Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows

# Financial Results for 2Q FY2016
## (April 1 to September 30, 2016)

October 28, 2016

Masayo Tada, President and CEO

Sumitomo Dainippon Pharma Co., Ltd.

# Financial Results for 2Q FY2016

# Financial Results for FY2016 Apr.-Sep.

Billions of yen

| | FY2015 Apr.-Sep. | FY2016 Apr.-Sep. | Change | | | FY2016 2Q (Apr.-Sep.) | | FY2016 | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Value | FX rate impact | % | Forecasts on May 11 | Achievement % | Forecasts on May 11 | Progress % |
| Net sales | 198.9 | 198.1 | (0.8) | (16.5) | (0.4) | 199.0 | 99.5 | 410.0 | 48.3 |
| Cost of sales | 52.1 | 47.9 | (4.2) | * (4.0) | (8.1) | 49.0 | 97.7 | 99.5 | 48.1 |
| Gross profit | 146.8 | 150.2 | 3.4 | (12.5) | 2.3 | 150.0 | 100.1 | 310.5 | 48.4 |
| SG&A expenses | 130.0 | 123.5 | (6.5) | (11.7) | (5.0) | 134.0 | 92.1 | 270.5 | 45.6 |
| SG&A expenses less R&D costs | 89.8 | 85.7 | (4.1) | (8.2) | (4.5) | 93.5 | 91.7 | 186.0 | 46.1 |
| R&D Costs | 40.2 | 37.7 | (2.5) | (3.5) | (6.1) | 40.5 | 93.2 | 84.5 | 44.7 |
| Operating income | 16.8 | 26.7 | 9.9 | (0.8) | 58.7 | 16.0 | 167.1 | 40.0 | 66.8 |
| Ordinary income | 17.5 | 23.9 | 6.4 | | 36.4 | 16.0 | 149.3 | 40.0 | 59.7 |
| Extraordinary income (loss) | 5.9 | (6.2) | (12.1) | | | – | | 2.5 | |
| Net income attributable to owners of the parent | 13.2 | 10.9 | (2.3) | | (17.3) | 8.0 | 136.5 | 25.0 | 43.7 |
| E B I T D A | 27.7 | 33.1 | 5.4 | | 19.6 | 26.0 | | 61.0 | |

＊ The number includes downward impact on cost of sales because unrealized profit of inventory on FY2015 FX rate realized in this period with stronger yen.

FX rates:
FY2015 2Q Results : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q Results : 1US$ = ¥ 105.2, 1RMB = ¥15.9
FY2016 Previous forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

# Sales of Major Products in Japan

Billions of yen

| | FY2015 Apr.-Sep. | FY2016 Apr.-Sep. | Change | | 2016 2Q (Apr.-Sep.) | |
|---|---|---|---|---|---|---|
| | | | Value | % | Forecasts on May 11 | Achievement % |
| AIMIX® | 7.0 | 8.3 | 1.3 | 18.9 | 7.9 | 105.4 |
| LONASEN® | 6.3 | 6.7 | 0.3 | 5.2 | 6.9 | 96.4 |
| TRERIEF® | 6.5 | 7.6 | 1.1 | 17.0 | 6.9 | 109.8 |
| Strategic Products Total | 19.8 | 22.6 | 2.8 | 13.9 | 21.7 | 103.9 |
| REPLAGAL® | 5.2 | 5.3 | 0.1 | 2.1 | 5.2 | 102.1 |
| AmBisome® | 2.1 | 2.2 | 0.1 | 3.4 | 2.2 | 100.7 |
| AVAPRO® | 5.4 | 5.3 | (0.1) | (2.5) | 4.8 | 109.9 |
| SUREPOST® | 1.7 | 2.2 | 0.5 | 29.4 | 2.2 | 98.1 |
| METGLUCO® | 8.4 | 5.7 | (2.7) | (32.3) | 5.0 | 113.9 |
| AMLODIN® | 8.4 | 6.7 | (1.6) | (19.5) | 6.4 | 105.3 |
| PRORENAL® | 4.6 | 3.5 | (1.1) | (23.9) | 3.6 | 96.4 |
| GASMOTIN® | 4.4 | 3.2 | (1.2) | (26.7) | 3.2 | 99.7 |
| MEROPEN® | 3.3 | 2.3 | (1.0) | (31.3) | 2.4 | 95.5 |
| Others | 10.8 | 11.6 | 0.9 | 8.2 | 11.8 | 98.7 |
| Other Products Total | 54.2 | 48.0 | (6.2) | (11.5) | 46.8 | 102.5 |
| **Japan Total** | 74.0 | 70.5 | (3.5) | (4.7) | 68.5 | 103.0 |

Note: Sales of each product above are shown by invoice price sales basis.

# Sales of Major Products in North America & China

| | FY2015 Apr.-Sep. | FY2016 Apr.-Sep. | Change | FY2015 Apr.-Sep. | FY2016 Apr.-Sep. | Change | | | FY2016 2Q (Apr.-Sep.) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Value | rate | FX rate impact | Forecasts on May 11 | | Yen-based Achievement |
| **North America** | Million $ | | | Billion yen | | | % | Billion yen | Million $ | Billion yen | % |
| LATUDA® | 472 | 584 | 112 | 57.6 | 61.4 | 3.9 | 6.7 | (9.7) | 558 | 61.4 | 100.0 |
| APTIOM® | 27 | 47 | 20 | 3.3 | 5.0 | 1.7 | 50.8 | (0.8) | 54 | 6.0 | 82.9 |
| BROVANA® | 120 | 153 | 33 | 14.6 | 16.1 | 1.5 | 10.3 | (2.5) | 130 | 14.3 | 112.5 |
| Ciclesonide | 31 | 23 | (8) | 3.7 | 2.4 | (1.3) | (36.1) | (0.4) | 28 | 3.1 | 76.9 |
| XOPENEX® | 29 | 25 | (4) | 3.5 | 2.6 | (0.9) | (25.9) | (0.4) | 25 | 2.8 | 93.4 |
| LUNESTA® | 22 | (5) | (27) | 2.7 | (0.5) | (3.2) | – | 0.1 | 13 | 1.5 | – |
| Others | 39 | 42 | 3 | 4.8 | 4.4 | (0.3) | (7.3) | (0.7) | 46 | 5.1 | 86.5 |
| Total | 740 | 868 | 129 | 90.2 | 91.4 | 1.2 | 1.3 | (14.5) | 856 | 94.2 | 97.0 |
| **China** | Million RMB | | | Billion yen | | | % | Billion yen | Million RMB | Billion yen | % |
| MEROPEN® | 417 | 505 | 88 | 8.1 | 8.0 | (0.1) | (0.8) | (1.8) | 418 | 7.1 | 113.2 |
| Others | 76 | 71 | (4) | 1.5 | 1.1 | (0.3) | (22.6) | (0.3) | 71 | 1.2 | 94.8 |
| Total | 492 | 576 | 84 | 9.6 | 9.2 | (0.4) | (4.1) | (2.0) | 488 | 8.3 | 110.5 |

