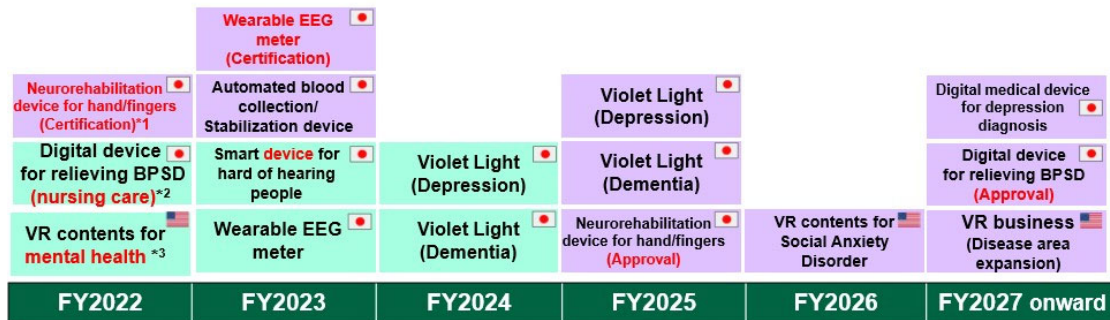
Regarding the product launch target, concerning MYFEMBREE® in FY2022, I mentioned earlier.

Research and Development

**Product Launch Target (Frontier business) (as of May 13, 2022)**

Revisions since the announcement of January 2022 are shown in red

■ : Medical device  
■ : Non-medical device



\*1 Certified medical device named "Active extension / flexion / extension rotation exercise device" (Accepted name for medical devices), sales by Sumitomo Pharma

\*2 Full-scale sales primarily by partners (Aikomi : our associated company)

\*3 Sales primarily by partners (BehaVR) (Profit share 50-50 with both companies)

The project description varies with the product (device sales, solution business, royalties, etc.)

Here is product launch target for the Frontier Business.

In FY2022, starting from the top, sales of the neurorehabilitation device for hand and finger paralysis, which I mentioned earlier will generate sales, will increase slightly.

Relieving BP&SD, which will be handled by Aikomi, will also be promoted to nursing care facilities. The mental health VR contents are to be sold by BehaVR, a US company, and we are assuming that the revenue will be split 50/50 with us. After FY2023, it is as you have seen.

## Neurorehabilitation Device for Hand/Fingers

- Commercialization of neurorehabilitation device for hand/fingers paralysis which has been co-developed by MELTIN and Sumitomo Pharma
- Under application for certification as a medical device (accepted name for medical devices: Active extension/flexion/extension rotation exercise device)
- Manufacturer: MELTIN, distributor (planned): Sumitomo Pharma
- Targeting to launch in FY2022



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- Even for post-stroke patients with hand/fingers paralysis, this robotic neurorehabilitation device is designed to read the patient's motion intention from biosignals with which AI will interpret them to motions and operate the device for training of hand/fingers movements in sync with the intention
- By repeating movements in sync with the patient's intention, it is aimed that the brain will learn again how to move the hand

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As I mentioned earlier, we expect sales to increase slightly this fiscal year, and would like to introduce the neurorehabilitation device for hand and fingers paralysis.

I have briefly explained the financial results for FY2021 and the outlook for FY2022.

After this, we would like to take your questions. Thank you very much.

**Harada:** Thank you very much, Mr. Nomura.



## Question & Answer

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**Harada** : I would now like to move on to the question-and-answer session.

**Yamaguchi, Citigroup Global Markets Japan**: First, let me ask you about ulotaront. We were told how to respond to the first indication. Described in Clinical.gov that the topline is at the beginning of next year. With this response, should we still think that is likely to be a bit of a setback, or is it possible that the response will be enough to make it possible? Please give us your initial outlook on this area.

**Kimura**: Thank you very much for your question. At present, we have not been able to analyze the details of how long the delay will be or what will happen, but we expect that there will be a slight delay in terms of the progress of the clinical studies, even in terms of its completion. However, as I explained earlier, we have not changed our plan in terms of the product launch in FY2024.

