Securities Code: 4506

# Supplementary Financial Data for the Year Ended March 31, 2019



**May 10, 2019**

Sumitomo Dainippon Pharma Co., Ltd.

- This material contains forecasts, projections, targets, 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 preparation of such statements and involve both known and unknown risks and uncertainties. Accordingly, 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.
- All values are rounded. Therefore totals may not be consistent with aggregated figures.

## I. Consolidated Financial Highlights

### 1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of yen)

| | FY2017 | FY2018 | Change % YoY | FY2019 Apr.-Sep. (Forecast) | Change % YoY | FY2019 (Forecast) | Change % YoY |
|---|---|---|---|---|---|---|---|
| **Revenue** | 466.8 | **459.3** | (1.6) | 226.5 | 0.2 | 460.0 | 0.2 |
| Cost of sales *1 | 112.3 | **113.1** | 0.7 | 56.0 | 0.7 | 116.0 | 2.6 |
| Gross profit | 354.5 | **346.2** | (2.4) | 170.5 | (0.0) | 344.0 | (0.6) |
| SG&A expenses *1 | 186.2 | **186.1** | (0.0) | 91.0 | (1.3) | 181.0 | (2.8) |
| R&D expenses *1 | 86.9 | **82.9** | (4.6) | 41.0 | (0.8) | 86.0 | 3.8 |
| Other operating income/expenses (Core Basis )*2 | 9.2 | **0.2** | (98.1) | 0.0 | — | 0.0 | — |
| **Core operating profit** | 90.6 | **77.3** | (14.7) | 38.5 | 3.6 | 77.0 | (0.4) |
| Changes in fair value of contingent consideration (negative number indicates loss) | 6.4 | **9.1** | | (3.5) | | (7.0) | |
| Other non-recurring items *3 (negative number indicates loss) | (8.8) | **(28.5)** | | (0.5) | | (1.0) | |
| **Operating profit** | 88.2 | **57.9** | (34.4) | 34.5 | 16.5 | 69.0 | 19.2 |
| **Net profit attributable to owners of the parent** | 53.4 | **48.6** | (9.0) | 25.0 | (10.3) | 49.0 | 0.8 |
| Basic earnings per share (yen) | 134.53 | 122.39 | | 62.93 | | 123.33 | |
| Net profit/ Equity attributable to owners of the parent (ROE) | 12.4% | 10.2% | | — | | 9.5% | |
| Return on inveted capital (ROIC) | 12.1% | 11.8% | | — | | 9.9% | |
| Payout ratio | 20.8% | 22.9% | | — | | 22.7% | |

*1 Exclude non-recurring items (impairment loss, changes in fair value of contingent consideration, etc.)
*2 "P/L on business transfer" and "share of P/L of associates accounted for using equity method"
*3 Non-recurring items ("other operating income and expenses" except for *2 items, impairment loss, etc.)

### 2. Consolidated Statement of Profit or Loss (Full Basis)

(Billions of yen)

| | FY2017 | FY2018 | Change % YoY |
|---|---|---|---|
| **Revenue** | 466.8 | **459.3** | (1.6) |
| Cost of sales | 112.3 | **113.6** | 1.1 |
| Gross profit | 354.5 | **345.7** | (2.5) |
| SG&A expenses | 183.7 | **180.4** | (1.7) |
| R&D expenses | 86.9 | **102.4** | 17.8 |
| Other operating income/expenses | 4.3 | **(5.0)** | |
| **Operating profit** | 88.2 | **57.9** | (34.4) |
| Finance income/costs | (3.3) | **7.2** | |
| Profit before taxes | 84.9 | **65.0** | (23.4) |
| **Net profit attributable to owners of the parent** | 53.4 | **48.6** | (9.0) |

### 3. Consolidated Statement of Cash Flows

(Billions of yen)

| | FY2017 | FY2018 |
|---|---|---|
| Net cash provided by operating activities | 93.4 | **48.7** |
| Net cash provided by (used in) investing activities | (16.5) | **(35.0)** |
| Net cash used in financing activities | (29.6) | **(28.6)** |
| Cash and cash equivalents at the end of period | 147.8 | **137.3** |

### 4. Foreign Exchange Rates

| | FY2017 | | FY2018 | | FY2019 assumption | Forex sensitivity FY2019 (Impact of yen depreciation by ￥1) | |
|---|---|---|---|---|---|---|---|
| | Period end rate | Average rate | **Period end rate** | **Average rate** | **Average rate** | Revenue | Core operating profit |
| Yen / USD | 106.3 | 110.9 | **111.0** | **110.9** | **110.0** | 2.4 | 0.1 |
| Yen / RMB | 16.9 | 16.7 | **16.5** | **16.5** | **16.5** | 1.6 | 0.2 |

(Billions of yen)

| 5. Capital Expenditures/ Depreciation and Amortization | FY2017 | FY2018 | Change | FY2019 (Forecast) | Change |
|---|---|---|---|---|---|
| | | | | | (Billions of yen) |
| Capital expenditures | 10.2 | **13.2** | 3.0 | 9.0 | (4.2) |
| Property, plant and equipment | 7.6 | **7.4** | (0.3) | 9.5 | 2.2 |
| Intangible assets | 5.2 | **6.6** | 1.4 | 6.7 | 0.1 |

Note: The amount of capital expenditures are for tangible fixed assets and software.

Major capital expenditure completed in FY2018
Central research laboratories : Manufacturing plant for regenerative medicine & cell therapy, ¥2.3billion
Workspace reform (Osaka/Tokyo head office), ¥0.7billion
Major capital expenditure project in FY2019
Reinforcement of production facilities, total budget ¥2.0billion, to be completed in FY2022

## II. Consolidated Statement of Profit or Loss

### 1. Consolidated Statement of Profit or Loss (Core Basis)

(Billions of yen)