FX rates:
FY2015 2Q Results : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q Results : 1US$ = ¥ 105.2, 1RMB = ¥15.9
FY2016 Previous forecasts : 1US$ = ¥ 110.0, 1RMB = ¥17.0

# Segment Information

Billions of yen

| | | Pharmaceuticals Business | | | | | Other Business | Total |
|---|---|---|---|---|---|---|---|---|
| | | Japan | North America | China | Other Regions | Subtotal | | |
| FY2016 2Q Results | Net sales (Sales to customers) | 70.5 | 91.4 | 9.2 | 5.3 | 176.4 | 21.7 | 198.1 |
| | Cost of sales | 22.5 | 4.1 | 1.4 | 2.5 | 30.5 | 17.3 | 47.9 |
| | Gross profit | 48.1 | 87.2 | 7.8 | 2.7 | 145.8 | 4.4 | 150.2 |
| | SG&A expenses less R&D costs | 28.5 | 49.0 | 3.5 | 1.5 | 82.5 | 3.2 | 85.7 |
| | Income (loss) of Segment | 19.6 | 38.3 | 4.3 | 1.2 | 63.4 | 1.1 | 64.5 |
| | R&D costs | | | | | 37.3 | 0.5 | 37.7 |
| | Operating income | | | | | 26.1 | 0.6 | 26.7 |
| FY2015 2Q Results | Net sales (Sales to customers) | 74.0 | 90.2 | 9.6 | 4.7 | 178.4 | 20.5 | 198.9 |
| | Cost of sales | 22.7 | 8.6 | 1.7 | 2.6 | 35.6 | 16.5 | 52.1 |
| | Gross profit | 51.3 | 81.6 | 7.8 | 2.1 | 142.8 | 4.0 | 146.8 |
| | SG&A expenses less R&D costs | 29.3 | 52.0 | 4.0 | 1.3 | 86.6 | 3.1 | 89.8 |
| | Income (loss) of Segment | 22.1 | 29.5 | 3.8 | 0.8 | 56.2 | 0.9 | 57.0 |
| | R&D costs | | | | | 39.8 | 0.4 | 40.2 |
| | Operating income | | | | | 16.4 | 0.4 | 16.8 |
| Change | Net sales (Sales to customers) | (3.5) | 1.2 | (0.4) | 0.6 | (2.0) | 1.2 | (0.8) |
| | SG&A expenses less R&D costs | (0.8) | (3.1) | (0.5) | 0.2 | (4.1) | 0.1 | (4.1) |
| | Income (loss) of Segment | (2.5) | 8.8 | 0.5 | 0.4 | 7.2 | 0.3 | 7.4 |
| | R&D costs | | | | | (2.5) | 0.0 | (2.5) |
| | Operating income | | | | | 9.7 | 0.2 | 9.9 |

FX rates:
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

# Ordinary income & Net income attributable to owners of parent

Billions of yen

| | FY2015 2Q Results | FY2016 2Q Results | Change | |
|---|---|---|---|---|
| | | | Value | % |
| Operating Income | 16.8 | 26.7 | 9.9 | 58.7 |
| Non-operating income and expenses | 0.7 | (2.8) | (3.5) | |
| Ordinary income | 17.5 | 23.9 | 6.4 | 36.4 |
| Extraordinary income | 6.1 | 3.8 | (2.3) | |
| Gain on sales of investment securities | 6.1 | 3.8 | | |
| Extraordinary loss | 0.2 | 10.0 | 9.8 | |
| Business structure improvement expenses | – | 10.0 | | |
| Impairment loss | 0.2 | – | | |
| Income taxes | 10.2 | 6.8 | (3.4) | |
| Net income attributable to owners of the parent | 13.2 | 10.9 | (2.3) | (17.3) |

FX rates:
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

# Financial Forecasts for FY2016

# Financial Forecasts for FY2016

Billions of yen

| | FY2015 Result (a) | FY2016 Forecasts on May 11 (b) | FY2016 Revised Forecasts (c) | Change from forecasts on May 11 (c)-(b) | | Change from FY2015 (c)-(a) | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Value | FX rate impact | Value | FX rate impact | % |
| Net sales | 403.2 | 410.0 | 398.0 | (12.0) | (10.1) | (5.2) | (30.4) | (1.3) |
| Cost of sales | 104.5 | 99.5 | 95.5 | (4.0) | (4.1) | (9.0) | (11.8) | (8.6) |
| Gross profit | 298.7 | 310.5 | 302.5 | (8.0) | (6.0) | 3.8 | (18.6) | 1.3 |
| SG&A expenses | 261.8 | 270.5 | 256.5 | (14.0) | (7.1) | (5.3) | (22.0) | (2.0) |
| SG&A expenses less R&D costs | 179.8 | 186.0 | 173.5 | (12.5) | (5.1) | (6.3) | (15.3) | (3.5) |
| R&D Costs | 82.0 | 84.5 | 83.0 | (1.5) | (2.0) | 1.0 | (6.7) | 1.2 |
| Operating income | 36.9 | 40.0 | 46.0 | 6.0 | 1.1 | 9.1 | 3.4 | 24.6 |
| Ordinary income | 35.2 | 40.0 | 44.0 | 4.0 | | 8.8 | | 24.9 |
| Extraordinary income (loss) | 4.3 | 2.5 | (3.0) | (5.5) | | (7.3) | | |
| Net income attributable to owners of the parent | 24.7 | 25.0 | 25.0 | – | | 0.3 | | 1.2 |
| E B I T D A | 55.8 | 61.0 | 63.0 | 2.0 | | 7.2 | | 12.9 |

FX rates:
FY2015 Result : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Previous Forecast : 1US$ = ¥ 110.0, 1RMB = ¥17.0
FY2016 Revised Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0

# Segment Information

Billions of yen

| | | Pharmaceuticals Business | | | | | Other Business | Total |
|---|---|---|---|---|---|---|---|---|
| | | Japan | North America | China | Other Regions | Subtotal | | |
| FY2016 Revised Forecasts | Net sales (Sales to customers) | 139.0 | 188.0 | 16.8 | 10.8 | 354.6 | 43.4 | 398.0 |
| | Cost of sales | 46.0 | 6.5 | 3.1 | 5.1 | 60.7 | 34.8 | 95.5 |
| | Gross profit | 93.0 | 181.5 | 13.7 | 5.7 | 293.9 | 8.6 | 302.5 |
| | SG&A expenses less R&D costs | 57.5 | 98.6 | 7.7 | 3.1 | 166.9 | 6.6 | 173.5 |
| | Income (loss) of Segment | 35.5 | 82.9 | 6.0 | 2.6 | 127.0 | 2.0 | 129.0 |
| | R&D costs | | | | | 82.0 | 1.0 | 83.0 |
| | Operating income | | | | | 45.0 | 1.0 | 46.0 |
| FY2016 Forecasts on May 11 | Net sales (Sales to customers) | 137.6 | 200.7 | 16.0 | 11.8 | 366.1 | 43.9 | 410.0 |
| | Cost of sales | 45.4 | 11.0 | 2.8 | 5.0 | 64.2 | 35.3 | 99.5 |
| | Gross profit | 92.2 | 189.7 | 13.2 | 6.8 | 301.9 | 8.6 | 310.5 |
| | SG&A expenses less R&D costs | 57.8 | 110.0 | 8.1 | 3.5 | 179.4 | 6.6 | 186.0 |
| | Income (loss) of Segment | 34.4 | 79.7 | 5.1 | 3.3 | 122.5 | 2.0 | 124.5 |
| | R&D costs | | | | | 83.5 | 1.0 | 84.5 |
| | Operating income | | | | | 39.0 | 1.0 | 40.0 |
| Change | Net sales (Sales to customers) | 1.4 | (12.7) | 0.8 | (1.0) | (11.5) | (0.5) | (12.0) |
| | SG&A expenses less R&D costs | (0.3) | (11.4) | (0.4) | (0.4) | (12.5) | – | (12.5) |
| | Income (loss) of Segment | 1.1 | 3.2 | 0.9 | (0.7) | 4.5 | – | 4.5 |
| | R&D costs | | | | | (1.5) | – | (1.5) |
| | Operating income | | | | | 6.0 | – | 6.0 |

