# Financial Results for the Nine Month Period Ended December 31, 2013 (Apr. 1 to Dec. 31, 2013)

January 31, 2014

Dainippon Sumitomo Pharma Co., Ltd.

# Financial Results for FY2013 Apr.-Dec.

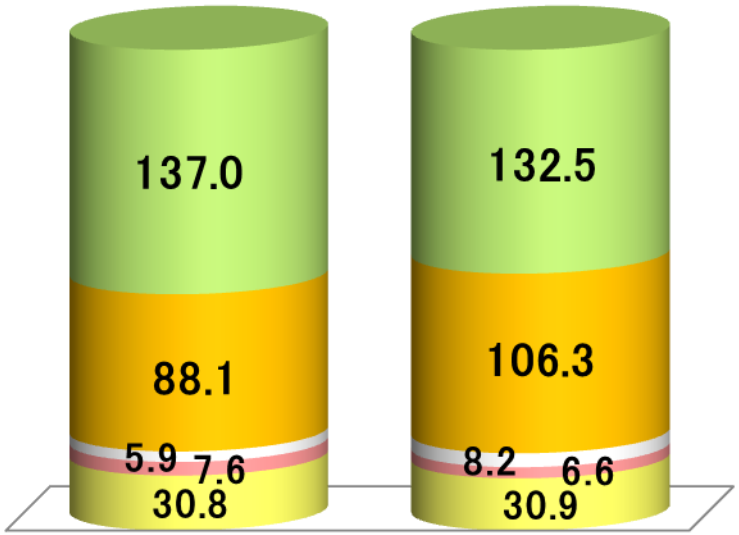
Billions of yen

| | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | | | FY2013 | |
|---|---|---|---|---|---|---|---|
| | | | Value | Exchange Rate Impact | Percentage (%) | Previous Forecasts | Progress (%) |
| Net sales | 269.2 | **284.5** | 15.3 | 23.2 | 5.7 | 381.0 | 74.7 |
| Cost of sales | 76.4 | **78.1** | 1.7 | 2.7 | 2.3 | 104.0 | 75.1 |
| Gross profit | 192.9 | **206.4** | 13.5 | 20.5 | 7.0 | 277.0 | 74.5 |
| SG&A expenses | 160.2 | **171.7** | 11.6 | 18.9 | 7.2 | 242.0 | 71.0 |
| SG&A expenses less R&D costs | 120.2 | **122.8** | 2.6 | 14.4 | 2.1 | 169.0 | 72.6 |
| R&D Costs | 39.9 | **49.0** | 9.0 | 4.5 | 22.6 | 73.0 | 67.1 |
| Operating income | 32.7 | **34.7** | 1.9 | 1.6 | 6.0 | 35.0 | 99.0 |
| Ordinary income | 32.7 | **34.3** | 1.6 | | 4.9 | 34.0 | 101.0 |
| Net income | 16.9 | **19.2** | 2.3 | | 13.6 | 17.0 | 112.7 |
| E B I T D A | 61.8 | **55.2** | (6.5) | | (10.6) | 61.0 | 90.5 |

Notes: 1. All values are rounded to the nearest 100 million yen.
2. Cost of sales includes provision for (reversal of) reserve for sales returns.
3. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization, and Extraordinary income / loss.

Exchange Rate:
FY2012 Apr.-Dec.: 1US$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 Apr.-Dec.: 1US$ = ¥ 99.4, 1RMB = ¥16.2

# Net Sales by Segment




| | FY2012 Apr.-Dec. | FY2013 Apr.-Dec. | Billions of yen change Value | Billions of yen change Percentage |
|---|---|---|---|---|
| | 269.2 | 284.5 | 15.3 | 5.7% |
| Japan | 137.0 | 132.5 | (4.4) | (3.2)% |
| North America | 88.1 | 106.3 | 18.3 | 20.7 % |
| China | 5.9 | 8.2 | 2.3 | 38.8 % |
| Other Regions | 7.6 | 6.6 | (1.0) | (13.2 )% |
| Other Business | 30.8 | 30.9 | 0.2 | 0.6 % |
| Overseas Sales | 37.8 % | 42.6 % | | |

【 Japan 】 Increase in sales for the product line of sales department, decrease in industrial property revenues and contract manufacture products