| | FY2017 | FY2018 | Change | Change % |
|---|---|---|---|---|
| **Revenue** | 466.8 | **459.3** | (7.6) | (1.6) |
| Overseas revenue | 281.4 | **293.3** | 11.9 | 4.2 |
| % of Revenue | 60.3% | **63.9%** | | |
| Cost of sales | 112.3 | **113.1** | 0.8 | 0.7 |
| % of Revenue | 24.1% | **24.6%** | | |
| **Gross profit** | 354.5 | **346.2** | (8.3) | (2.4) |
| SG&A expenses | 186.2 | **186.1** | (0.0) | (0.0) |
| Labor costs | 77.4 | **76.1** | (1.3) | (1.6) |
| Advertising and promotion costs | 22.6 | **23.2** | 0.6 | 2.8 |
| Sales promotion costs | 15.6 | **14.8** | (0.9) | (5.6) |
| Amortization/Depreciation | 6.5 | **7.9** | 1.3 | 20.2 |
| Others | 64.0 | **64.2** | 0.1 | 0.2 |
| R&D expenses | 86.9 | **82.9** | (4.0) | (4.6) |
| % of Revenue | 18.6% | **18.0%** | | |
| Other operating income/expenses (Core Basis ) | 9.2 | **0.2** | (9.0) | (98.1) |
| **Core operating profit** | 90.6 | **77.3** | (13.3) | (14.7) |
| Changes in fair value of contingent consideration * | 6.4 | **9.1** | 2.8 | |
| Other non-recurring items * | (8.8) | **(28.5)** | (19.7) | |
| **Operating profit** | 88.2 | **57.9** | (30.3) | (34.4) |
| Finance income | 2.4 | **7.4** | 4.9 | |
| Finance costs | 5.7 | **0.2** | (5.5) | |
| **Profit before taxes** | 84.9 | **65.0** | (19.8) | (23.4) |
| Income tax expenses | 31.4 | **16.4** | (15.0) | |
| **Net profit** | 53.4 | **48.6** | (4.8) | (9.0) |
| **Net profit attibutable to owners of the parent** | 53.4 | **48.6** | (4.8) | (9.0) |

* Negative number indicates loss.

・Japan Segment (¥14.0B)
・North America Segment ¥11.8B
[ incl. FX rate impact (¥0.2B) ]
・China Segment ¥1.3B
[ incl. FX rate impact (¥0.3B) ]
・Other Regions Segment (¥2.2B)
・Other (¥4.4B)

・FY17: Profit on business transfer

| Changes in fair value of contingent consideration | FY17 | FY18 |
|---|---|---|
| LONHALA®MAGNAIR® | (6.9) | 1.9 |
| BBI | 14.7 | 4.0 |
| Tolero | (1.5) | 3.2 |

・Restructuring cost (FY17: 3.7 FY18: 3.8)
Impairment loss (FY17: 2.1 FY18: 23.0)

・Foreign exchange gain /loss on financial assets denominated in USD
FY17: loss (Finance cost) FY18: gain (Finance income)

### 2. Adjustmnents to Core Operating Profit

(Billions of yen)

| FY2018 Results | Full Basis | Core Basis | Adjustment | Major adjustment items |
|---|---|---|---|---|
| **Revenue** | 459.3 | **459.3** | - | |
| Cost of sales | 113.6 | **113.1** | (0.4) | |
| **Gross profit** | 345.7 | **346.2** | 0.4 | |
| SG&A expenses | 180.4 | **186.1** | 5.7 | Changes in fair value of contingent consideration 9.1 Impairment loss (3.4) |
| R&D expenses | 102.4 | **82.9** | (19.5) | Impairment loss (19.5) |
| Other operating income | 0.9 | **0.2** | (0.7) | |
| Other operating expenses | 5.9 | **0.0** | (5.9) | Restructuring cost (3.8) |
| **Operating profit** | 57.9 | **77.3** | 19.4 | |

## III. Segment Information (Core Basis)

(Billions of yen)

| FY2018 Results | Pharmaceuticals Business | | | | | Other Business | Total |
|---|---|---|---|---|---|---|---|
| | Japan | North America | China | Other Regions | Subtotal | | |
| Revenue (Sales to customers) | 129.3 | 252.5 | 24.7 | 14.3 | 420.9 | 38.4 | 459.3 |
| Cost of sales | 52.4 | 21.7 | 3.7 | 5.6 | 83.4 | 29.7 | 113.1 |
| Gross profit | 77.0 | 230.8 | 21.0 | 8.7 | 337.5 | 8.6 | 346.2 |
| SG&A expenses | 51.9 | 116.3 | 8.7 | 3.6 | 180.6 | 5.6 | 186.1 |
| **Core segment profit** | **25.1** | **114.5** | **12.3** | **5.0** | **157.0** | **3.1** | **160.0** |
| R&D expenses *1 | | | | | 81.8 | 1.1 | 82.9 |
| Other operating income/expenses (Core basis)*2 | | | | | 0.2 | 0.0 | 0.2 |
| **Core operating profit** | | | | | **75.3** | **2.0** | **77.3** |

(Billions of yen)

| FY2019 Forecasts | Pharmaceuticals Business | | | | | Other Business | Total |
|---|---|---|---|---|---|---|---|
| | Japan | North America | China | Other Regions | Subtotal | | |
| Revenue (Sales to customers) | 119.3 | 260.0 | 27.0 | 13.7 | 420.0 | 40.0 | 460.0 |
| Cost of sales | 50.8 | 23.2 | 5.5 | 5.2 | 84.7 | 31.3 | 116.0 |
| Gross profit | 68.5 | 236.8 | 21.5 | 8.5 | 335.3 | 8.7 | 344.0 |
| SG&A expenses | 50.0 | 112.8 | 9.5 | 3.2 | 175.5 | 5.5 | 181.0 |
| **Core segment profit** | **18.5** | **124.0** | **12.0** | **5.3** | **159.8** | **3.2** | **163.0** |
| R&D expenses *1 | | | | | 85.0 | 1.0 | 86.0 |
| Other operating income/expenses (Core basis)*2 | | | | | - | - | - |
| **Core operating profit** | | | | | **74.8** | **2.2** | **77.0** |

(Billions of yen)

| (Ref.) FY2017 Results | Pharmaceuticals Business | | | | | Other Business | Total |
|---|---|---|---|---|---|---|---|
| | Japan | North America | China | Other Regions | Subtotal | | |
| Revenue (Sales to customers) | 143.3 | 240.8 | 23.4 | 16.5 | 424.0 | 42.8 | 466.8 |
| Cost of sales | 51.7 | 15.1 | 4.6 | 7.3 | 78.7 | 33.7 | 112.3 |
| Gross profit | 91.7 | 225.7 | 18.9 | 9.1 | 345.4 | 9.1 | 354.5 |
| SG&A expenses | 51.5 | 116.2 | 8.2 | 4.0 | 179.8 | 6.4 | 186.2 |
| **Core segment profit** | **40.3** | **109.5** | **10.7** | **5.1** | **165.6** | **2.7** | **168.3** |
| R&D expenses *1 | | | | | 85.8 | 1.1 | 86.9 |
| Other operating income/expenses (Core basis)*2 | | | | | 9.2 | 0.0 | 9.2 |
| **Core operating profit** | | | | | **89.0** | **1.6** | **90.6** |

*1 R&D expenses for pharmaceuticals business are controlled globally and not allocated to each segment.