**Yamaguchi, Citigroup Global Markets Japan**: Thank you very much. The next one is adjunctive major depressive disorder (aMDD), and the third one is under consideration, but I was wondering if you could give me an idea of the size of the market for aMDD and schizophrenia. I think that schizophrenia is not a very big market, and there are many drugs that are like an entry in this area and I have an image that the market for aMDD is not very big.

**Kimura**: In fact, it is a compound with a completely new mechanism of action, including schizophrenia, so I cannot give you any figures on how well it will be accepted in clinical practice, especially for MDD, because we are still in the process of conducting clinical studies to confirm this aspect of the compound. However, I would like to just mention that, in general, the number of patients with MDD is many times larger than that of patients with schizophrenia.

**Yamaguchi, Citigroup Global Markets Japan**: I understand. Let me ask one more question. When will the second trial of Phase III study for SEP-4199 be conducted?

**Ikeda**: We are currently conducting the first trial of Phase III study, and the second trial of Phase III study will follow, so we are aiming for approval in the late 2020s.

**Yamaguchi, Citigroup Global Markets Japan**: I understand. Also, lastly, in the overall section, you mentioned that the difference from last year's Mid-term Business Plan is quite large. I think it means that the US sales are not going as well as expected, but next term, LATUDA<sup>®</sup> is going to face the cliff this time.

Regarding this, the next fiscal year is the next fiscal year, but I wonder if you will further curb costs and put in place a system to protect profits. Or do you see it as inevitable that a major decline in short-term performance will be unavoidable, with the direct impact?

I know that profits are a little low this fiscal year as well, before the cliff came along, but could you please give us some guidance as far as you know what your plans are for the next fiscal year? That's all.

**Nomura**: Thank you for your question. In order to overcome the LATUDA<sup>®</sup> LOE, we have been trying to cover the gap with Napabucasin, and products from Sumitovant after the abandonment of Napabucasin launch. I do believe that the potential of Sumitovant products has no change at all.

Unfortunately, the market did not grow as much as we would have liked due to COVID-19 and other factors at the time of launch of these new products, but I believe that they will become products that will support

the backbone of our company in the future. However, it was a bit off, and I think that is where it differed from what was expected.

As you pointed out, in FY2023, we expect that sales of LATUDA® in the U.S. will be smaller, so from the standpoint of profit and loss, we will do everything we can as a Group, as I said at the beginning of the presentation. We are now in the process of planning our five-year Mid-term Business Plan starting in FY2023, and a major issue for us is what we should do in order to achieve growth from FY2023 onward.

In this context, we will consider various possible measures to reduce operating costs as much as possible. In this context, we are working on the growth of new items and the development of ulotaront and SEP-4199, which we have been working on with Otsuka Pharmaceutical. We are also looking at the pipelines that are in the early stages, or pre-clinical stage that may not be certified at this time, but we are trying to develop a scenario where we can somehow grow them from FY2023 onward, while implementing measures a little ahead of schedule this year to ensure that we operate business properly over the next five years. We are currently in the process of considering various measures within the Company.

**Yamaguchi, Citigroup Global Markets Japan:** Thank you very much.**Hashiguchi, Daiwa Securities:** First, I would like to confirm the status of ulotaront. You mentioned earlier that the detailed analysis has not yet made to see how it will be delayed. Judging from the contents of page 23, may I understand that it is becoming more difficult to obtain the top line result in the second half of this fiscal year, which you mentioned three months ago?

Also, on page 24, you mentioned earlier that you have not changed the launch plan for FY2024, but what this means is that at this point, do you have a certain feeling that you will be able to meet the target in time, or is the possibility of a delay increasing? Or is it better to understand that the possibility of delay is increasing, but it is not yet clear when the revision should be made, so you are not reviewing the plan at this time?

