

# Financial Results for FY2008 (ended March 31, 2009)

May 12, 2009
Masayo Tada
President and CEO
Dainippon Sumitomo Pharma Co., Ltd.



## Financial Results for FY2008



## Summary of Financial Results for FY2008

- 1. Profit target achieved.
- Net sales remained steady due to launch of new products in spite of NHI price revision and decreased sales of AMLODIN<sup>®</sup>.
- Clinical development of lurasidon successfully in progress.
- 4. Operating income decreased due to rise in cost of sales ratio and increase in R&D costs.



### **Financial Results**

Billions of Yen

|                  | EV0007 | E\/0000 | C     | hange      | Ганадаа  | Difference |
|------------------|--------|---------|-------|------------|----------|------------|
|                  | FY2007 | FY2008  | Value | Percentage | Forecast | Difference |
| Net sales        | 264.0  | 264.0   | 0.0   | 0.0 %      | 266.0    | - 2.0      |
| Operating income | 39.8   | 31.2    | - 8.6 | - 21.7 %   | 30.5     | 0.7        |
| Ordinary income  | 37.7   | 31.4    | - 6.3 | - 16.6 %   | 30.5     | 0.9        |
| Net income       | 25.6   | 20.0    | - 5.6 | - 21.9 %   | 18.5     | 1.5        |

Note: All values are rounded to the nearest 100 million yen.



## Increase and Decrease Factors of Net Sales

#### Billions of Yen

|           | FY2007 | FY2008 | Ch    | ange       |  |
|-----------|--------|--------|-------|------------|--|
|           | F12007 | F12006 | Value | Percentage |  |
| Net sales | 264.0  | 264.0  | 0.0   | 0.0 %      |  |

#### (Positives)

- Sales of new products (LONASEN® / AVAPRO®)
- Start of new contract manufacturing

#### (Negatives)

- •NHI price revision
- Decreased sales of AMLODIN®



### Sales of Pharmaceutical Products

Billions of yen

|                            | FY2007 FY2008 |          | Cha   | nge        |
|----------------------------|---------------|----------|-------|------------|
|                            | F 1 2007      | F 1 2008 | Value | Percentage |
| AMLODIN <sup>®</sup>       | 63.6          | 57.9     | - 5.7 | - 9.0 %    |
| GASMOTIN®                  | 19.5          | 20.2     | 0.7   | 3.4 %      |
| PRORENAL®                  | 14.5          | 14.8     | 0.3   | 2.1 %      |
| MEROPEN®                   | 14.8          | 14.8     | 0.0   | 0.1 %      |
| 4 Strategic Products Total | 112.4         | 107.7    | - 4.8 | - 4.2 %    |
| LONASEN®                   |               | 3.4      | 3.4   |            |
| AVAPRO®                    |               | 1.5      | 1.5   |            |
| TRERIEF®                   |               | 0.1      | 0.1   |            |
| New Products Total         | 1             | 5.0      | 5.0   |            |
| EBASTEL®                   | 11.1          | 10.6     | - 0.5 | - 4.1 %    |
| SUMIFERON®                 | 6.0           | 6.0      | - 0.0 | - 0.7 %    |
| AmBisome®                  | 2.5           | 3.1      | 0.5   | 20.0 %     |
| Other Products             | 52.4          | 52.7     | 0.3   | 0.5 %      |
| Domestic Sales Total       | 184.5         | 185.0    | 0.5   | 0.3 %      |
| Overseas Sales Total       | 24.1          | 21.8     | - 2.3 | - 9.6 %    |
| Pharmaceuticals Total      | 208.7         | 206.8    | - 1.8 | - 0.9 %    |