【 North America 】 Increase of sales for LATUDA®, impact of weak yen

【 China 】 Increase of sales for MEROPEN®, impact of weak yen

Exchange Rate:
FY2012 Apr.-Dec.: 1US$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 Apr.-Dec.: 1US$ = ¥ 99.4, 1RMB = ¥16.2

# Sales in Japan

Billions of yen

| | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | | FY2013 | |
|---|---|---|---|---|---|---|
| | | | Value | Percentage (%) | Forecasts | Progress (%) |
| AIMIX® | 1.9 | **4.9** | 3.0 | 160.6 | 6.1 | 80.2 |
| AVAPRO® | 9.0 | **9.4** | 0.4 | 3.9 | 12.1 | 77.5 |
| LONASEN® | 8.4 | **9.3** | 1.0 | 11.4 | 13.0 | 71.8 |
| TRERIEF® | 5.4 | **6.8** | 1.4 | 26.5 | 9.2 | 74.3 |
| Strategic products total | 24.7 | **30.4** | 5.8 | 23.3 | 40.4 | 75.3 |
| METGLUCO® | 9.1 | **11.7** | 2.6 | 28.0 | 15.2 | 76.7 |
| SUREPOST® | 0.5 | **1.2** | 0.7 | 148.2 | 1.9 | 62.3 |
| New products total | 9.6 | **12.8** | 3.3 | 34.0 | 17.1 | 75.1 |
| AmBisome® | 3.6 | **3.8** | 0.3 | 7.1 | 5.0 | 77.0 |
| MIRIPLA® | 0.9 | **0.9** | 0.0 | 3.4 | 1.3 | 70.7 |
| REPLAGAL® | 7.8 | **7.7** | (0.1) | (0.7) | 10.5 | 73.6 |
| Specialty products total | 12.3 | **12.5** | 0.2 | 1.9 | 16.8 | 74.4 |
| AMLODIN® | 22.8 | **21.2** | (1.6) | (7.1) | 26.9 | 78.9 |
| GASMOTIN® | 15.7 | **11.9** | (3.8) | (24.2) | 15.1 | 78.9 |
| PRORENAL® | 11.2 | **10.7** | (0.5) | (4.2) | 13.3 | 80.7 |
| MEROPEN® | 8.2 | **7.8** | (0.4) | (4.5) | 9.6 | 81.4 |
| Others in product line of Sales Department | 26.6 | **23.8** | (2.8) | (10.5) | 33.6 | 70.8 |
| Product line of Sales Department total | 131.1 | **131.3** | 0.2 | 0.1 | 172.8 | 76.0 |
| Others | 5.9 | **1.3** | (4.6) | (78.4) | 1.2 | 106.2 |
| **Japan total** | 137.0 | **132.5** | (4.4) | (3.2) | 174.0 | 76.2 |

Note: Sales figures before reduction of rebates

# Sales in North America & China

| | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | | FY2013 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Value | Exchange Rate Impact | Previous Forecasts | | Progress (%) |
| **North America** | (Million $) | | | (Billion yen) | | | | (Million $) | (Billion yen) | |
| LATUDA® | 140 | **289** | 149 | 11.1 | **28.7** | 17.6 | 5.8 | 364 | 36.2 | 79.4 |
| LUNESTA® | 419 | **432** | 14 | 33.2 | **42.9** | 9.7 | 8.6 | 555 | 55.2 | 77.8 |
| XOPENEX® | 263 | **95** | (168) | 20.9 | **9.4** | (11.5) | 1.9 | 117 | 11.7 | 80.6 |
| BROVANA® | 117 | **124** | 7 | 9.3 | **12.3** | 3.0 | 2.5 | 177 | 17.6 | 69.7 |
| Ciclesonide | 47 | **65** | 18 | 3.7 | **6.5** | 2.7 | 1.3 | 88 | 8.8 | 73.5 |
| Industrial property revenues | 85 | **32** | (54) | 6.8 | **3.1** | (3.6) | 0.6 | 37 | 3.7 | 85.0 |
| Others | 38 | **33** | (4) | 3.0 | **3.3** | 0.3 | 0.7 | 41 | 4.0 | 82.6 |
| Total | 1,109 | **1,070** | (39) | 88.1 | **106.3** | 18.3 | 21.4 | 1,379 | 137.1 | 77.5 |
| **China** | (Million RMB) | | | (Billion yen) | | | | (Million RMB) | (Billion yen) | |
| MEROPEN® | 385 | **409** | 24 | 4.8 | **6.6** | 1.8 | 1.5 | 566 | 8.8 | 75.5 |
| Others | 83 | **93** | 10 | 1.0 | **1.5** | 0.5 | 0.3 | 141 | 2.2 | 68.7 |
| Total | 468 | **502** | 34 | 5.9 | **8.2** | 2.3 | 1.8 | 706 | 11.0 | 74.1 |