**Kimura:** Thank you very much for your question. As I mentioned earlier, it is true that the progress of the clinical studies is currently behind schedule, but as a result of a detailed study of the future process, we have found that there are several areas where we can shorten the timeframe compared to the original plan. We have therefore decided not to change our launch target for FY2024.

Let me explain that this is a little different from leaving it as it is because it has not been evaluated.

**Hashiguchi, Daiwa Securities:** Thank you very much. How do you feel about the timing of the results of the Phase III studies?

**Kimura:** It also depends on how the new site will be set up, but we expect a slight delay in that area. After that, we are in the process of seeing where we can shorten the time in the way I mentioned earlier.

**Hashiguchi, Daiwa Securities:** Thank you very much. Second, I would like to talk about the Mid-term Business Plan announced by Sumitomo Chemical in March. I think the core operating profit of the pharmaceutical division was planned to be JPY73 billion in FY2024. I believe the slide showed that the rationalization and fixed cost difference will have an effect of about JPY80 billion compared to FY2021.

Conversely, the plan is that profits will not be generated without streamlining and fixed cost differentials, etc., which will become effective from now on. What is Sumitomo Pharma's plan, and at what pace do you expect to see the effects of the rationalization and the fixed cost difference toward FY2024?

**Nomura:** Thank you. I can't disclose this at this stage, but as I mentioned earlier, in response to your earlier question, I would like to say that we will pursue how efficient the Sumitomo Pharma Group as a whole can be in its operations.

We understand that the fundamental basis of Sumitomo Chemical's announced profit/loss for the pharmaceuticals segment is that the Company is considering measures to somehow reduce fixed costs in this context, starting this fiscal year, if possible, ahead of schedule. In that sense, I would say that it is a fairly stretch goal.

**Hashiguchi, Daiwa Securities:** Thank you very much.

**Wakao, JP Morgan Securities Japan:** I would like to know about the slide on page 14, the North America segment, and I don't want to go into too much detail, but this part that differed from expectations is Sumitovant-related products. Should we simply consider that the sales portion is significantly below forecast, or is the downward swing including sales milestones and other factors associated with sales? Could you tell us a little more about this North America segment, which is JPY90 billion lower than expected?

Also, we have been told for some time that you have not been able to market your Sumitovant-related products well due to the pandemic, and we believe that this is simply a matter of time, so if marketing is aggressive, from the next fiscal year onward, we should see growth closer to what your company had envisioned in the past. Do you think that the growth rate will be closer to the growth rate that your company had assumed in the past?

**Nomura:** Thank you. First, to answer your last question first, I understand that you are correct. As I explained earlier in my explanation of ORGOVYX® and MYFEMBREE® with two slides, we have received very good sensitivity from clinical doctors, so we are not particularly concerned about these products, as we believe they have very high potential.

In FY2022, the revenue from sales on page 14, is not that large, although there were some milestones, such as the approval of endometriosis at that time, so I think there was a one-time payment for such approval. In this sense, it is difficult to provide direct information to medical institutions because of the variety of COVID-19 variants that have appeared in the U.S. just as it was expected the end of COVID-19 to be approaching. Especially in ORGOVYX®-related medical institutions, it is difficult to visit such places because some patients' immunity is still weakened.

The same is true of obstetrics and gynecology, where patients are sometimes reluctant to come to see a doctor because of concerns about infection. I believe that the local people worked very hard, but unfortunately, the results were less than we had expected.

**Wakao, JP Morgan Securities Japan:** Thank you. Secondly, I have been informed that there have been a number of factors, such as the influence of COVID-19, that have led to delays. If that is the case, the JPY120 billion in core operating profit that you mentioned last year in your outlook for FY2025 may be slightly off, but I believe that you will be able to achieve it with the products that you have now and the products that we are developing. May I understand like this? I am sure you will be able to elaborate on this in your Mid-term Business Plan, but if you have any comments now, please let me know.