FX rates:
FY2016 Previous Forecast : 1US$ = ¥ 110.0, 1RMB = ¥17.0
FY2016 Revised Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0

# To strengthen robust revenue base

# Strengthen robust revenue base in Japan

## Maximize value of strategic products and new products

- Strengthen sales structure to enable response to local healthcare, and concentrate marketing resources on strategic products and new products to quickly maximize product value
- Dosing period limitation for Trulicity® lifted on September 1, 2016

## Achieve optimal number of personnel; early retirement program offered from September to October 2016

- Number of applications received: 295

## Schedule change for the production sites integration

- Integration of Ibaraki Plant functions into Suzuka Plant, schedule for which changed to be completed by the end of FY2018 (No change for Ehime Plant closure in FY2018)

## Establish a subsidiary for promotion of Authorized Generics (AG) (Commence business in December 2016)

- Main Products: AG which it plans to deal in and METGLUCO®

  (Work together with Sumitomo Dainippon Pharma to promote proper usage of the products)
- Sales force: approx. 40

# Strengthen robust revenue base in the U.S. (Psychiatry & Neurology Area)

## Sunovion acquired Cynapsus in October 2016

### Acquisition of APL-130277

- ✓ **High Unmet Needs : OFF episodes associated with Parkinson's disease**
- ✓ **Phase 3 Stage : Plan to submit NDA in 1H FY2017 in the U.S.**
  (Fast Track Designation granted)
- ✓ **Expected Peak Sales : About 50 billion yen**

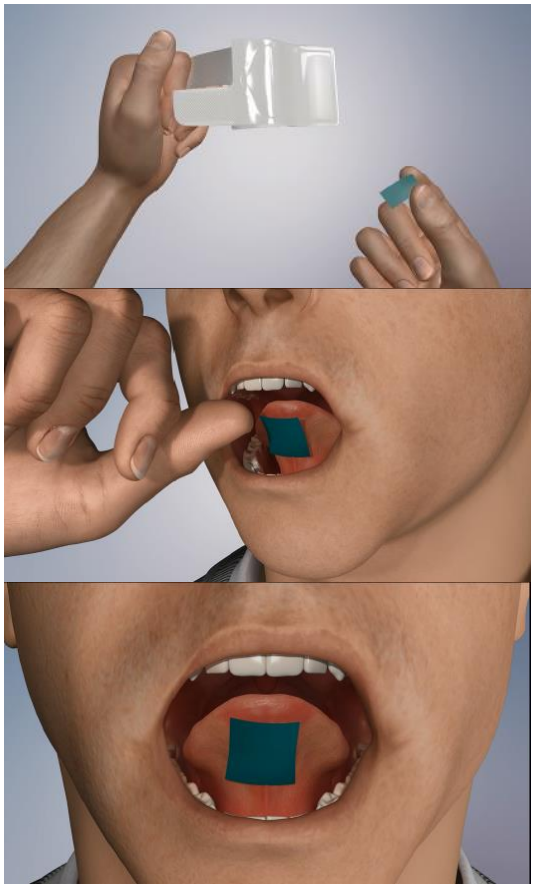
- **Outline of the acquisition**
  - ✓ Sunovion acquired all shares and warrants by cash in accordance with plan of arrangement under Canadian law

- **Financial Impact**
  - ✓ The total value for the acquisition is approximately US$ 635 million.
  - ✓ Valuations and accounting procedures outline will be disclosed at 3Q financial briefing

# Outline of APL-130277

- **Profile of APL-130277**
  - ✓ Including apomorphine* as API

    *Apomorphine (dopamine agonist) is the only molecule approved for acute intermittent treatment of OFF episodes associated with Parkinson's disease, as a subcutaneous injection in the U.S.
  - ✓ Conveniently administered sublingual film
  - ✓ Rapid onset to effect
  - ✓ Bi-layer thin film (unique formulation technology)



- **Development stage: Phase 3 in the U.S.**
  - ✓ Cynapsus successfully completed a Phase 2 study
  - ✓ Phase 3 studies expected to complete in FY2016
  - ✓ NDA submission expected in 1H FY2017 in the U.S.

- **Sales structure**
  - ✓ Leverage Sunovion's sales infrastructure
  - ✓ Synergy with APTIOM® in the U.S.
  - ✓ Considering expansion in Europe and in Japan

# Strengthen robust revenue base in the U.S. (Respiratory Area)

## NDA Submission of SUN-101 in July 2016

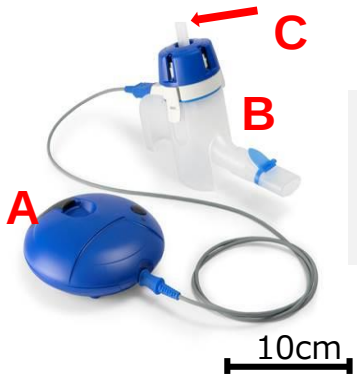
- **Indication:** Long-term, maintenance treatment of airflow obstruction in patients with Chronic Obstructive Pulmonary Disease (COPD)

- **Features:**
  - ✓ SUN-101 will be the first nebulizer delivered LAMA for COPD in the U.S.
  - ✓ This nebulizer system is portable and provides delivery of medication in approx. two to three minutes.
- **The expected action date by the FDA is May 29, 2017**

- **Sales structure:**
  - ✓ Leverage Sunovion's sales infrastruct
  - ✓ Synergy with BROVANA®