Note: FY2012 Apr.-Dec. figures are for sales of Jan. to Sep. 2012.

Exchange Rate:
FY2012 Apr.-Dec.: 1US$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 Apr.-Dec.: 1US$ = ¥ 99.4, 1RMB = ¥16.2

# Segment Breakdown for North America

＜Excluding amortization of patent rights and goodwill, etc.＞

| | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | Exchange Rate Impact |
|---|---|---|---|---|---|---|---|
| | (Million $) | | | (Billion yen) | | | |
| Net sales | 1,109 | **1,070** | (39) | 88.1 | **106.3** | 18.3 | 21.4 |
| Cost of sales | 123 | **114** | (9) | 9.7 | **11.3** | 1.6 | 2.3 |
| Gross profit | 986 | **956** | (30) | 78.3 | **95.0** | 16.7 | 19.1 |
| SG&A expenses | 555 | **533** | (23) | 44.1 | **52.9** | 8.8 | 10.6 |
| Income of segment | 431 | **424** | (8) | 34.2 | **42.1** | 7.9 | 8.5 |

＜Impact from amortization of patent rights and goodwill, etc.＞

| | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | Exchange Rate Impact |
|---|---|---|---|---|---|---|---|
| | (Million $) | | | (Billion yen) | | | |
| SG&A expenses | 272 | **140** | (131) | 21.6 | **14.0** | (7.6) | 2.8 |
| Income (loss) of segment | (272) | **(140)** | 131 | (21.6) | **(14.0)** | 7.6 | (2.8) |

Exchange Rate:
FY2012 Apr.-Dec.: 1US$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 Apr.-Dec.: 1US$ = ¥ 99.4, 1RMB = ¥16.2

# Segment Information

Billions of yen

| | | Pharmaceuticals Business | | | | | | Other Business | Total |
|---|---|---|---|---|---|---|---|---|---|
| | | Japan | North America※1 | Amortization※2 | China | Other Regions | Subtotal | | |
| FY2013 Apr.-Dec. | Net sales（Sales to customers） | 132.5 | 106.3 | — | 8.2 | 6.6 | 253.6 | 30.9 | 284.5 |
| | Cost of sales | 37.3 | 11.3 | — | 1.9 | 3.4 | 53.8 | 24.3 | 78.1 |
| | Gross profit | 95.3 | 95.0 | — | 6.3 | 3.2 | 199.8 | 6.6 | 206.4 |
| | SG&A expenses less R&D costs | 46.1 | 52.9 | 14.0 | 4.6 | 0.7 | 118.3 | 4.5 | 122.8 |
| | **Income (loss) of segment** | 49.3 | 42.1 | (14.0) | 1.7 | 2.5 | 81.6 | 2.1 | 83.6 |
| | R&D costs | | | | | | 48.3 | 0.6 | 49.0 |
| | Operating income | | | | | | 33.2 | 1.4 | 34.7 |
| FY2012 Apr.-Dec. | Net sales（Sales to customers） | 137.0 | 88.1 | — | 5.9 | 7.6 | 238.5 | 30.8 | 269.2 |
| | Cost of sales | 37.7 | 9.7 | — | 1.4 | 3.8 | 52.6 | 23.7 | 76.4 |
| | Gross profit | 99.5 | 78.3 | — | 4.5 | 3.7 | 186.0 | 6.8 | 192.9 |
| | SG&A expenses less R&D costs | 47.2 | 44.1 | 21.6 | 2.6 | 0.3 | 115.8 | 4.4 | 120.2 |
| | **Income (loss) of segment** | 52.2 | 34.2 | ( 21.6) | 1.9 | 3.4 | 70.3 | 2.4 | 72.7 |
| | R&D costs | | | | | | 39.4 | 0.6 | 39.9 |
| | Operating income | | | | | | 30.9 | 1.8 | 32.7 |
| Change | Net sales（Sales to customers） | (4.4) | 18.3 | — | 2.3 | (1.0) | 15.1 | 0.2 | 15.3 |
| | SG&A expenses less R&D costs | (1.2) | 8.8 | (7.6) | 2.0 | 0.4 | 2.5 | 0.1 | 2.6 |
| | **Income (loss) of segment** | (3.0) | 7.9 | 7.6 | (0.3) | (1.0) | 11.3 | (0.3) | 11.0 |
| | R&D costs | | | | | | 8.9 | 0.1 | 9.0 |
| | Operating income | | | | | | 2.3 | (0.4) | 1.9 |