# Cost of Sales and Selling, General & Administrative Expenses

Billions of yen

| Г |                 | FY2007 |                | FY2   | FY2008         |       | Change     |  |
|---|-----------------|--------|----------------|-------|----------------|-------|------------|--|
|   |                 |        | % of net sales |       | % of net sales | Value | Percentage |  |
| N | et sales        | 264.0  | 1              | 264.0 | l              | 0.0   | 0.0%       |  |
|   | Cost of sales   | 99.4   | 37.6%          | 103.7 | 39.3%          | 4.4   | 4.4%       |  |
| G | ross profit     | 164.6  | 62.4%          | 160.3 | 60.7%          | - 4.3 | - 2.6%     |  |
|   | SG&A expenses   | 124.8  | 47.3%          | 129.1 | 48.9%          | 4.3   | 3.5%       |  |
| l | SG&A expenses   | 77.5   | 29.4%          | 76.3  | 28.9%          | - 1.2 | - 1.6%     |  |
|   | R&D costs       | 47.3   | 17.9%          | 52.8  | 20.0%          | 5.6   | 11.7%      |  |
| 0 | perating income | 39.8   | 15.1%          | 31.2  | 11.8%          | - 8.6 | - 21.7%    |  |

Note: Cost of sales includes provision for (reversal of) reserve for sales returns.

#### (Cost of sales)

- •Rise in cost of sales ratio due to NHI price revision and the application of
- "Accounting Standard for Measurement of Inventories"

#### (SG&A expenses)

Increase in R&D costs due to overseas clinical trials of lurasidon in progress



# Non-operating Income & Expenses and Extraordinary Income & Loss

Billions of yen

|   | FY2007 | FY2008 | Change |            |
|---|--------|--------|--------|------------|
|   | F12007 | F12006 | Value  | Percentage |
| Operating income                                      | 39.8   | 31.2   | - 8.6  | - 21.7%    |
| Non-operating income and expenses                     | - 2.2  | 0.2    | 2.4    |            |
| Finance income and expenses including dividend income | 1.4    | 1.6    | 0.2    |            |
| Contribution  | - 1.8  | - 1.8  | - 0.1  |            |
| Others  | - 1.8  | 0.4    | 2.2    |            |
| Ordinary income                                       | 37.7   | 31.4   | - 6.3  | - 16.6%    |
| Extraordinary income and loss                         | 3.8    | 0.8    | - 3.0  |            |
| Reversal of reserve for loss on litigation            | _      | 1.1    | 1.1    |            |
| Gain on sales of investment securities                | 3.8    | _      | - 3.8  |            |
| Loss on valuation of investment securities            | _      | - 0.3  | - 0.3  |            |
| Income taxes and minority interests                   | - 15.9 | - 12.2 | 3.7    |            |
| Net income  | 25.6   | 20.0   | - 5.6  | - 21.9%    |



### **Financial Position**

Billions of yen

|  |                      |                      | _               |
|--|----------------------|----------------------|-----------------|
|  | As of March 31, 2008 | As of March 31, 2009 | Change          |
| ASSETS                                       | 399.8                | 391.3                | - 8.5           |
| Current assets Fixed assets                  | 251.1<br>148.7       | 263.5<br>127.8       | 12.5<br>- 21.0  |
| LIABILITIES                                  | 81.5                 | 66.8                 | - 14.7          |
| Current liabilities<br>Long-term liabilities | 67.9<br>13.6         | 53.3<br>13.4         | - 14.6<br>- 0.1 |
| NET ASSETS                                   | 318.3                | 324.5                | 6.2             |
| (shareholders' equity ratio)                 | 70.6%                | 82 0%                |                 |

(shareholders' equity ratio) 79.6% 82.9%

#### (ASSETS)

- Increase in short-term loans · · · · · · · · 10.0 billion yen
- •Decrease in investment securities (valuation adjustments, etc.) ••••• 10.4 billion yen (LIABILITIES)