- **Expected Peak Sales:**
  About 50 billion yen

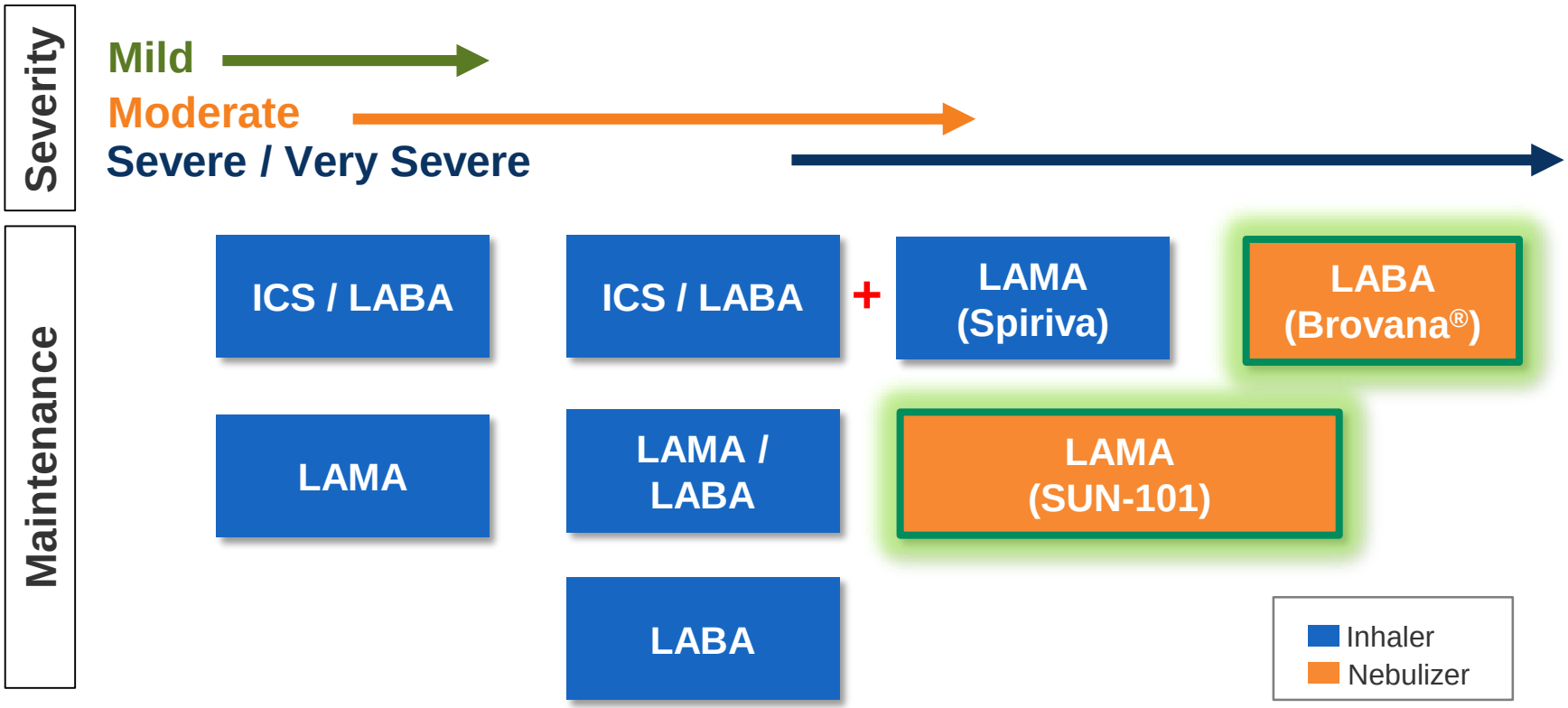
**Investigational eFlow® nebulizer system**
**portable, hand-held**




**A: Controller**
**B: Handset**
**(includes aerosol head)**
**C: Drug**

# Respiratory products portfolio in the U.S.

## Treatment of moderate-to-very severe COPD




LAMA: Long-acting muscarinic antagonist
LABA: Long-acting beta-agonists
ICS: Inhaled corticosteroid

: Sunovion products and development products

* Patients with increasing severity are often treated with both a LAMA and a LABA

Brovana® & SUN-101 could be used as a combination therapy.

# Clinical Development Status

# Clinical Development Status (Major Changes since July 27, 2016)

**Glycopyrronium (SUN-101)**

- ✓ NDA filed in the U.S. in July 2016

**Apomorphine (APL-130277)**

- ✓ Newly added in Phase 3 through the acquisition of Cynapsus by Sunovion in October 2016

**Napabucasin (BBI608)**

- ✓ Started global Phase 3 study for Colorectal cancer (combination therapy with FOLFIRI, or FOLFIRI and bevacizumab) in Japan

**SEP-363856**

- ✓ Started Phase 2 study for Schizophrenia in the U.S.
- ✓ Started Phase 2 study for Parkinson's disease psychosis in the U.S.

**DSP-7888**

- ✓ Started Phase 2 of Phase 1 / 2 study for Pediatric malignant gliomas in Japan

**Thiotepa (DSP-1958)**

- ✓ Drug for which pharmaceutical companies were recruited to develop new use of unapproved or off-labeled drugs
- ✓ Started Phase 1 study for Conditioning treatment prior to hematopoietic cell transplantation (HPCT) in Japan

# Dasotraline Pediatric ADHD Top Line Results

- **Study design**
  - ✓ Phase 2 / 3 study, six-week, randomized, double-blind, multi-center, placebo-controlled, parallel-group, children ages 6 to 12 years with ADHD
  - ✓ Enrolled patients: 342

    (dasotraline 2mg/day 111, dasotraline 4mg/day 115, Placebo 116)
  - ✓ Primary endpoint: Change from baseline at Week 6 in ADHD symptoms as measured by ADHD RS IV HV score

- **Study Results**
  - ✓ Efficacy: The 4mg/day dose arm demonstrated a statistically significant and clinically relevant difference compared to placebo.
  - ✓ Safety: Dasotraline was generally well tolerated.

- **Future Plan (Adult and Pediatric ADHD)**
  - ✓ Phase 3 studies to complete in FY2016
  - ✓ NDA submission is planned in FY2017

# Napabucasin Clinical Development Status

- **Change of timeline for NDA submission**
  - ✓ Timeline for NDA submission changed from FY2017 to FY2018 in consideration of the enrollment progress of BRIGHTER study

- **Outline of CCTG's presentation for CO.23 study at ESMO 2016**

∗CO.23 study: A phase 3 study on CRC, closed to accrual and protocol treatment stopped in May, 2014

  - ✓ No significant difference in OS between napabucasin and placebo in the ITT analysis
  - ✓ Napabucasin significantly improved OS in patients with high p-STAT3 expression

| Subset | Median OS (mos) | | HR[95%CI], p value |
|---|---|---|---|
| | Placebo | Napabucasin | |
| ITT | | | |
| All Pts (n=282) | 4.8 | 4.4 | 1.13 [0.88 – 1.46], p=0.34 |
| p-STAT3 + (n=55) | 3.0 | 5.1 | 0.24 [0.12 – 0.51], p=0.0002 |
| p-STAT3 - (n=196) | 4.9 | 4.0 | 1.44 [1.06 – 1.95], p=0.02 |
| Pre-defined Minimum Effective Treatment | | | |
| All Pts (n=128) | 5.8 | 6.6 | 0.88 [0.61 – 1.28], p=0.50 |
| p-STAT3 + (n=25) | 4.0 | 9.0 | 0.28 [0.11 – 0.69], p=0.0057 |
| p-STAT3 - (n=88) | 6.4 | 6.4 | 1.27 [0.80 – 2.01], p=0.32 |