※1. Excluding amortization of patent rights and goodwill, etc.
※2. Amortization of patent rights and goodwill, etc.

Exchange Rate:
FY2012 Apr.-Dec.: 1US$ = ¥ 79.4, 1RMB = ¥12.6
FY2013 Apr.-Dec.: 1US$ = ¥ 99.4, 1RMB = ¥16.2

# Ordinary income & Net income

Billions of yen

| | FY2012 Apr.-Dec. | **FY2013 Apr.-Dec.** | Change | |
|---|---|---|---|---|
| | | | Value | Percentage(%) |
| Operating income | 32.7 | 34.7 | 1.9 | 6.0 |
| Non-operating income and expenses | 0.0 | (0.3) | (0.3) | |
| Ordinary income | 32.7 | 34.3 | 1.6 | 4.9 |
| Extraordinary income | — | 3.8 | 3.8 | |
| Gain on sales of investment securities | — | 2.8 | 2.8 | |
| Fair value adjustment of contingent consideration | — | 1.1 | 1.1 | |
| Extraordinary loss | 4.4 | 6.4 | 2.0 | |
| Impairment loss | 0.4 | 4.6 | 4.2 | |
| Business structure improvement expenses | 3.9 | 1.8 | (2.1) | |
| Income taxes | 11.5 | 12.6 | 1.1 | |
| Net income | 16.9 | 19.2 | 2.3 | 13.6 |

【 Gain on sales of investment securities 】 Gain on a sale of the listed stock

【 Business structure improvement expenses 】 Restructuring in the U.S. and Japan

【 Impairment loss 】 Impairment loss for production facility and in-process R&D in the U.S.

# Revised Financial Forecasts for FY2013

Billions of yen

| | FY2012 (a) | FY2013 Previous Forecasts (b) | **FY2013 Revised Forecasts (c)** | Change (c)-(a) Value | Change (c)-(a) Value: Exchange Rate Impact | Change (c)-(b) Value |
|---|---|---|---|---|---|---|
| Net sales | 347.7 | 381.0 | **385.0** | 37.3 | 32.3 | 4.0 |
| Cost of sales | 101.7 | 104.0 | **104.4** | 2.7 | 4.3 | 0.4 |
| Gross profit | 246.0 | 277.0 | **280.6** | 34.6 | 28.0 | 3.6 |
| SG&A expenses | 221.0 | 242.0 | **245.6** | 24.6 | 27.2 | 3.6 |
| SG&A expenses less R&D costs | 161.2 | 169.0 | **172.6** | 11.4 | 20.4 | 3.6 |
| R&D costs | 59.8 | 73.0 | **73.0** | 13.2 | 6.8 | — |
| Operating income | 25.0 | 35.0 | **35.0** | 10.0 | 0.8 | — |
| Ordinary income | 24.5 | 34.0 | **34.0** | 9.5 | | — |
| Extraordinary income and loss | (6.3) | (3.0) | **(3.0)** | 3.3 | | — |
| Net income | 10.0 | 17.0 | **17.0** | 7.0 | | — |
| EBITDA | 60.3 | 61.0 | **61.0** | 0.7 | | — |

Notes:

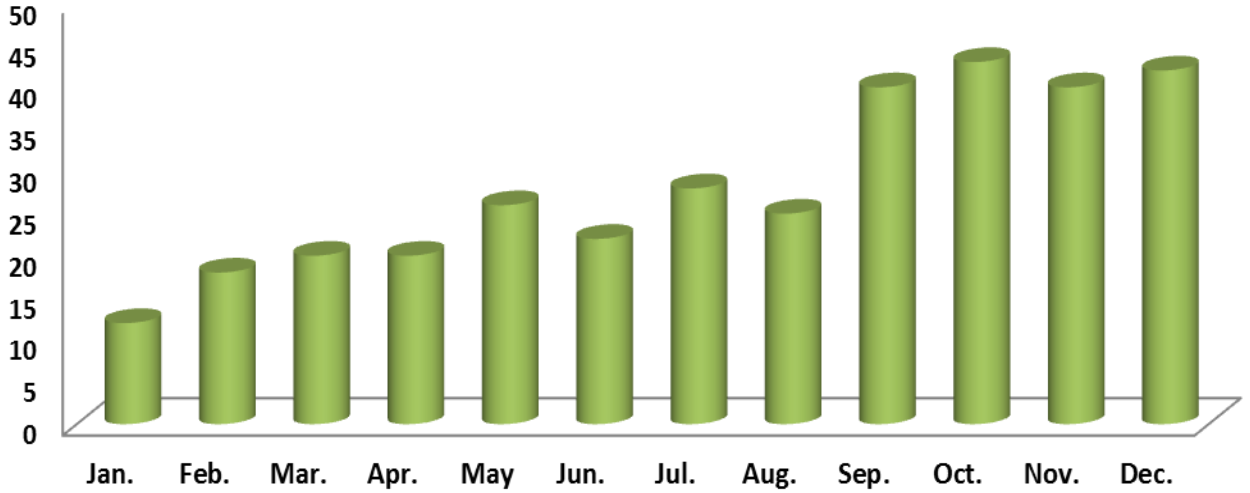
1. All values are rounded to the nearest 100 million yen.
2. EBITDA: Earnings before Interest, Taxes, Depreciation and Amortization, and Extraordinary income / loss.

Exchange Rate:

FY2012 : 1US$ = ¥ 79.8, 1RMB = ¥12.7
FY2013 Original Forecast : 1US$ = ¥ 99.4, 1RMB = ¥15.6
FY2013 Revised Forecast : 1US$ = ¥ 99.5, 1RMB = ¥15.9

# Factors for Revised Financial Forecasts for FY2013

- **Raised Sales Forecasts for LATUDA® by 3.0 billion yen（36.2 to 39.2 billion yen）**
  - ✓ LATUDA® sales boosted by the new indication of Bipolar I depression
    （Sales in 2013 by month :$M）




- **Raised Sales Forecasts for LUNESTA® by 1.0 billion yen（55.2 to 56.2 billion yen）**
- **Raised Forecasts in SG&A expenses less R&D costs by 3.6 billion yen**
  - ✓ LATUDA® and LUNESTA®：Marketing expenses to increase
  - ✓ APTIOM®（plan to launch in 1Q 2014）: Expenses for launch preparation to increase

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# Development Pipeline (1) (as of January 31, 2014)

## Psychiatry & Neurology Field

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase I | Phase II | Phase III | Submitted |
|---|---|---|---|---|---|---|---|
| LATUDA® (SM-13496) | lurasidone hydrochloride | Schizophrenia | Europe ※1 | | | | |
| | | Schizophrenia | Australia, Taiwan | | | | |
| | | (New indication) Bipolar I depression | Canada | | | | |
| | | Schizophrenia | Japan/China | | | | |
| | | Bipolar I depression, Bipolar maintenance | Japan | | | | |
| | | (New indication) Bipolar maintenance | U.S./Europe, etc. | | | | |
| | | (New indication) MDD with mixed features | U.S./Europe, etc. | | | | |
| APTIOM® (SEP-0002093) | eslicarbazepine acetate | Epilepsy- Adjunctive therapy | U.S. | | | | ✦ |
| | | Epilepsy- Adjunctive therapy | Canada | | | | |
| | | (New indication) Epilepsy- Monotherapy | U.S. | | | | |
| LONASEN® | blonanserin | Schizophrenia | China | | | | |
| | | (Addition of pediatric usage) Schizophrenia | Japan | | | | |
| | | (New formulation: Transdermal patch) Schizophrenia | Japan | | | | |
| AS-3201 | ranirestat | Diabetic neuropathy | Japan | | | | |
| EPI-743 | TBD | Leigh syndrome | Japan | | | | ※2 |
| SEP-225289 | TBD | Attention-deficit hyperactivity disorder (ADHD) | U.S. | | | | |
| TRERIEF® | zonisamide | (New indication) Parkinsonism in Dementia with Lewy Bodies (DLB) | Japan | | | | |
| DSP-1053 | TBD | Major depressive disorder | U.S. | | | | |
| DSP-2230 | TBD | Neuropathic pain | U.K. /U.S. | | | | |
| SEP-363856 | TBD | Schizophrenia | U.S. | | | | |