### Cash Flows

Billions of yen

| I Net cash provided by operating activities                            | + 26.3          |
|--|-----------------|
| <ul> <li>Income before income taxes and minority interests</li> </ul>  | + 32.2          |
| <ul> <li>Depreciation and amortization</li> </ul>                      | + 11.5          |
| <ul> <li>Decrease in notes and accounts receivable</li> </ul>          | + 6.6           |
| <ul> <li>Increase in inventories</li> </ul>                            | - 6.0           |
| Income taxes paid  | - 18.6          |
| II Net cash used in investing activities                               | - 21.3          |
| <ul> <li>Purchases of property, plant and equipment</li> </ul>         | - 13.6          |
| Net increase in short-term loans                                       | - 10.0          |
|  |                 |
| III Net cash used in financing activities                              | - 11.8          |
| III Net cash used in financing activities  Repayment of long-term debt | - 11.8<br>- 4.6 |

Cash and cash equivalents at the end of period: 49.5 billion yen (compared with the beginning of period: - 6.8 billion yen)



## Financial Forecasts for FY2009



### Points of Forecasts for FY2009

- 1. Slight decrease in sales of pharmaceuticals according to the influence of generics
- 2. Rise in cost of sales ratio due to changes of sales structure
- 3. Development cost of lurasidone reaching its peak
- 4. Significant decrease in operating income



### Financial Forecasts for FY2009

Billions of yen

|                  | FY08    | FY09      | Ch    | ange       |
|------------------|---------|-----------|-------|------------|
|                  | Results | Forecasts | Value | Percentage |
| Net sales        | 264.0   | 264.0     | _     | _          |
| Operating income | 31.2    | 25.0      | - 6.2 | - 19.8%    |
| Ordinary income  | 31.4    | 24.0      | - 7.4 | - 23.6%    |
| Net income       | 20.0    | 15.0      | - 5.0 | - 25.0%    |

<sup>\*</sup> Sumitomo Pharmaceuticals (Suzhou) Co.,Ltd. is newly added as a consolidated subsidiary from FY09.

| R&D costs | 52.8 | 54.5 | 1.7 | 3.2% |
|-----------|------|------|-----|------|
|-----------|------|------|-----|------|



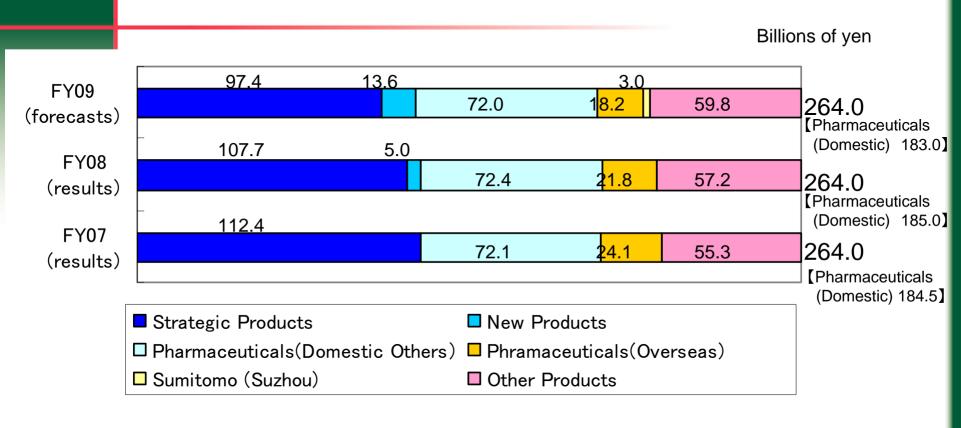
## Forecasts of Net Sales (1)