# Target submission date of key late-stage pipeline

(Updated October 2016)

| Area | Development | Submission target | | | |
|---|---|---|---|---|---|
| | | FY2016 | FY2017 | FY2018 | FY2019 or later |
| Respiratory | **SUN-101 <glycopyrronium>** (Chronic obstructive pulmonary disease) U.S. | July 2016 Submitted | | | |
| Psychiatry & Neurology | **SEP-225289 <dasotraline>** (Adult , Pediatric ADHD) U.S. | | ● | | |
| | **APL-130277 <apomorphine >** (Parkinson's disease) U.S. | | ● | | |
| | **TRERIEF® <zonisamide>** (Parkinsonism in Dementia with Lewy Bodies) Japan | | ● | | |
| | **SEP-225289 <dasotraline>** (BED) U.S. | | | ● | |
| | **LONASEN® <blonanserin>** (Schizophrenia / Transdermal patch) Japan | | | ● | |
| | **SM-13496 <lurasidone >** (Schizophrenia / Bipolar I depression / Bipolar maintenance) Japan | | | | ● |
| Oncology | **BBI608 <napabucasin>** (Gastric and Gastro-esophageal junction adenocarcinoma / Combination therapy) U.S./ Japan | | | ● | |
| | **BBI608 <napabucasin>** (Colorectal cancer / Combination therapy) U.S./ Japan | | | | ● |
| | **BBI608 <napabucasin>** (NSCLC /Combination therapy) U.S. | | | | ● |

New Chemical Entities | New Indication, etc.

# Appendices

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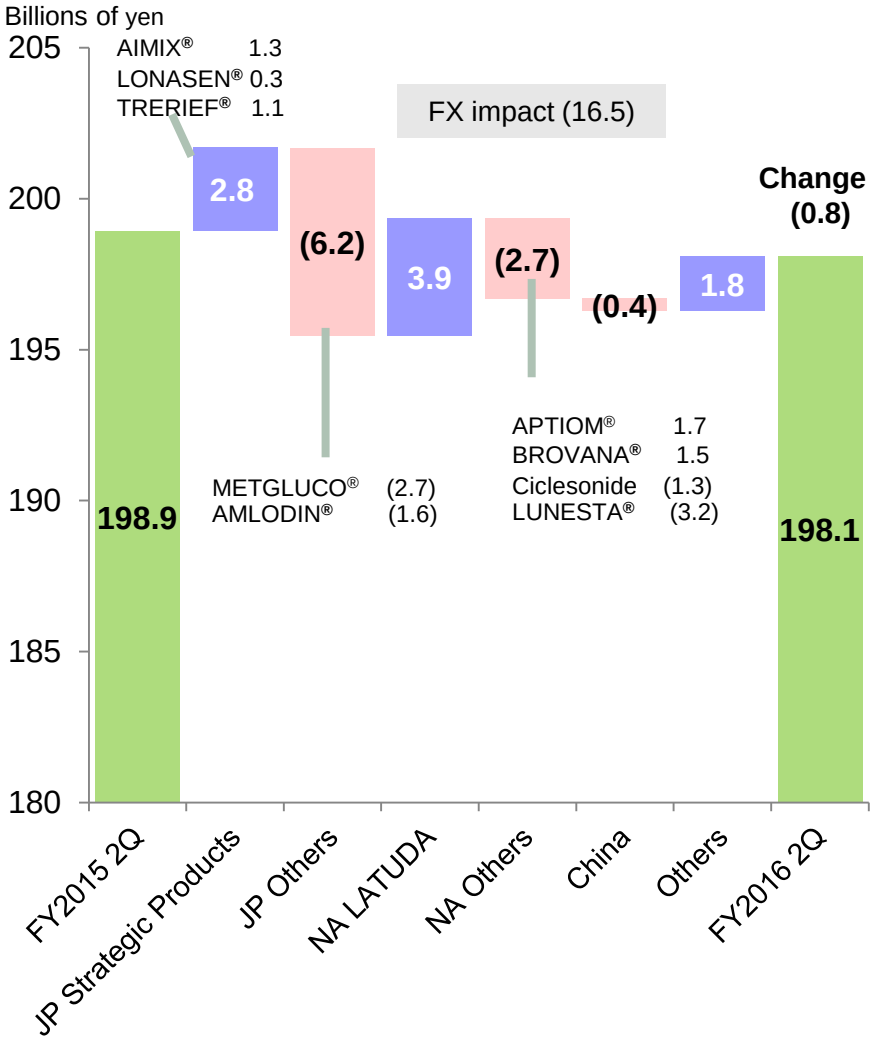
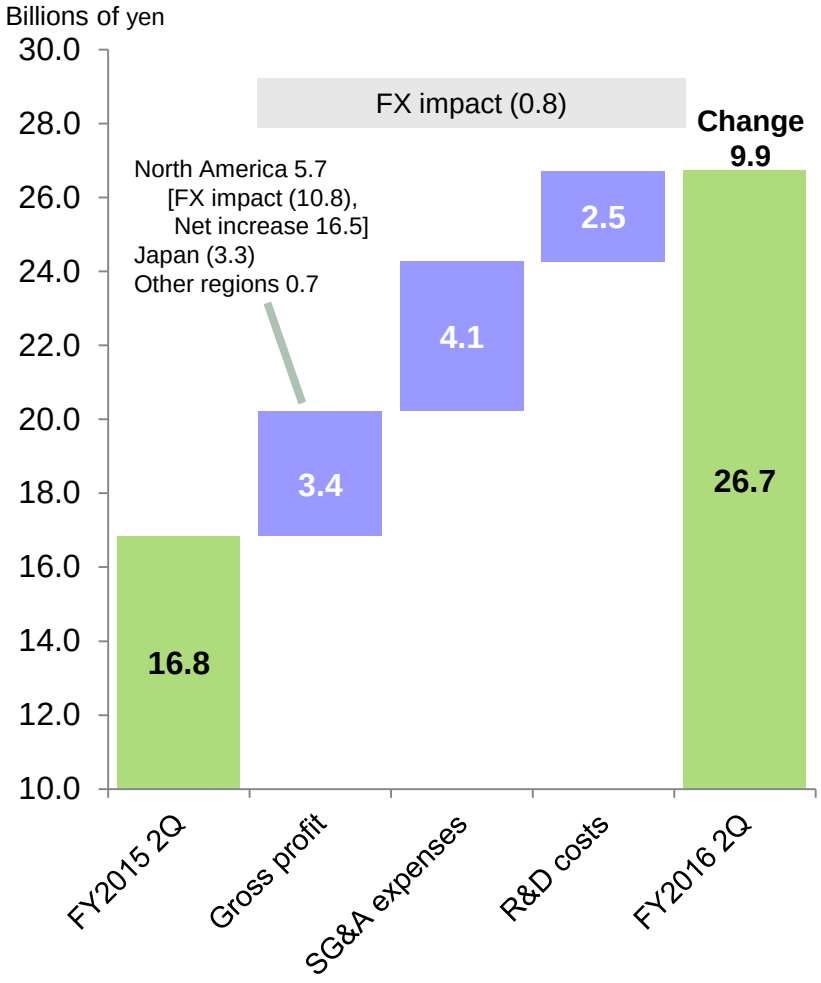
# Changes from FY2015 2Q

## Sales




## Operating Income




FX rates:
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# Net Sales by Segment