※1 Lurasidone (SM-13496) : Co-development with Takeda Pharmaceutical in Europe
※2 Phase II/III study

Revisions since the previous announcement are in red.

✦ Approved / Preparing for Launch

# Development Pipeline (2) (as of January 31, 2014)

## Cancer Field

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase I | Phase II | Phase III | Submitted |
|---|---|---|---|---|---|---|---|
| CALSED® (Brand name in Japan) | amrubicin hydrochloride | Small cell lung cancer | China | | | | |
| BBI608 | TBD | Colorectal cancer (Monotherapy) (Global clinical trial) | U.S./Canada/ Japan, etc. | | | | |
| | | Colorectal cancer (Combination therapy) | U.S./Canada | | | | |
| | | Solid cancer (Combination therapy) | U.S./Canada | | | ※1 | |
| | | Gastrointestinal cancer (Combination therapy) | U.S. /Canada | | | | |
| | | Gastric cancer (Combination therapy) | Japan | | | | |
| WT4869 | TBD | Myelodysplastic syndromes | Japan | | ※2 | | |
| | | Solid cancer | Japan | | | | |
| WT2725 | TBD | Solid cancer, Hematologic cancer | U.S. | | | | |
| | | Solid cancer | Japan | | | | |
| BBI503 | TBD | Solid cancer (Monotherapy) | U.S./Canada | | | | |

Revisions since the previous announcement are in red.

※1 Phase II of Phase I/II study

※2 Phase I of Phase I/II study

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# Development Pipeline (3) (as of January 31, 2014)

## Respiratory Field

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase I | Phase II | Phase III | Submitted |
|---|---|---|---|---|---|---|---|
| SUN-101 | glycopyrrolate bromide | Chronic obstructive pulmonary disease (COPD) | U.S. | | | | |
| DSP-3025 | TBD | Bronchial asthma/Allergic rhinitis | Japan | | | | |

## Cardiovascular / Diabetes Field

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase I | Phase II | Phase III | Submitted |
|---|---|---|---|---|---|---|---|
| METGLUCO® | metformin hydrochloride | (Addition of pediatric usage) Type 2 diabetes | Japan | | | | |
| SUREPOST® | repaglinide | (New indication) Type 2 diabetes<br>(All combination therapies including DPP-4 inhibitors) | Japan | | | | |

## Other Fields

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase I | Phase II | Phase III | Submitted |
|---|---|---|---|---|---|---|---|
| MEROPEN® | meropenem hydrate | (Change of dose)<br>Bacterial meningitis: 6g daily | Japan | | | | ✦ |
| DSP-1747 | obeticholic acid | Nonalcoholic steatohepatitis (NASH) | Japan | | | | |
| DSP-6952 | TBD | IBS with constipation, Chronic idiopathic constipation | Japan | | | | |
| DSP-5990 | ceftaroline fosamil | MRSA infection | Japan | | | | |

✦ Approved

Revisions since the previous announcement are in red.