*2 P/L on business transfer and share of P/L of associates accounted for using equity method

## IV. Revenues Information

### 1. Sales of Pharmaceuticals Business (Sales to customers)

(Billions of yen)

| Segment | FY2017 | FY2018 | Change | Change % | FY2019 Apr.-Sep. (Forecast) | FY2019 (Forecast) |
|---|---|---|---|---|---|---|
| Japan | 143.3 | **129.3** | (14.0) | (9.8) | 61.0 | 119.3 |
| North America | 240.8 | **252.5** | 11.8 | 4.9 | 128.1 | 260.0 |
| China | 23.4 | **24.7** | 1.3 | 5.6 | 12.9 | 27.0 |
| Other Regions | 16.5 | **14.3** | (2.2) | (13.2) | 5.0 | 13.7 |

### 2. Sales of Major Products (1)

(Invoice price basis, Billions of yen)

| Brand name<br>Therapeutic indication | FY2017 | FY2018 | Change | Change % | FY2019 Apr.-Sep. (Forecast) | FY2019 (Forecast) |
|---|---|---|---|---|---|---|
| **Japan** | | | | | | |
| **Promoted products** | | | | | | |
| **Trulicity®** * <br>Therapeutic agent for type 2 diabetes (Launch:Sep. 2015) | 15.9 | **23.1** | 7.2 | 45.1 | 14.0 | 28.2 |
| **TRERIEF®** <br>Therapeutic agent for Parkinson's disease | 16.1 | **15.7** | (0.4) | (2.5) | 8.6 | 17.1 |
| **REPLAGAL®** <br>Anderson-Fabry disease | 11.7 | **12.5** | 0.8 | 7.0 | 6.1 | 11.8 |
| **LONASEN® tablet/powder** <br>Atypical antipsychotic | 12.6 | **12.2** | (0.4) | (3.4) | 4.0 | 5.2 |
| **METGLUCO®** <br>Therapeutic agent for type 2 diabetes | 10.9 | **10.1** | (0.8) | (7.5) | 4.7 | 9.3 |
| **SUREPOST®** <br>Therapeutic agent for type 2 diabetes | 5.0 | **6.1** | 1.0 | 20.4 | 3.1 | 6.2 |
| **AmBisome®** <br>Therapeutic agent for systemic fungal infection | 4.3 | **4.0** | (0.3) | (6.0) | 1.8 | 3.9 |
| **LONASEN® patch** <br>Atypical antipsychotic | — | **–** | – | – | 0.2 | 1.8 |
| **Other products** | | | | | | |
| **AMLODIN®** <br>Therapeutic agent for hypertension and angina pectoris | 11.4 | **9.1** | (2.3) | (20.2) | 4.1 | 7.5 |
| **AIMIX®** <br>Therapeutic agent for hypertension | 18.8 | **8.2** | (10.6) | (56.3) | 2.0 | 3.7 |
| **PRORENAL®** <br>Vasodilator | 5.4 | **4.0** | (1.4) | (26.0) | 1.8 | 3.3 |
| **GASMOTIN®** <br>Gastroprokinetic | 4.9 | **3.8** | (1.1) | (23.3) | 1.6 | 3.1 |
| **AVAPRO®** <br>Therapeutic agent for hypertension | 8.4 | **2.8** | (5.6) | (66.8) | 1.0 | 1.9 |
| **Authorized Generics** | 0.7 | **5.5** | 4.9 | 707.0 | 3.4 | 6.9 |

* Revenue of Trulicity® is shown on NHI price basis.

## 2. Sales of Major Products (2)

(Billions of yen)

| Brand name<br>Therapeutic indication | FY2017 | FY2018 | Change | Change % | FY2019 Apr.-Sep. (Forecast) | FY2019 (Forecast) |
|---|---|---|---|---|---|---|
| **North Amrerica** | | | | | | |
| **LATUDA®**<br>Atypical antipsychotic | 178.6 | **184.5** | 5.9 | 3.3 | 93.5 | 189.3 |
| **BROVANA®**<br>Therapeutic agent for COPD | 33.1 | **33.7** | 0.6 | 1.7 | 16.6 | 33.0 |
| **APTIOM®**<br>Antiepileptic | 15.7 | **20.5** | 4.8 | 30.9 | 10.9 | 22.5 |
| **LONHALA® MAGNAIR®**<br>Therapeutic agent for COPD<br>(Launch: Apr. 2018) | — | **1.4** | 1.4 | — | 1.3 | 4.2 |
| **Therapeutic agent for COPD** * | 0.5 | **0.5** | (0.0) | (2.1) | 0.2 | 0.3 |
| **XOPENEX®**<br>Therapeutic agent for asthma | 4.0 | **4.6** | 0.6 | 15.8 | 2.2 | 4.1 |
| **China** | | | | | | |
| **MEROPEN®** | 20.4 | **21.2** | 0.9 | 4.4 | 10.8 | 22.6 |
| **Other Regions** | | | | | | |
| **MEROPEN®** | 10.2 | **7.9** | (2.3) | (22.2) | 3.0 | 7.0 |

**(Ref.) Products sales in North America (based on local currency)**

(Millions of dollar)

| 品目 | FY2017 | FY2018 | Change | Change % | FY2019 Apr.-Sep. (Forecast) | FY2019 (Forecast) |
|---|---|---|---|---|---|---|
| LATUDA® | 1,611 | **1,663** | 52 | 3.3 | 850 | 1,721 |
| BROVANA® | 299 | **304** | 5 | 1.6 | 151 | 300 |
| APTIOM® | 141 | **185** | 44 | 30.8 | 99 | 205 |
| LONHALA® MAGNAIR® | — | **13** | 13 | — | 12 | 38 |
| Therapeutic agent for COPD * | 5 | **5** | (0) | (2.1) | 2 | 3 |
| XOPENEX® | 36 | **42** | 6 | 15.8 | 20 | 37 |

* UTIBRON® , SEEBRI® , ARCAPTA®

## V. Consolidated Statement of Financial Position

(Billions of yen)