Billions of yen


**Changes (0.8) (0.4) %**
**Achievement 99.5 %**

Japan ・Changes (3.5) (4.7) %
- NHI drug price revision Approx.(3.9)
  Decrease in long-listed products sales

・Achievement 103.0 %

North America
・Changes +1.2 +1.3 %
- Growth of LATUDA®, APTIOM® and BROVANA® offset impact of yen appreciation

・Achievement 97.0 %

China ・Changes (0.4) (4.1) %
- Slight decrease due to FX impact despite MEROPEN® increase

・Achievement 110.5 %

Other Regions
・Changes +0.6 +13.4 %
- Increase in MEROPEN® export

・Achievement 76.5 %

Other Business
・Changes +1.2 +5.8 %
・Achievement 103.0 %

FX rates:
FY2015 2Q : 1US$ = ¥ 121.9, 1RMB = ¥19.5
FY2016 2Q : 1US$ = ¥ 105.2, 1RMB = ¥15.9

# Financial Position / Cash Flows

Billions of yen

| B/S | As of March 31, 2016 | As of Sep. 30, 2016 | Change |
|---|---|---|---|
| Assets | 707.7 | 641.2 | (66.6) |
| Current assets | 421.6 | 384.3 | (37.2) |
| Fixed assets | 286.1 | 256.8 | (29.3) |
| Liabilities | 261.2 | 222.3 | (38.9) |
| Current liabilities | 179.7 | 159.7 | (20.0) |
| Long-term liabilities | 81.5 | 62.6 | (18.9) |
| Net assets | 446.5 | 418.8 | (27.6) |
| Shareholders' equity ratio | 63.1% | 65.3% | |

**【Assets】**

| | |
|---|---|
| Cash and time deposits | 42.5 |
| Marketable securities | (37.7) |
| Short-term loans receivable | (35.3) |
| Intangible assets | (19.5) |

**【Liabilities】**

| | |
|---|---|
| Income taxes payable | (15.6) |
| Total interest-bearing debt | (23.0) |
| Long-term ⇒Short-term | 8.0 |
| Balance | 28.0 |

| C/F | FY2015 2Q | FY2016 2Q | Change |
|---|---|---|---|
| Operating CF | 14.3 | 13.5 | (0.8) |
| Investment CF | 28.2 | 31.6 | 3.4 |
| Financial CF | (8.3) | (26.5) | (18.3) |
| Effect of exchange rate changes | (0.8) | (13.7) | (12.9) |
| Cash / Cash equivalents | 154.5 | 140.4 | (14.1) |
| Operating funds | 197.6 | 153.9 | (43.7) |

**(Reference)**

Balance as of end of FY2015

| | |
|---|---|
| Cash / CE | 135.6 |
| Operating funds | 184.4 |

# Sales of Major Products in Japan

Billions of yen

| | FY2015 | FY2016 Forecasts on May 11 | FY2016 Revised Forecasts | Change from Forecasts on May 11 |
|---|---|---|---|---|
| AIMIX® | 14.9 | 16.1 | 16.1 | – |
| LONASEN® | 12.6 | 13.8 | 13.8 | – |
| TRERIEF® | 13.1 | 14.5 | 14.5 | – |
| Strategic Products Total | 40.7 | 44.4 | 44.4 | – |
| REPLAGAL® | 10.2 | 10.5 | 10.5 | – |
| AmBisome® | 4.3 | 4.3 | 4.3 | – |
| AVAPRO® | 10.8 | 9.3 | 10.0 | 0.7 |
| SUREPOST® | 3.6 | 4.6 | 4.6 | – |
| METGLUCO® | 14.7 | 9.8 | 10.8 | 1.0 |
| AMLODIN® | 16.4 | 12.2 | 12.2 | – |
| PRORENAL® | 8.7 | 7.0 | 7.0 | – |
| GASMOTIN® | 8.4 | 6.0 | 6.0 | – |
| MEROPEN® | 6.2 | 4.5 | 4.5 | – |
| Others | 22.4 | 25.0 | 24.7 | (0.3) |
| Other Products Total | 105.8 | 93.2 | 94.6 | 1.4 |
| **Japan Total** | 146.5 | 137.6 | 139.0 | 1.4 |

Note: Sales of each product above are shown by invoice price sales basis.

# Sales of Major Products in North America & China

| | FY2015 | FY2016 Forecasts on May 11 | FY2016 Revised Forecasts | Change from Forecasts on May 11 | FY2015 | FY2016 Forecasts on May 11 | FY2016 Revised Forecasts | Change from Forecasts on May 11 |
|---|---|---|---|---|---|---|---|---|
| **North America** | Million $ | | | | Billion yen | | | |
| LATUDA® | 1,002 | 1,152 | 1,210 | 58 | 120.4 | 126.7 | 127.1 | 0.4 |
| APTIOM® | 64 | 124 | 117 | (7) | 7.6 | 13.7 | 12.3 | (1.4) |
| BROVANA® | 249 | 286 | 286 | – | 29.9 | 31.5 | 30.0 | (1.5) |
| Ciclesonide | 58 | 55 | 49 | (6) | 7.0 | 6.1 | 5.1 | (1.0) |
| XOPENEX® | 56 | 43 | 52 | 9 | 6.7 | 4.7 | 5.5 | 0.8 |
| LUNESTA® | 38 | 26 | 7 | (19) | 4.6 | 2.9 | 0.7 | (2.2) |
| Others | 72 | 139 | 69 | (70) | 8.7 | 15.1 | 7.3 | (7.8) |
| Total | 1,539 | 1,825 | 1,790 | (35) | 184.9 | 200.7 | 188.0 | (12.7) |
| **China** | Million RMB | | | | Billion yen | | | |
| MEROPEN® | 826 | 805 | 902 | 97 | 15.6 | 13.7 | 14.4 | 0.7 |
| Others | 148 | 138 | 148 | 10 | 2.8 | 2.3 | 2.4 | 0.1 |
| Total | 974 | 943 | 1,050 | 107 | 18.4 | 16.0 | 16.8 | 0.8 |

FX rates:
FY2015 Results : 1US$ = ¥ 120.2, 1RMB = ¥18.9
FY2016 Previous Forecast : 1US$ = ¥ 110.0, 1RMB = ¥17.0
FY2016 Revised Forecast : 1US$ = ¥ 105.0, 1RMB = ¥16.0

## Appendix (Clinical Development Status)

# Development Pipeline (1) (Psychiatry & Neurology Area)

**(as of October 27, 2016)**

Revisions since the previous announcement are in red.