Billions of yen

|                            | FY08  | FY09  | Change |
|----------------------------|-------|-------|--------|
| AMLODIN®                   | 57.9  | 48.0  | - 9.9  |
| GASMOTIN®                  | 20.2  | 21.0  | 0.8    |
| PRORENAL®                  | 14.8  | 15.5  | 0.7    |
| MEROPEN®                   | 14.8  | 12.9  | - 1.9  |
| 4 Strategic Products Total | 107.7 | 97.4  | - 10.3 |
| LONASEN®                   | 3.4   | 6.5   | 3.1    |
| AVAPRO®                    | 1.5   | 6.0   | 4.5    |
| TRERIEF®                   | 0.1   | 1.1   | 1.0    |
| New Products Total         | 5.0   | 13.6  | 8.6    |
| EBASTEL®                   | 10.6  | 8.6   | - 2.0  |
| SUMIFERON®                 | 6.0   | 6.0   | 0.0    |
| AmBisome®                  | 3.1   | 4.3   | 1.2    |
| Other Products             | 52.7  | 53.1  | 0.4    |
| Domestic Sales Total       | 185.0 | 183.0 | - 2.0  |
| Overseas Sales Total       | 21.8  | 21.2  | - 0.6  |
| Pharmaceuticals Total      | 206.8 | 204.2 | - 2.6  |



## Forecasts of Net Sales (2)



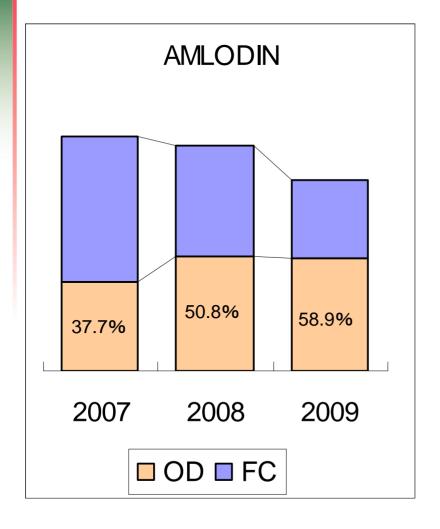
#### (Pharmaceuticals)

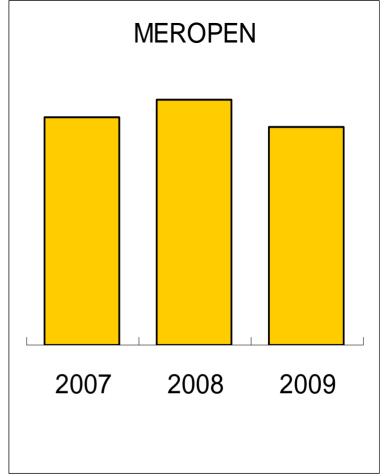
The influence of generics products is covered by increasing the sales of new products, etc.



## Forecasts of Net Sales (3)

#### Transition of Amount of AMLODIN® and MEROPEN®







# Cost of Sales and Selling, General & Administrative Expenses

Billions of yen

|    |                | FY08<br>Results |       | F     | -Y09    | Change |            |
|----|----------------|-----------------|-------|-------|---------|--------|------------|
|    |                |                 |       | Foi   | recasts | Value  | Percentage |
| Ne | t sales        | 264.0           |       | 264.0 | I       | 0.0    | 0.0%       |
| C  | Cost of sales  | 103.7           | 39.3% | 106.5 | 40.3%   | 2.8    | 2.7%       |
| G  | Gross profit   | 160.3           | 60.7% | 157.5 | 59.7%   | - 2.8  | - 1.7%     |
| S  | G&A expenses   | 129.1           | 48.9% | 132.5 | 50.2%   | 3.4    | 2.6%       |
|    | SG&A expenses  | 76.3            | 28.9% | 78.0  | 29.5%   | 1.7    | 2.2%       |
|    | R&D costs      | 52.8            | 20.0% | 54.5  | 20.6%   | 1.7    | 3.2%       |
| Op | erating income | 31.2            | 11.8% | 25.0  | 9.5%    | - 6.2  | - 19.8%    |

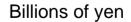
Note: Cost of sales includes provision for (reversal of) reserve for sales returns