| | Mar.31 2018 | Mar. 31 2019 | Change |
|---|---|---|---|
| **Assets** | **809.7** | **834.7** | **25.0** |
| **Non-current assets** | **461.1** | **461.4** | **0.3** |
| **Property, plant and equipment** | 58.2 | 59.5 | 1.3 |
| Buildings and structures | 36.7 | 36.9 | 0.2 |
| Machinery, equipment and carrier | 9.7 | 10.7 | 1.0 |
| Tools, equipment and fixtures | 4.1 | 4.9 | 0.8 |
| Land | 5.1 | 5.0 | (0.1) |
| Construction in progress | 2.7 | 2.0 | (0.7) |
| **Goodwill** | 95.1 | 99.3 | 4.3 |
| **Intangible assets** | 189.7 | 171.4 | (18.3) |
| Patent rights/Marketing rights | 30.8 | 24.0 | (6.8) |
| In-process research & development | 153.9 | 141.4 | (12.5) |
| Others | 4.9 | 5.9 | 1.0 |
| **Other financial assets** | 71.0 | 74.7 | 3.7 |
| **Other non-current assets** | 5.5 | 5.8 | 0.3 |
| **Deferred tax assets** | 41.6 | 50.7 | 9.1 |
| **Current assets** | **348.6** | **373.3** | **24.7** |
| **Inventories** | 60.2 | 66.9 | 6.7 |
| **Trade and other receivables** | 113.0 | 118.8 | 5.8 |
| **Other financial assets** | 22.1 | 43.8 | 21.7 |
| **Other current assets** | 5.6 | 6.6 | 1.0 |
| **Cash and cash equivalents** | 147.8 | 137.3 | (10.5) |
| **Liabilities** | **357.0** | **336.6** | **(20.4)** |
| **Non-current liabilities** | **146.7** | **138.4** | **(8.3)** |
| **Bonds and borrowings** | 30.9 | 28.0 | (3.0) |
| **Other financial liabilities** | 88.4 | 80.4 | (8.0) |
| **Retirement benefit liabilities** | 20.7 | 23.6 | 2.9 |
| **Other non-current liabilities** | 6.6 | 6.4 | (0.1) |
| **Deferred tax liabilities** | 0.1 | — | (0.1) |
| **Current liabilities** | **210.2** | **198.2** | **(12.1)** |
| **Bonds and borrowings** | 16.5 | 3.0 | (13.5) |
| **Trade and other payables** | 58.7 | 49.2 | (9.5) |
| **Other financial liabilities** | 6.3 | 8.7 | 2.4 |
| **Income taxes payable** | 14.4 | 15.7 | 1.4 |
| **Provisions** | 84.4 | 92.2 | 7.7 |
| **Other current liabilities** | 30.0 | 29.4 | (0.6) |
| **Equity** | **452.7** | **498.1** | **45.4** |
| **Share capital** | 22.4 | 22.4 | — |
| **Capital surplus** | 15.9 | 15.9 | 0.0 |
| **Treasury shares** | (0.7) | (0.7) | (0.0) |
| **Retained earnings** | 396.0 | 431.8 | 35.8 |
| **Other components of equity** | 19.1 | 28.8 | 9.7 |
| **Equity attributable to owners of the parent** | **452.7** | **498.1** | **45.4** |

| **Goodwill** | 18/3 | 19/3 |
|---|---|---|
| Sunovion | 71.8 | 75.0 |
| Oncology | 23.3 | 24.3 |

| **IPR&D** | 18/3 | 19/3 |
|---|---|---|
| apomorphine | 71.1 | *55.2 |
| BBI products | 28.7 | 30.0 |
| Tolero products | 42.5 | 44.4 |
| Others | 11.7 | 11.9 |

*Decrease due to impairment loss

← Increase in short-term loan receivable

Total interest-bearing debt
47.4 → 30.9
[Redemption 10.0
Repayment 6.5]

| **Contingent consideration liabilities** * | 18/3 | 19/3 | Total probable payment (Max) |
|---|---|---|---|
| LONHALA®MAGNAIR® | 10.3 | 8.9 | $210M |
| BBI | 46.4 | 44.5 | $2,405M |
| Tolero | 29.8 | 27.9 | $580M |
| Total | 86.6 | 81.4 | |

*Included in "Other financial liabilities (Non current/Current)"

← FX rate 18/3 19/3
USD ¥106.3 ⇒ ¥111.0
RMB ¥ 16.9 ⇒ ¥ 16.5

## VI. Change in Quarterly Results

(Billions of yen)

| | FY2017 | | | | FY2018 | | | |
|---|---|---|---|---|---|---|---|---|
| | 1Q | 2Q | 3Q | 4Q | 1Q | 2Q | 3Q | 4Q |
| **Revenue** | 116.2 | 115.2 | 123.8 | 111.7 | 115.9 | 110.2 | 120.7 | **112.4** |
| Cost of sales | 27.5 | 29.5 | 31.4 | 23.9 | 28.9 | 26.7 | 29.6 | **27.9** |
| Gross profit | 88.7 | 85.7 | 92.4 | 87.8 | 87.0 | 83.6 | 91.1 | **84.5** |
| SG&A expenses | 44.2 | 43.1 | 47.5 | 51.3 | 47.8 | 44.4 | 51.8 | **42.1** |
| R&D expenses | 19.9 | 20.4 | 22.8 | 23.8 | 20.9 | 20.5 | 20.6 | **20.9** |
| Other operating income/expenses (Core Basis) | 0.2 | 8.9 | 0.1 | (0.0) | 0.0 | 0.0 | 0.1 | **0.0** |
| **Core operating profit** | 24.8 | 31.0 | 22.2 | 12.6 | 18.4 | 18.7 | 18.7 | **21.4** |
| Changes in fair value of contingent consideration (negative number indicates loss) | 7.1 | (3.0) | (8.3) | 10.7 | (2.5) | (4.4) | 1.4 | **14.6** |
| Other non-recurring items (negative number indicates loss) | (0.2) | (0.2) | (2.5) | (6.0) | (0.1) | (0.6) | (2.9) | **(25.0)** |
| **Operating profit** | 31.6 | 27.8 | 11.4 | 17.3 | 15.8 | 13.8 | 17.2 | **11.1** |
| **Net profit attributable to owners of the parent** | 24.6 | 20.7 | (1.4) | 9.7 | 15.2 | 12.6 | 12.1 | **8.7** |

## VII. Major Consolidated Subsidiaries (As of Mar. 31, 2019)

| **Domestic** | DSP Gokyo Food & Chemical Co., Ltd. | DS Pharma Animal Health Co., Ltd. | DS Pharma Biomedical Co., Ltd. |
|---|---|---|---|
| Establishment | October 1947 | July 2010 | June 1998 |
| Ownership | 100% | 100% | 100% |
| Number of employees | 190 | 80 | 43 |
| Businesses | Manufacturing and sales of food ingredients, food additives, chemical product materials, etc. | Manufacturing, and sales of veterinary medicines, etc. | Manufacturing and sales of pharmaceuticals and diagnostics, etc. |

| **Overseas** | Sunovion Pharmaceuticals Inc. | Boston Biomedical, Inc. | Tolero Pharmaceuticals, Inc. | Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. |
|---|---|---|---|---|
| Establishment | January 1984 | November 2006 | June 2011 | December 2003 |
| Ownership | 100% | 100% | 100% | 100% |
| Number of employees | 1,683 | 117 | 45 | 700 |
| Businesses | Manufacturing and sales of pharmaceuticals | R&D in the oncology area | R&D in the oncology area | Manufacturing and sales of pharmaceuticals |

### (Reference) Number of employees and MRs

| | | As of Mar. 31, 2017 | As of Mar. 31, 2018 | As of Mar. 31, 2019 |
|---|---|---|---|---|
| **consolidated** | | 6,492 | 6,268 | **6,140** |
| **non-consolidated** | | 3,572 | 3,402 | **3,067** |
| **MRs** | | | | |
| **Japan** | (excluding managers) | 1,130 | 1,130 | **1,120** |
| | (including managers) | 1,260 | 1,260 | **1,240** |
| **U.S.** | (excluding managers) | 870 | 830 | **720** |
| | (including managers) | 990 | 930 | **820** |
| **China** | (excluding managers) | 340 | 330 | **340** |
| | (including managers) | 410 | 400 | **400** |

Number of contracted MRs is included in MRs.