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase 1 | Phase 2 | Phase 3 | Submitted |
|---|---|---|---|---|---|---|---|
| APTIOM® | eslicarbazepine acetate | (New indication) Epilepsy- Monotherapy | Canada | | | | |
| LONASEN® | blonanserin | Schizophrenia | China | | | | |
| | | (Addition of pediatric usage) Schizophrenia | Japan | | | | |
| | | (New formulation: Transdermal patch) Schizophrenia | Japan | | | | |
| LATUDA® （SM-13496） | lurasidone hydrochloride | Schizophrenia | China | | | | |
| | | Schizophrenia | Japan | | | | |
| | | Bipolar I depression, Bipolar maintenance | Japan | | | | |
| EPI-743 | vatiquinone | Leigh syndrome | Japan | | | | ※1 |
| SEP-225289 | dasotraline | Adult attention-deficit hyperactivity disorder (ADHD) | U.S. | | | | |
| | | Pediatric attention-deficit hyperactivity disorder (ADHD) | U.S. | | | | ※2 |
| | | Binge eating disorder (BED) | U.S. | | | | ※2 |
| APL-130277 | apomorphine hydrochloride | OFF episodes associated with Parkinson's disease | U.S. | | | | |
| TRERIEF® | zonisamide | (New indication) Parkinsonism in Dementia with Lewy Bodies (DLB) | Japan | | | | |
| EPI-589 | TBD | Parkinson's disease | U.S. | | | | |
| | | Amyotrophic lateral sclerosis (ALS) | U.S. | | | | |
| SEP-363856 | TBD | Schizophrenia | U.S. | | | | |
| | | Parkinson's disease psychosis | U.S. | | | | |
| | | Schizophrenia | Japan | | | | |
| DSP-2230 | TBD | Neuropathic pain | U.K. / U.S. / Japan | | | | |
| DSP-3748 | TBD | Cognitive Impairment Associated with Schizophrenia | U.S. | | | | |
| DSP-1200 | TBD | Treatment-resistant depression | U.S. | | | | |

※1／A Phase 2 / 3 study completed, development strategy under consideration　※2／Phase 2 / 3 study

# Development Pipeline (2) (Oncology Area) (as of October 27, 2016)

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase 1 | Phase 2 | Phase 3 | Submitted |
|---|---|---|---|---|---|---|---|
| BBI608 | napabucasin | Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) (Global clinical study) | U.S. / Canada / Japan, etc. | | | | |
| | | Colorectal cancer (Combination therapy) (Global clinical study) | U.S. / Japan | | | | |
| | | Non-small cell lung cancer (Combination therapy) (Global clinical study) | U.S. | | | | |
| | | Colorectal cancer (Combination therapy) | U.S. / Canada | | | ※1 | |
| | | Solid tumors (Ovarian cancer, Breast cancer, Melanoma, etc.) (Combination therapy) | U.S. / Canada | | | | |
| | | Malignant pleural mesothelioma (Combination therapy) | Japan | | | ※1 | |
| | | Solid tumors (Combination therapy) ※3 Hematologic malignancies (Monotherapy / Combination therapy) | U.S. / Canada | | | | |
| | | Solid tumors (Combination therapy) ※4 | Japan | | | | |
| BBI503 | amcasertib | Solid tumors (Colorectal cancer, Head and Neck cancer, Ovarian cancer, etc.) (Monotherapy) | U.S. / Canada | | | ※1 | |
| | | Solid tumors (Renal cell carcinoma, Urothelial carcinoma, Hepatocellular carcinoma, Cholangiocarcinoma, etc.) (Monotherapy) | Canada | | | | |
| | | Ovarian Cancer (Monotherapy) | U.S. | | | | |
| | | Hepatocellular carcinoma (Combination therapy) | U.S | | ※2 | | |
| | | Solid tumors (Combination therapy) | U.S. / Canada | | | | |
| | | Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy) | Japan | | | | |
| BBI608 + BBI503 | napabucasin amcasertib | Solid tumors (Combination therapy) | U.S. | | | | |

※1／Phase 2 of Phase 1 / 2 study　※2／Phase 1 of Phase 1 / 2 study
※3／Multiple studies for different tumor types (Gastrointestinal cancer , Hepatocellular carcinoma, Glioblastoma, Pancreatic cancer)
※4／Multiple studies for different tumor types (Hepatocellular carcinoma)

# Development Pipeline (3) (Oncology & Others Area)

(as of October 27, 2016)

## Oncology Area (Excluding napabucasin, amcasertib)

Revisions since the previous announcement are in red.

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase 1 | Phase 2 | Phase 3 | Submitted |
|---|---|---|---|---|---|---|---|
| DSP-7888 | TBD | Myelodysplastic syndromes | Japan | | | ※1 | |
| | | Pediatric malignant gliomas | Japan | | | ※1 | |
| | | Solid tumors, Hematologic malignancies | U.S. | | | | |
| WT4869 | TBD | Myelodysplastic syndromes | Japan | | ※2 | | |
| | | Solid tumors | Japan | | | | |
| WT2725 | TBD | Solid tumors, Hematologic malignancies | U.S. | | | | |
| | | Solid tumors | Japan | | | | |
| DSP-1958 ※3 | Thiotepa | Conditioning treatment prior to hematopoietic cell transplantation (HPCT) | Japan | | | | |

※1／Phase 2 of Phase 1 / 2 study　※2／Phase 1 of Phase 1 / 2 study　※3／Development for the use of unapproved or off-labeled drugs

## Respiratory Area

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase 1 | Phase 2 | Phase 3 | Submitted |
|---|---|---|---|---|---|---|---|
| SUN-101 | glycopyrronium bromide | Chronic obstructive pulmonary disease (COPD) | U.S. | | | | |

## Other Areas

| Brand name/ Product code | Generic name | Proposed indication | Development location | Phase 1 | Phase 2 | Phase 3 | Submitted |
|---|---|---|---|---|---|---|---|
| DSP-1747 | obeticholic acid | Nonalcoholic steatohepatitis (NASH) | Japan | | | | |
| DSP-6952 | TBD | IBS with constipation, Chronic idiopathic constipation | Japan | | | | |

## Appendix (Clinical Development Status)

# Napabucasin – Clinical development progress

**(as of October 27, 2016)**

Sumitomo Dainippon Pharma

Revisions since the previous announcement are in red.

| Development stage | Development location | Proposed indication | Combination products | Study number | Start date |
|---|---|---|---|---|---|
| Phase 3 | U.S. / Canada / Japan, etc. | Gastric and Gastro-esophageal junction adenocarcinoma (Combination therapy) | paclitaxel | BRIGHTER (BBI608-336) | Aug. 2014 |
| | U.S. / Japan | Colorectal cancer (Combination therapy) | FOLFIRI, FOLFIRI + bevacizumab | CanStem303C (BB608-303CRC) | June 2016 |
| | U.S. | Non-small cell lung cancer (Combination therapy) | paclitaxel | CanStem43L | Oct. 2016 |
| Phase 2 | U.S. / Canada | Colorectal cancer (Combination therapy) | cetuximab, panitumumab, capecitabine | BBI608-224 | Mar. 2012 |
| | U.S. / Canada | Solid tumors*1 (Combination therapy) | paclitaxel | BBI608-201 | Apr. 2011 |
| | Japan | Malignant pleural mesothelioma (Combination therapy) | cisplatin + pemetrexed | D8807005 | Feb. 2015 |
| Phase 1 | U.S. / Canada | Gastrointestinal cancer (Combination therapy) | FOLFOX, FOLFOX + bevacizumab, CAPOX, FOLFIRI, FOLFIRI + bevacizumab, regorafenib, irinotecan | BBI608-246 | Jan. 2014 |
| | U.S. | Hepatocellular carcinoma (Combination therapy) | sorafenib | BBIHCC-103 | Dec. 2014 |
| | U.S. | Pancreatic cancer (Combination therapy) | gemcitabine + nab-paclitaxel, FOLFIRINOX, irinotecan liposome injection + fluorouracil + leucovorin | BBI608-118 | Aug. 2014 |
| | Canada | Glioblastoma (Combination therapy) | temozolomide | BBI608-251 | Mar. 2015 |
| | U.S. | Hematologic Malignancies (Monotherapy / Combination therapy) | dexamethasone, bortezomib, imatinib, ibrutinib | BBI608-103HEME | May 2015 |
| | Japan | Hepatocellular carcinoma (Combination therapy) | sorafenib | D8808001 | Feb. 2015 |
| | U.S. | Solid tumors (Combination therapy) | iplimumab, pembrolizumab, nivolumab | BBI608-201CIT | Aug. 2015 |

*1／Ovarian cancer, Breast cancer, Melanoma, etc.