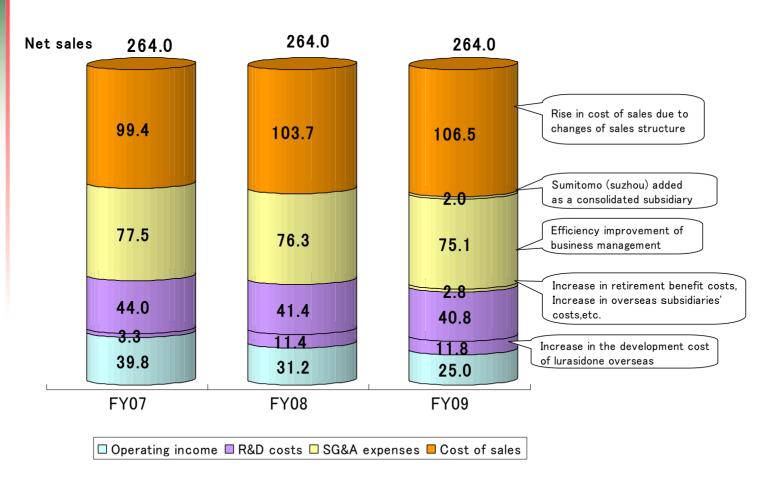
#### (Cost of sales)

- Rise in cost of sales ratio due to changes of sales structure (SG&A expenses)
- Aggressive investment on the development of lurasidone overseas
- Reduction in other costs by thorough pursuit of management efficiency improvement
- Increase in SG&A expenses by adding Sumitomo (Suzhou) as a consolidated subsidiary



### **Profit and Cost Structure**







# Financial influence by Sumitomo (Suzhou) Co.,Ltd.

#### Billions of yen

|                  | Sumitomo<br>(Suzhou) | Elimination of internal transactions | Influence on consolidation |
|------------------|----------------------|--------------------------------------|----------------------------|
| Net sales        | 5.0                  | - 2.0                                | 3.0                        |
| Cost of sales    | 1.5                  | - 1.0                                | 0.5                        |
| Gross profit     | 3.5                  | - 1.0                                | 2.5                        |
| SG&A expenses    | 2.5                  | - 0.5                                | 2.0                        |
| Operating income | 1.0                  | - 0.5                                | 0.5                        |



### Return to Shareholders

#### 1. Basic Policy

- Returning our profits adequately to our shareholders is one of our most important management policies
- Dividend amount is decided by evaluating the following factors overall;
  - The company performance should be appropriately allocated
  - Positive investment should be done for the future growth to further increase the corporate value
  - Solid business foundation and sound financial condition should be ensured

#### 2. Changes in dividends

|                           | FY07  | FY08 (planned) | FY09 (planned) |
|---------------------------|-------|----------------|----------------|
| Dividends per share (yen) | 18.00 | 18.00          | 18.00          |
| Payout ratio (%)          | 28.0  | 35.8           | 47.7           |

#### ⟨reference⟩

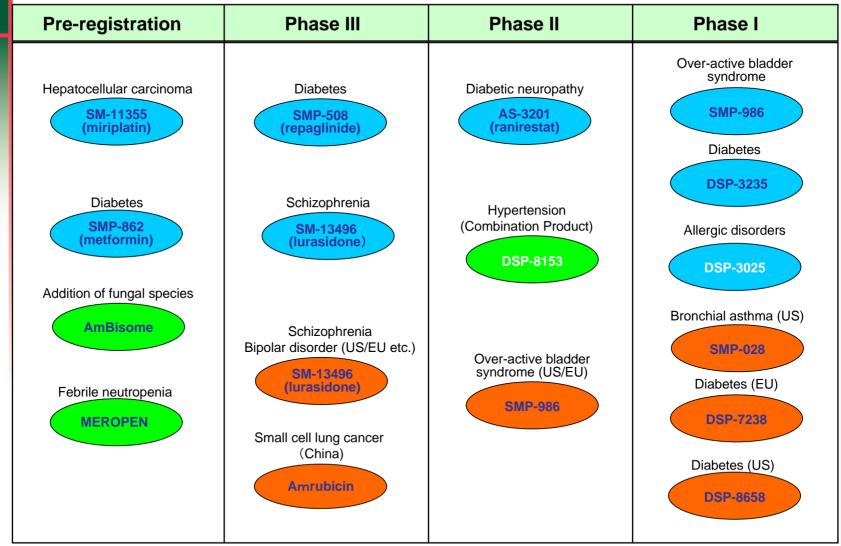
| Dividends to         | 2.2 | 2.2 | S C |
|----------------------|-----|-----|-----|
| net assets ratio (%) | 2.3 | ۷.۷ | ۷.۷ |