## VIII. Shareholder Positioning (As of March 31, 2019)

**1. Total number of authorized shares:** 1,500,000,000

**2. Total number of shares outstanding:** 397,900,154 (Including number of treasury stock 603,851)

**3. Number of shareholders by category:**

| | Number of shareholders | Number of shares (Thousands) | Percentage of total (%) |
|---|---|---|---|
| Financial institutions | 55 | 94,581 | 23.77 |
| Securities companies | 50 | 3,227 | 0.81 |
| Other Japanese corporations | 267 | 234,546 | 58.95 |
| Corporations outside Japan, etc. | 609 | 46,042 | 11.57 |
| Individuals and others (Including treasury stock) | 18,526 | 19,502 | 4.90 |
| Total | 19,507 | 397,900 | 100 |

Note: The numbers of shares are rounded down to the nearest thousand shares.

**4. Major shareholders:**

| Shareholders | Number of shares held (Thousands) | Percentage of shareholding(%) |
|---|---|---|
| Sumitomo Chemical Co., Ltd. | 205,634 | 51.76 |
| The Master Trust Bank of Japan, Ltd. (Trust account) | 28,769 | 7.24 |
| Inabata & Co., Ltd. | 20,182 | 5.08 |
| Japan Trustee Services Bank, Ltd. (Trust account) | 12,756 | 3.21 |
| Nippon Life Insurance Company | 7,581 | 1.91 |
| SMBC Trust Bank Ltd. (Trust account for Sumitomo Mitsui Banking Corporation's retirement benefits) | 7,000 | 1.76 |
| Sumitomo Life Insurance Company | 5,776 | 1.45 |
| Aioi Nissay Dowa Insurance Co., Ltd. | 4,435 | 1.12 |
| Trust & Custody Services Bank, Ltd. (Securities investment trust account) | 3,251 | 0.82 |
| Japan Trustee Services Bank, Ltd. (Trust account 5) | 2,908 | 0.73 |

Notes: 1: Percentage of shareholding is calculated excluding treasury stock (603,851 stocks).
2: The numbers of shares held are rounded down to the nearest thousand shares.

**IX. Development Pipeline (As of May 10, 2019)**

- This table shows clinical studies on indications for which the Sumitomo Dainippon Pharma Group aims to obtain approval in Japan, U.S. or China, and does not cover all clinical studies.
- For oncology area, the study for the most advanced development stage is listed if there are multiple studies with the same indication.
- The development stage is changed when Investigational New Drug Application/amended IND/ Clinical Trial Notification is filed/approved by the authority.

**1. Psychiatry & Neurology**

| Brand name/ Product code (Generic name) | Proposed indication | Region | Development stage |
|---|---|---|---|
| SM-13496 (lurasidone hydrochloride) | Schizophrenia | Japan | Phase 3 |
| | Bipolar I depression | Japan | Phase 3 |
| SEP-225289 （dasotraline） | Attention-deficit hyperactivity disorder (ADHD) | U.S. | Submitted in August 2017 Received Complete Response Letter in August 2018 |
| | | Japan | Phase 1 |
| | Binge eating disorder (BED) | U.S. | Phase 3 |
| APL-130277 (apomorphine hydrochloride) | OFF episodes associated with Parkinson’s disease | U.S. | Submitted in March 2018 Received Complete Response Letter in January 2019 |
| LONASEN® (blonanserin) | (New formulation – Transdermal patch) Schizophrenia | Japan | Submitted in July 2018 |
| | (New usage: pediatric) Schizophrenia | Japan | Phase 3 |
| EPI-743 (vatiquinone) | Leigh syndrome | Japan | Phase 2/3 |
| EPI-589 | Parkinson’s disease | U.S. | Phase 2 |
| | Amyotrophic lateral sclerosis (ALS) | U.S. | Phase 2 |
| | | Japan | Phase 1 |
| SEP-363856 | Schizophrenia | U.S. | Phase 2 |
| | | Japan | Phase 1 |
| | Parkinson’s disease psychosis | U.S. | Phase 2 |
| SEP-4199 | Bipolar I depression | U.S., Japan | Phase 2 (Global clinical study) |
| DSP-6745 | Parkinson’s disease psychosis | U.S. | Phase 1 |
| SEP-378608 | Bipolar disorder | U.S. | Phase 1 |
| DSP-3905 | Neuropathic pain | U.S. | Phase 1 |
| SEP-378614 | Treatment resistant depression | U.S. | Phase 1 |
| SEP-380135 | Agitation in Alzheimer's disease | U.S. | Phase 1 |

**2. Oncology (1/2)**

| Brand name/ Product code (Generic name) | Proposed indication | Region | Development stage |
|---|---|---|---|
| RETHIO® (thiotepa) | (New indication) Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation (HSCT) for Pediatric malignant lymphoma<br>* Development for the use of unapproved or off-labeled drugs | Japan | Submitted in March 2019 |
| BBI608 (napabucasin) | Colorectal cancer (Combination therapy) | U.S., Japan | Phase 3 (Global clinical study) |
| | Pancreatic cancer (Combination therapy) | U.S., Japan | Phase 3 (Global clinical study) |
| | Hepatocellular carcinoma (Combination therapy) | U.S. | Phase 1/2 |
| | Gastrointestinal cancer (Combination therapy) | U.S. | Phase 1/2 |
| | Solid tumors (Combination therapy) | U.S. | Phase 1/2 |
| BBI503 (amcasertib) | Hepatocellular carcinoma (Combination therapy) | U.S. | Phase 1/2 |
| | Solid tumors (Monotherapy/ Combination therapy) | U.S. | Phase 1/2 |
| DSP-2033 (alvocidib) | Acute myeloid leukemia (AML) (Combination therapy) (Refractory or relapsed patients) | U.S. | Phase 2 (Global clinical study) |
| | Myelodysplastic syndromes (MDS) (Combination therapy) | U.S. | Phase 1/2 |
| | Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed patients) | U.S. | Phase 1 |
| | Acute myeloid leukemia (AML) (Combination therapy) (Newly diagnosed and refractory or relapsed patients) | Japan | Phase 1 |
| DSP-7888 (adegramotide/ nelatimotide) | Glioblastoma (Combination therapy) | U.S., Japan | Phase 2 (Global clinical study) |
| | Myelodysplastic syndromes (MDS) (Monotherapy) | Japan | Phase 1/2 |
| | Pediatric malignant gliomas (Monotherapy) | Japan | Phase 1/2 |
| | Solid tumors, Hematologic malignancies (Monotherapy) | U.S. | Phase 1 |
| | Solid tumors (Combination therapy) | U.S. | Phase 1 |
| BBI608+BBI503 (napabucasin +amcasertib) | Solid tumors (Combination therapy) | U.S. | Phase 1 |