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# Development Pipeline State of Progress
## (Main changes after October 30, 2013)

- **APTIOM® (eslicarbazepine acetate)**
  - ✓ Approved for partial-onset seizures (Adjunctive therapy) in the U.S. (November 2013)

- **MEROPEN® (Change of dose)**
  - ✓ Approved change of dose (6g daily) for bacterial meningitis in Japan (December 2013)

- **SUREPOST® (New indication)**
  - ✓ NDA submitted for type 2 diabetes (All combination therapies including DPP-4 inhibitors) in Japan (December 2013)

- **BBI608**
  - ✓ Phase I study for gastrointestinal cancer (Combination therapy with FOLFOX[*1],FOLFOX[*1] and bevacizumab, CAPOX[*2], FOLFIRI[*3], FOLFIRI[*3] and bevacizumab, or regorafenib) initiated in the U.S. and Canada.
  - ✓ Phase I study for gastric cancer with paclitaxel (Combination therapy with paclitaxel) initiated in Japan

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*1：FOLFOX（Combination with Fluorouracil, Leucovorin, Oxaliplatin）
*2：CAPOX（Combination with Capecitabine, oxaliplatin)
*3：FOLFIRI（Combination with Fluorouracil, Leucovorin, Irinotecan）

# BBI608 and BBI503 - Clinical development status

## BBI608

### U.S., Canada, Japan, etc.

- Colorectal cancer (Monotherapy)
  - ✓ Phase III in progress (initiated in 1Q 2013)

→ **Launch Goal**
**North America :FY2015**
**Japan :FY2016**

### U.S., Canada

- Colorectal cancer (Combination with Cetuximab, Panitumumab, or Capecitabine)
  Phase II in progress (initiated in 1Q 2012)
- Solid cancer (Combination with paclitaxel)
  Phase II of Phase I / II in progress (initiated in 2Q 2013)
- Gastrointestinal cancer (Combination with FOLFOX[*1],FOLFOX[*1] and Bevacizumab, CAPOX[*2], FOLFIRI[*3], FOLFIRI[*3] and Bevacizumab, or Regorafenib)
  Phase I in progress (initiated in 4Q 2013)

*1：FOLFOX（Combination with Fluorouracil, Leucovorin, Oxaliplatin）
*2：CAPOX（Combination with Capecitabine, oxaliplatin)
*3：FOLFIRI（Combination with Fluorouracil, Leucovorin, Irinotecan）

### Japan

- Gastric cancer (Combination with paclitaxel) Phase I in progress (initiated in 4Q 2013)

## BBI503

### U.S., Canada

- Solid cancer (Monotherapy)

Phase I in progress (initiated in 1Q 2012) → **Launch Goal FY2017**

Revisions since the previous announcement are in red.

# LATUDA®（Lurasidone）– Clinical development status

## U.S. (Schizophrenia)

**Key Current (or Ongoing) Studies in Schizophrenia**

- Schizophrenia Maintenance Study: Completed and data analysis in progress
- Pediatric (6-17 yrs) PK Study: Completed in 4Q 2013
- Low-dose Schizophrenia Study with 20mg/day: initiated in 2Q 2013, in progress
- Pediatric (6-17 yrs) Efficacy Study: initiated in 3Q 2013, in progress

## U.S. (Bipolar disorder, others)

- **Bipolar maintenance**
  - Phase III study initiated in 2Q 2011
- **MDD with mixed features**
  - Phase III study initiated in 2Q 2011
- **IM depot formulation**
  - Pre-clinical stage

## Outside the U.S.

| | |
|---|---|
| Japan: | Schizophrenia/ Phase III study in progress (Initiated in 2Q 2012)<br>Bipolar I depression , Bipolar maintenance/ Phase III study in progress (Initiated in 3Q 2013) |
| Canada: | Bipolar I depression/ NDA submitted in August 2012 |
| China: | Schizophrenia/ Phase III study in progress (Initiated in 3Q 2013) |
| Europe: | Schizophrenia/ MAA submitted by Takeda<br>- Switzerland : Approved in 3Q 2013<br>- Europe: MAA submitted by the centralized authorization procedure in 3Q 2012<br>- Europe: The Committee for Medicinal Products for Human Use (CHMP) of EMA recommended approval in January 2014<br>Bipolar disorder/ Plan to submit by Takeda in Europe (in Phase III stage)<br>DSP plans to commercialize lurasidone independently in the U.K. |
| Australia: | Schizophrenia/ MAA submitted in 1Q 2013 |
| Taiwan: | Schizophrenia/ Submitted by Standard Chem. & Pharm in 3Q 2013 |

Revisions since the previous announcement are in red.

# Disclaimer Regarding Forward-looking Statements

The statements made in this presentation material are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties.

Actual financial results may differ materially from those presented in this document, being dependent on a number of factors.

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