**Nomura:** Thank you for your questions. We will have to review that figure once more as we create our five-year Mid-term Business Plan starting in FY2023. As I mentioned earlier, the potential of three products ORGOVYX®, MYFEMBREE®, and GEMTESA® are not changed, but I think we should carefully evaluate how much room there is for growth after COVID-19. As to whether or not we can achieve the JPY120 billion in core operating profit at this point in time, it is difficult to answer without another review.

**Wakao, JP Morgan Securities Japan:** I understand. Am I correct in understanding that since you see no change in potential, we have to scrutinize the speed of the start-up process?

**Nomura:** Yes. That is how I understand it. We have unwavering faith in the potential of these products and potential of peak sales, but I think we need to look a little more closely at what how quickly they can achieve such results.

**Wakao, JP Morgan Securities Japan:** I understand very well. Thank you very much. That's all.**Sakai, Credit Suisse Securities (Japan):** I would like to ask you about the domestic business. It is clear that North America will face a difficult situation in terms of profit if LATUDA® disappears, but on the other hand, domestic earnings have been decreasing considerably. I will ask one more question later, but I couldn't hear President Nomura's voice very well when he mentioned reorganization of sales reps for LATUDA®, but anyway, how do you plan to rebuild the domestic business first? Can you first tell us if you have any prospects in this regard?

**Nomura:** Looking at the current status of our domestic business reconstruction, we are well aware of the fact that we are experiencing negative growth, with revenue declining every year, and we are also aware of the major issue of what we can do to address this.

If you look at our current drugs, there are many diabetes-related drugs, and then there are many psychiatric drugs such as LATUDA® and LONASEN®. Our focus areas are Psychiatry & Neurology, Oncology, and Regenerative Medicine & Cell Therapy. We have a variety of psychiatric drugs. Unfortunately, the market for psychiatry is not very large in Japan, and our main market is in North America.

In this sense, in order to increase sales in areas other than Psychiatry & Neurology, we have decided to step into the Diabetes area, where we have built relationships with various doctors. We handle items launched through alliances, partnerships or licensing of other companies.

At the moment, it is difficult to say whether there is a pipeline for significant growth in Japan. In this sense, we are working steadily to launch our own products in the Psychiatry & Neurology area in North America and Japan. Then, through alliances, we will deepen our cooperation with other companies. Such a way of doing things will continue anyway.

In the meantime, the Frontier Business and regenerative medicine products are also expected to be launched, so we are determined to obtain approval and make them available to patients. I think this is the best way to look at it, so we will start with the Psychiatry & Neurology area, Regenerative Medicine & Cell Therapy field, and then the Frontier Business. Until such a thing somehow becomes a pillar of revenue, I think we should try to do our best in the Japanese market through alliances and other means.

Of course, this is just what I am assuming now, but I am also thinking that we should consider what we can do in the next five years from a new angle with a little more insight.

I mentioned earlier that we will promote LATUDA® through LOE, but after that, we will reorganize the LATUDA® sales system.

**Sakai, Credit Suisse Securities (Japan):** How many sales reps are dedicated to LATUDA® now?

**Nomura:** I think there are less than 400 full-time LATUDA® members.

**Sakai, Credit Suisse Securities (Japan):** I understand. So those people will be subject to that restructuring, in a manner of speaking.

**Nomura:** Yes, that's right.

**Harada:** I would like to supplement to question about the number of sales reps in Sunovion's LATUDA®, which is about 300 as of the end of March 2022.

**Sakai, Credit Suisse Securities (Japan):** Just one last point. You mentioned that GEMTESA® is still lagging behind and that Mirabegron has a high stronghold in the market, but I think it is a fact that Mirabegron's stronghold has been high since the product was introduced, as well as when it was launched. The fact that the penetration of the product has not progressed is due to the influence of COVID-19, which you have mentioned many times, but there is something else that you have misjudged. Sooner or later, a generic will appear for Mirabegron, so I think your company's approach is naturally to secure some market share before the generic appears.