**3. Oncology (2/2)**

| Brand name/ Product code (Generic name) | Proposed indication | Region | Development stage |
|---|---|---|---|
| TP-0903 | Chronic lymphocytic leukemia (CLL) (Monotherapy / Combination therapy) | U.S. | Phase 1/2 |
| | Solid tumors (Monotherapy / Combination therapy) | U.S., Japan | Phase 1 |
| DSP-0509 | Solid tumors (Monotherapy) | U.S. | Phase 1 |
| TP-0184 | Solid tumors (Monotherapy) | U.S. | Phase 1 |
| DSP-0337 | Solid tumors (Monotherapy) | U.S. | Phase 1 |
| TP-1287 | Solid tumors (Monotherapy) | U.S. | Phase 1 |
| TP-3654 | Solid tumors (Monotherapy) | U.S. | Phase 1 |

**4. Regenerative medicine / cell therapy**

| Brand name/ Product code (Generic name) | Proposed indication | Region | Development stage |
|---|---|---|---|
| SB623 | Chronic stroke | U.S. | Phase 2 |
| Allo iPS cell-derived dopamine neural progenitor | Parkinson's disease | Japan | Phase 1/2 (Investigator-initiated clinical study) |
| HLCR011 (Allo iPS cell-derived retinal pigment epithelium) | Age-related macular degeneration (AMD) | Japan | Preparing for start of clinical study |

**5. Others**

| Brand name/ Product code (Generic name) | Proposed indication | Region | Development stage |
|---|---|---|---|
| PXL008 (imeglimin) | Type 2 diabetes | Japan | Phase 3 |

【Main revisions since the announcement of January 2019】

| Changes | Brand name/ Product code (Generic name) | Proposed indication | Area | Development stage |
|---|---|---|---|---|
| Approval | RETHIO® (thiotepa) * Development for the use of unapproved or off-labeled drugs | Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation (HSCT) for Pediatric Solid Tumors | Japan | Approved in March 2019 |
| Submitted | | Conditioning Treatment Prior to Autologous Hematopoietic Stem Cell Transplantation (HSCT) for Pediatric Malignant lymphoma | | Sbmitted in March 2019 |
| Newly added | SEP-380135 | Agitation in Alzheimer's disease | U.S. | Started Phase 1 study |
| | TP-0903 | Solid tumors (Monotherapy / Combination therapy) | Japan | Started Phase 1 study |
| Deleted from the table due to the study completed | BBI608 (napabucasin) | Malignant pleural mesothelioma (Combination therapy) | Japan | Phase 1/2 |
| | | Hematologic malignancies (Monotherapy / Combination therapy) | U.S. | Phase 1 |
| | BBI503 (amcasertib) | Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy) | Japan | Phase 1 |
| Deleted from the table due to cave out | DSP-2230 | Neuropathic pain | U.S., Japan | Phase 1 |

## X. Profiles of Major Products under Development (As of May 10, 2019)

### 1. Psychiatry & Neurology

**dasotraline（SEP-225289）** Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-225289 is a dopamine and norepinephrine reuptake inhibitor (DNRI). SEP-225289 has an extended half-life (47-77 hours) that supports the potential for plasma concentrations yielding a continuous therapeutic effect over the 24-hour dosing interval.
- Development stage:
  Attention-deficit hyperactivity disorder (ADHD): NDA submitted in the U.S. in August 2017, Complete Response Letter received in August 2018, development strategy under consideration
  Binge eating disorder (BED): Phase 3 in the U.S.
  Attention-deficit hyperactivity disorder (ADHD): Phase 1 in Japan

**apomorphine hydrochloride (APL-130277)** Developed in-house (Sunovion Pharmaceuticals Inc., from former Cynapsus Therapeutics), Formulation: sublingual film

- APL-130277 is a sublingual film formulation of apomorphine, a dopamine agonist, which is the molecule approved for acute intermittent treatment of OFF episodes associated with Parkinson's disease. It is designed to rapidly, safely and reliably convert a Parkinson's disease patient from the OFF to the ON state while avoiding many of the issues associated with subcutaneous delivery of apomorphine.
- Development stage: NDA submitted in the U.S. in March 2018.
  Complete Response Letter received in January 2019

**vatiquinone (EPI-743)** In-licensed from BioElectron Technology Corporation (former Edison Pharmaceuticals, Inc.), Formulation: oral

- EPI-743 is expected to show efficacy by removing the oxidative stress that is generated excessively by decreased mitochondrial function. It is expected to be the world's first treatment for mitochondrial diseases, beginning with Leigh syndrome, for which there is no effective therapy.
- Development stage:
  A Phase 2 / 3 study for Leigh syndrome in Japan completed, development strategy under consideration

**EPI-589** In-licensed from BioElectron Technology Corporation (former Edison Pharmaceuticals, Inc.), Formulation: oral

- EPI-589 is expected to show efficacy by removing the oxidative stress that is generated excessively by decreased mitochondrial function. It is expected to be developed for neurodegenerative indications arising through redox stress.
  Development stage:
  Parkinson's disease: Phase 2 in the U.S. by BioElectron Technology Corporation
  Amyotrophic lateral sclerosis (ALS): Phase 2 in the U.S. by BioElectron Technology Corporation
  Amyotrophic lateral sclerosis (ALS): Phase 1 in Japan

**SEP-363856** Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-363856 is an antipsychotic agent with a novel mechanism of action discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform and doesn't show affinity to dopamine $D_2$ receptors. The molecular target(s) responsible for the profile of effects is unknown, but may include agonist effects at serotonin 5-$HT_{1A}$ and TAAR1 (trace amine-associated receptor 1) receptors. Results obtained with the preclinical models suggest that SEP-363856 may be able to treat the positive and negative symptoms of schizophrenia as well as Parkinson's disease psychosis. SEP-363856 is expected to have high efficacy in the treatment of

schizophrenia and Parkinson's disease psychosis, with an improved safety profile compared with currently marketed antipsychotics.