Start date is based on Clinical Trials.gov (as of October 26, 2016)

# Amcasertib, Napabucasin– Clinical development progress

(as of October 27, 2016)

Revisions since the previous announcement are in red.

## Amcasertib

| Development stage | Development location | Proposed indication | Combination products | Study number | Start date |
|---|---|---|---|---|---|
| Phase 2 | U.S. / Canada | Solid tumors*1 (Monotherapy) | – | BBI503-101 | Feb. 2012 |
| | Canada | Renal cell carcinoma, Urothelial carcinoma (Monotherapy) | – | BBI503-205a | Jan. 2017 |
| | Canada | Hepatocellular carcinoma, Cholangiocarcinoma (Monotherapy) | – | BBI503-205b | Feb. 2015 |
| | Canada | Gastrointestinal stromal tumor (Monotherapy) | – | BBI503-205c | Jan. 2017 |
| | U.S. | Ovarian cancer (Monotherapy) | – | BBI503-205GYN-M | June 2015 |
| Phase 1 | U.S. | Hepatocellular carcinoma (Combination therapy) | sorafenib | BBIHCC-103 | Dec. 2014 |
| | Japan | Solid tumors (Monotherapy), Hepatocellular carcinoma (Combination therapy) | sorafenib | DA101003 | Mar. 2015 |
| | U.S. / Canada | Solid tumors (Combination therapy) | capecitabine, doxorubicin, nivolumab, pembrolizumab, paclitaxel, sunitinib | BBI503-201 | Sep. 2015 |

*1／Colorectal cancer, Head and neck cancer, Ovarian cancer, etc.

## Napabucasin + Amcasertib

| Development stage | Development location | Proposed indication | Combination products | Study number | Start date |
|---|---|---|---|---|---|
| Phase 1 | U.S. | Solid tumors (Combination therapy) | – | BBI401-101 | Apr. 2015 |

Start date is based on Clinical Trials.gov (as of October 26, 2016)

# LATUDA® (lurasidone) – Clinical development progress

Revisions since the previous announcement are in red.

## Japan / China (In-house)

| Indication, Proposed indication | Development location | Development status | Submission plan |
|---|---|---|---|
| Schizophrenia | China | Submitted | — |
| Schizophrenia | Japan | Phase 3 | FY2019 |
| Bipolar I depression , Bipolar maintenance | | Phase 3 | FY2019 |

## Europe (In-house)

- The license agreement with Takeda for the joint development and exclusive commercialization in Europe was terminated on January 31st, 2016
- The Marketing Authorization (MA) for LATUDA® in EU and Switzerland was transferred to Sunovion Pharmaceuticals Europe Ltd. (SPE) in February 2016.
  - ✓ SPE started commercializing LATUDA® in May 2016 in the countries where the product has already been launched.
  - ✓ For other countries, we will continuously seek a licensing partner.

  (Reference)

  MA Submitted in: Turkey

  Approved in: Russia

  Launched in: UK, Switzerland, Denmark, Norway, the Netherlands, Finland, and Sweden

## Asia, South America, etc. (Partnering)

- MA Submitted in: Thailand, Hong Kong, Singapore, Venezuela, Brazil
- Approved in: Singapore (DKSH is preparing for the launch.)
- Launched in: Australia (commercialization partnership with Servier Australia),
  Taiwan (commercialization partnership with Standard Chem. & Pharm.)

# Product Launch Plan (Updated October 2016)

Sumitomo Dainippon Pharma

| Area | FY2017 | FY2018 | FY2019 | FY2020 - FY2022 | |
|---|---|---|---|---|---|
| Japan | | TRERIEF® (Parkinsonism in Dementia with Lewy Bodies ) | LONASEN® (Schizophrenia / Transdermal patch) | lurasidone (Schizophrenia / Bipolar I depression / Bipolar maintenance) | obeticholic acid (NASH) |
| | | thiotepa (Conditioning treatment prior to HPCT) | napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma) | napabucasin (Colorectal cancer, etc.) | DSP-6952 (IBS with constipation, Chronic idiopathic constipation) |
| | | | | amcasertib (Solid tumors) | iPS cell-derived RPE cells (Age-related macular degeneration) |
| | | | | DSP-7888 (Solid tumors/ Hematologic cancer) | |
| U.S. | glycopyrronium (COPD) | dasotraline (ADHD) | dasotraline (BED) | SB623 (Chronic stroke) | napabucasin (Colorectal cancer, Pancreatic cancer, NSCLC) |
| | | apomorphine (Parkinson's disease) | napabucasin (Gastric and Gastro-esophageal junction adenocarcinoma) | DSP-2230 (Neuropathic pain) | amcasertib (Solid tumors) |
| | | | | SEP-363856 (Schizophrenia) | DSP-7888 (Solid tumors/ Hematologic cancer) |
| China | LONASEN® (Schizophrenia) | lurasidone (Schizophrenia) | | | |

／Psychiatry & Neurology ／Oncology ／Liver / Digestive ／Respiratory

New Chemical Entities | New Indication , etc.

# Regenerative Medicine / Cell Therapy Business Plan (Updated July 2016)

| | Partnering | Region (planned) | Cell type | Schedule for practical use (Calendar year) 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|---|
| Chronic Stroke | **SanBio** | North America | Allo MSC | **Phase 2b** | | **Phase 3** | | **Approval Target** |
| AMD (age-related macular degeneration) | **Healios RIKEN** | Japan | Allo iPS cell | **Clinical research** | ※ **Investigator or corporate initiated clinical study** | | | **Approval Target** |
| Parkinson's disease | **Kyoto Univ CiRA** | Global | Allo iPS cell | **Clinical research or clinical study** | | | | |
| Retinitis pigmentosa | **RIKEN** | Global | Allo iPS cell | | | **Investigator initiated clinical study** | | |
| Spinal Cord Injury | **Keio Univ Osaka National Hospital** | Global | Allo iPS cell | | | **Clinical research** | | |

※Start of clinical studies originally scheduled in 2017 may be delayed due to changes in non-clinical study plans.

# 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.

Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice.

Sumitomo Dainippon Pharma

Innovation today, healthier tomorrows