**Nomura:** I have different views on the evaluation of GEMTESA®. We evaluate that GEMTESA® is growing well. For us, there are many factors that differentiate our product from Mirabegron, such as no warnings for elevated blood pressure, no drug interactions, no prolongation of QTC, and since it is used by elderly patients, it can also be crushed and taken. There are many factors that differentiate our product from Mirabegron. We understand that there is room for further growth for us if we can firmly penetrate the market.

Rather than being sluggish, Mirabegron's market share has always been very large, and it will be difficult to break that market share, but the current sales situation and penetration are a little better than we expected. We are not particularly pessimistic. We had originally thought that it would take some time to break the stronghold of Mirabegron in the market for  $\beta$ 3 agonists, so it is not that we were mistaken in this respect. We have not made any major misjudgment about this. We consider it is performing as expected or even better.

**Sakai, Credit Suisse Securities (Japan):** I understand. Thank you very much. **Muraoka, Morgan Stanley MUFG Securities:** As for GEMTESA®, I think I heard the president say in his presentation earlier that you are in a situation where you have to deal with the price.

What I'd like to ask is, if the generic entry will be later than in 2024 for Mirabegron, but if you continue to have to discount the price a little bit when you fight against Mirabegron, I think it's natural to assume that you will have to deal with even bigger prices when the generic of Mirabegron comes out, although we don't know when that will be. Should you be prepared for that?

**Nomura:** In terms of price response, we have differentiation points as I mentioned earlier, so if we keep increasing insurance coverage, we will be asked to offer big discounts, so we want to have a balance between coverage expansion and price maintenance as much as possible. Once the price has gone down significantly, it is very difficult to restore it, so we are trying to do so carefully.

As I mentioned in earlier questions, there are many points of differentiation between Mirabegron and GEMTESA®, and although they have the same mechanism of action, they are completely different drugs. We believe that we will be able to differentiate Mirabegron and generic Mirabegron well enough, although there will be some impact when generics become available.

**Muraoka, Morgan Stanley MUFG Securities:** I understand. Thank you very much. One more thing, on Roivant-related topic, I think Genevant, a subsidiary of Roivant, recently sued Moderna for patent infringement, and I think Genevant was on the list of the last six companies that your company could exercise its rights, and the exercise should be done by 2024. It's hard to ask the question of whether or not you are going to exercise your rights, but I feel that if 2024 is the exercise deadline, the patent result is not yet available, but considering the bonus points, I feel that it would be better to exercise your rights and get 100% of the patent. How do you think about this area now, Mr. President? As a matter of fact, is it correct to say that Genevant is included in the scope of the exercise of rights up to 2024?

**Kimura:** As for Genevant's patent lawsuit, we have terminated our rights and options to Genevant in the negotiations with Roivant after the alliance, so the outcome of the lawsuit will not affect our business.

**Hashiguchi, Daiwa Securities:** I think you are talking mostly on a quantity basis when you write about the status of ORGOVYX®, MYFEMBREE®, and GEMTESA® on pages seven, eight, and nine. We also received a price discussion about GEMTESA®. I would like to ask you about MYFEMBREE®. The scale of sales seems to be a bit small compared to these volume trends.

I feel that the sample discounts and rebates are a bit too much compared to the preceding products, but what can you tell us about the volume base, the timing for linking MYFEMBREE® with larger sales, and what measures your company is taking to achieve this? What is your company's strategy to achieve this?

**Nomura:** Thank you for your questions. For quantity basis, we will also provide free samples. We are a latecomer to the market, so we are doing this because we need to raise awareness. Thanks to the launch of our GnRH agonist, the market has also increased 2.4 times, in some cases. I think that will gradually translate into sales.

As I mentioned earlier, there seems to be an increase in terms of the willingness of obstetricians and gynecologists to prescribe the drug, so at this point, sales are low and there may be some concern that they are not being properly linked to sales. However, we are hopeful that this will show up in sales in the future.

**Hashiguchi, Daiwa Securities:** Thank you very much. That's all.

**Harada:** Since there are no other questions, we will conclude the question-and-answer session. This concludes today's briefing. Thank you very much.

[END]