- Development stage:
  Schizophrenia: Phase 2 in the U.S.
  Parkinson's disease psychosis: Phase 2 in the U.S.
  Schizophrenia: Phase 1 in Japan

**SEP-4199** Developed in-house (Sunovion Pharmaceuticals Inc.), Formulation: oral

- SEP-4199 is investigated for the treatment of major depressive episodes associated with bipolar I disorder. The mechanism of action is not disclosed at this time.
- Development stage:
  Bipolar I depression: Phase 2 in the U.S. and Japan

**DSP-6745** Developed in-house, Formulation: oral

- DSP-6745 is a serotonin 5-$HT_{2A}$ and serotonin 5-$HT_{2C}$ receptors dual antagonist, which is expected to be effective for Parkinson's disease psychosis and one or more Parkinson's disease non-motor symptoms (depression, anxiety, or cognitive impairment). In addition, DSP-6745 has negligible affinity for dopamine $D_2$ receptors.
- Development stage: Parkinson's disease psychosis: Phase 1 in the U.S.

**SEP-378608** Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-378608 is a novel CNS-active molecule discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform. Pre-clinical studies suggest that it may modulate neuronal activity in key areas of the brain associated with the regulation of mood.
- Development stage: Bipolar disorder: Phase 1 in the U.S.

**DSP-3905** Developed in-house, Formulation: oral

- DSP-3905 is an agent that selectively inhibits voltage-gated sodium channels Nav1.7. Based on its inhibitory mode of action, the agent is expected to show a potent analgesic effect on the pain occurring when neurons get excessively excited. In addition, DSP-3905 has a high selectivity for Nav1.7 expressed in peripheral neuron and may not produce central nervous system or cardiovascular system side effects, which are present with the current drugs for neuropathic pain.
- Development stage: Neuropathic pain: Phase 1 in the U.S.

**SEP-378614** Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-378614 is a novel CNS-active molecule discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform. Pre-clinical studies suggest that it showed rapid onset and long lasting antidepressant-like activity and neuroplasticity effects.
- Development stage: Treatment resistant depression: Phase 1 in the U.S.

**SEP-380135** Developed in-house (Joint research with Sunovion Pharmaceuticals Inc. and PsychoGenics Inc.), Formulation: oral

- SEP-380135 is a novel CNS-active molecule discovered using a variety of preclinical models, including the PsychoGenics' SmartCube® System phenotypic screening platform. Pre-clinical studies suggest that it showed a broad range of in vivo activities suggesting efficacy against a number of behavioral and psychological symptoms in dementia, including agitation/aggression, psychomotor hyperactivity, depression and deficits in social interaction.
- Development stage: Agitation in Alzheimer's disease: Phase 1 in the U.S.

## 2. Oncology

**napabucasin (BBI608)** Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI608 is an orally administered small molecule agent with a novel mechanism of action which is bioactivated by the enzyme NQO1 in cancer cells, and may inhibit cancer stemness and tumor progression pathways including STAT3. By inhibiting pathways involved in the maintenance of cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis. BBI608 has been shown to inhibit STAT3 pathways, Nanog pathways and β-catenin pathways in pre-clinical studies.
- Development stage:

| Stage | Proposed indication | Country/ Area | Combination products | Study number |
|---|---|---|---|---|
| Phase 3 | Colorectal cancer (combination therapy) | U.S., Japan | FOLFIRI*3, FOLFIRI*3 + bevacizumab | CanStem303C |
| | Pancreatic cancer (combination therapy) | U.S., Japan | gemcitabine + nab-paclitaxel | CanStem111P |
| Phase 2 | Colorectal cancer (combination therapy) | U.S. | cetuximab, panitumumab, capecitabine | 224 |
| Phase 1 / 2 | Solid tumors*1 (combination therapy) | U.S. | paclitaxel | 201 |
| | Hepatocellular carcinoma*2 (combination therapy) | U.S. | sorafenib | HCC-103 |
| | Solid tumors (combination therapy) | U.S. | ipilimumab, pembrolizumab, nivolumab | 201CIT |
| | Gastrointestinal cancer (combination therapy) | U.S., Canada | FOLFOX*3, FOLFOX*3 + bevacizumab, CAPOX*3, FOLFIRI*3, FOLFIRI*3 + bevacizumab, regorafenib, irinotecan | 246 |
| Phase 1 | Pancreatic cancer (combination therapy) | U.S. | gemcitabine + nab-paclitaxel, FOLFIRINOX*3, FOLFIRI*3, irinotecan liposome injection + fluorouracil + leucovorin | 118 |
| | Solid tumors (combination therapy) | U.S. | amcasertib | 401-101 |

*1 Phase 2 stage: Ovarian cancer, Breast cancer, Melanoma, etc.
*2 Phase 2 stage
*3 FOLFOX: Combination therapy with fluorouracil, leucovorin, oxaliplatin
CAPOX: Combination therapy with capecitabine, oxaliplatin
FOLFIRI: Combination therapy with fluorouracil, leucovorin, irinotecan
FOLFIRINOX: Combination therapy with fluorouracil, leucovorin, irinotecan, oxaliplatin

**amcasertib（BBI503）** Developed in-house (Boston Biomedical, Inc.), Formulation: oral

- BBI503 is an orally administered small molecule agent with a novel mechanism of action designed to inhibit cancer stemness pathways, including Nanog, by targeting stemness kinases. By inhibiting pathways involved in the maintenance of cancer stemness, it may provide a new therapeutic option against the challenges in cancer treatment such as treatment resistance, recurrence and metastasis. BBI503 has been shown to inhibit multiple kinases in pre-clinical studies.
- Development stage:

| Stage | Proposed indication | Country/ Area | Combination products | Study number |
|---|---|---|---|---|
| Phase 2 | Hepatocellular carcinoma, Cholangiocarcinoma (monotherapy) | Canada | - | 205b |

| Stage | Proposed indication | Country/ Area | Combination products | Study number |
|---|---|---|---|---|
| Phase 1 / 2 | Solid tumors* (monotherapy) | U.S. | - | 101 |
| | Hepatocellular carcinoma (combination therapy) | U.S. | sorafenib | HCC-103 |
| Phase 1 / 2 | Solid tumors (combination therapy) | U.S. | capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib | 201 |
| | Solid tumors (combination therapy) | U.S. | napabucasin | 401-101 |

* Phase 2 stage: Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

**alvocidib（DSP-2033）** In-licensed from Sanofi S.A., Formulation: injection

- Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), a member of cyclin-dependent kinase family, which activates transcription of cancer-related genes. The subsequent down-regulation of MCL-1, an anti-apoptotic gene, may be responsible for the potential clinical anti-cancer activity observed with alvocidib.
- Development stage:

| Stage | Proposed indication | Country/ Area | Combination products | Study number |
|---|---|---|---|---|
| Phase 2 | Acute myeloid leukemia (combination therapy) (refractory or relapsed patients) | U.S. | cytarabine, mitoxantrone | TPI-ALV-201 (Zella 201) |
| Phase 1/2 | Myelodysplastic syndromes (combination therapy) | U.S. | decitabine | TPI-ALV-102 (Zella 102) |
| Phase 1 | Acute myeloid leukemia (combination therapy) (newly diagnosed patients) | U.S. | cytarabine, daunorubicin | TPI-ALV-101 (Zella 101) |
| | Acute myeloid leukemia (combination therapy) (newly diagnosed and refractory or relapsed patients) | Japan | newly diagnosed: cytarabine, daunorubicin refractory or relapsed : cytarabine, mitoxantrone | DC850101 |
| | Acute myeloid leukemia (combination therapy) (refractory or relapsed patients) | U.S. | venetoclax | M16-186* |

***** Co-development with AbbVie

**adegramotide/nelatimotide（DSP-7888）** Developed in-house, Formulation: injection

- DSP-7888 is a therapeutic cancer peptide vaccine derived from Wilms' tumor gene 1 (WT1) protein. DSP-7888 is a vaccine containing peptides that induces WT1-specific cytotoxic T lymphocytes (CTLs) and helper T cells. DSP-7888 is expected to become a treatment option for patients with various types of hematologic malignancies and solid tumors that express WT1, by inducing WT1-specific CTLs that attack WT1-expressing cancer cells. By adding a helper T cell-inducing peptide, improved efficacy over that observed with a CTL-inducing peptide alone may be achieved. DSP-7888 is expected to be an option for a wide range of patients.
- Development stage:

| Stage | Proposed indication | Country/ Area | Combination products | Study number |
|---|---|---|---|---|
| Phase 2 | Glioblastoma (combination therapy) | U.S., Japan | Bevacizumab | BBI-DSP7888-201G |
| Phase 1/2 | Myelodysplastic syndromes (monotherapy)* | Japan | - | DB650027 |
| | Pediatric malignant gliomas (monotherapy)* | Japan | - | DB601001 |

| Stage | Proposed indication | Country/ Area | Combination products | Study number |
|---|---|---|---|---|
| Phase 1 | Solid tumors, Hematologic malignancies (monotherapy) | U.S. | - | BBI-DSP7888-101 |
| | Solid tumors (combination therapy) | U.S. | nivolumab, atezolizumab | BBI-DSP7888-102CI |

* Phase 2 stage

**TP-0903** In-licensed from University of Utah, Formulation: oral

- TP-0903 is an AXL receptor tyrosine kinase inhibitor, which is known to be involved in acquiring resistance to conventional agents and developing metastatic capacity in cancer cells. TP-0903 may have anti-cancer activities on various cancer types through blocking transition from epithelial to mesenchymal phenotype by inhibiting AXL. TP0903 has been shown to inhibit AXL signaling and reverse the mesenchymal to epithelial phenotype in pre-clinical studies.
- Development stage:
  Chronic lymphocytic leukemia (monotherapy / combination therapy): Phase 1/2 in the U.S.
  Solid tumors (monotherapy / combination therapy): Phase 1 in the U.S. and Japan

**DSP-0509** Developed in-house, Formulation: injection

- DSP-0509 is a novel Toll-like receptor (TLR) 7 agonist. DSP-0509 may promote the cytokine induction and cytotoxic T lymphocyte (CTL) activation mediated by agonistic effect of TLR 7 expressing in plasmacytoid dendritic cell. Furthermore, DSP-0509 is expected to sustain the immune-mediated anti-cancer activity by induction of immune system memory T cells.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

**TP-0184** Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-0184 inhibits activin A receptor type 1 (ACVR1, also known as ALK2), part of the transforming growth factor beta (TGFβ) receptor superfamily. Mutations in the ACVR1 gene have been identified in various tumors, including diffuse intrinsic pontine glioma (DIPG; one of common pediatric brain tumors). TP-0184 has been shown to inhibit the growth of tumors harboring ACVR1 mutations in the pre-clinical studies.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

**DSP-0337** Developed in-house, Formulation: oral

- DSP-0337 is a small molecule oral prodrug of napabucasin. DSP-0337 is expected to be stable and dispersed in the stomach, and converted to napabucasin in the intestine, which may be absorbed and exert its pharmacologic activities.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

**TP-1287** Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-1287 is a small molecule oral agent that inhibits cyclin-dependent kinase 9 (CDK9). TP-1287 has shown favorable oral bioavailability in preclinical studies. It is enzymatically cleaved, yielding alvocidib, a potent inhibitor of CDK9. The oral administration of TP-1287 may allow for administration for a prolonged period, which may lead to a continuous inhibition of CDK9.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

**TP-3654** Developed in-house (Tolero Pharmaceuticals, Inc.), Formulation: oral

- TP-3654 inhibits the inflammatory signaling pathways through inhibition of PIM (proviral integration site for Moloney murine leukemia virus) kinases. PIM kinases are frequently overexpressed in various hematologic malignancies and solid tumors, allowing cancer cells to evade apoptosis and promoting tumor growth.
- Development stage: Solid tumors (monotherapy): Phase 1 in the U.S.

### 3. Regenerative medicine / cell therapy

**SB623** In-licensed from and co-developed with SanBio, Inc., Formulation: injection

- SB623 is an allogeneic cell product, derived from bone marrow stromal cells isolated from healthy donors. SB623 is expected to be effective for chronic stroke, which has no effective treatments available, by promoting regeneration of central nerve cells. Unlike autologous cell therapies that require individualized cell preparation at the clinical site, SB623 production can be scaled up from a single donor's cells, enabling delivery of uniform-quality products to a large number of stroke patients.
- Development stage: Chronic stroke: Phase 2 in the U.S. (Co-development with SanBio)

**Allo iPS cell-derived products**

- In cooperation with the partners in the industry-academia collaboration, we are promoting toward the commercialization of regenerative medicine / cell therapy using allo iPS cell (healthy patients) for AMD (age-related macular degeneration), Parkinson's disease, retinitis pigmentosa, and spinal cord injury.
- Development stage:

| Development code | Partnering | Proposed indication | Area | Development stage |
|---|---|---|---|---|
| - | Kyoto University CiRA | Parkinson's disease | Japan | Phase 1/2 (Investigator-initiated clinical study) |
| HLCR011 | RIKEN, Healios | Age-related macular degeneration (AMD) | Japan | Preparing for start of clinical study |

### 4. Others

**imeglimin (PXL008)** In-licensed from and co-developed with Poxel SA, Formulation: oral

- Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins by the World Health Organization. Imeglimin has a unique mechanism of action that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles, and the pancreas, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis.
- Development stage: Type 2 diabetes: Phase 3 in Japan (Co-development with Poxel)