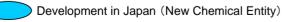


## R&D Pipeline



## Development Pipeline









## Development Pipeline Highlight

■ GASMOTIN (mosapride):

Deleted because of approval in April 2009 Indication: Adjunctive treatment to the pretreatment with orally gastrointestinal lavage solution for barium enema X-ray exam.

**DSP-8153**:

Newly added in "Phase II"

Combination Product of Amlodipine and Irbesartan

Indication: Hypertension

DSP-3025:

"Phase I" study is ongoing

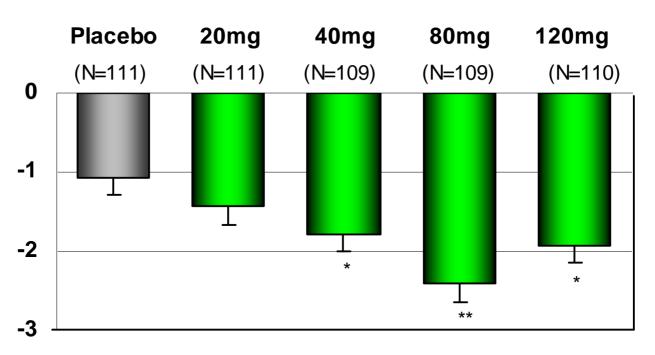
AC-3933 :

Deleted because of discontinuation



## SMP-986 Phase 2 study in US/EU Efficacy result

#### Change of voiding frequency per 24 hours



Mean change from baseline at 8 week (LOCF analysis) \*: p<0.05, \*\*: p<0.01 vs placebo



# SMP-986 Phase 2 study in US/EU Summary

#### Efficacy

The mean decreases of number of voids per 24 hours (primary efficacy endpoint) were statistically significantly decreased in SMP-986 40 mg, 80 mg and 120 mg.

#### Safety

Although there was a relationship between SMP-986 dose levels and incidence of anti-muscarinic related adverse events, there was no other concern for adverse events. SMP-986 was generally well tolerated.



## Basic policy in and after FY2009



## Progress in Business Goals Pursued in the Mid-term Business Plan

#### Billions of Yen

|                  | FY2009                                  |                        |        |
|------------------|---|------------------------|--------|
|                  | Business<br>goals<br>(Mid-term<br>Plan) | Forecasts<br>2009.5.11 | Change |
| Net sales        | 295.0                                   | 264.0                  | - 31.0 |
| Pharmaceuticals  | 233.0                                   | 204.2                  | - 28.8 |
| Operating income | 50.0                                    | 25.0                   | - 25.0 |
| Net income       | 30.0                                    | 15.0                   | - 15.0 |

| R&D costs | 55.0 | 54.5 | - 0.5 |
|-----------|------|------|-------|
|           |      |      |       |

#### About the variance in sales

 Large deviations from the target of four strategic products

| Amlodin  | ¥58.0billion | ¥48.0billion |
|----------|--------------|--------------|
| Gasmotin | 28.0billion  | 21.0billion  |
| Prorenal | 18.0billion  | 15.5billion  |
| Meropen  | 16.0billion  | 12.9billion  |
| Total    | 120.0billion | 97.4billion  |
|          |              |              |

(-¥226billion)

- Factor in the deviations
- Understanding of the market of each product and market transition
- Evaluation of the sales force



## Basic Strategies of the Mid-term Business Plan

Strengthen our business foundation for the first step to become a global corporation

- 1. Strengthening our domestic business foundation
- 2. Strengthening our R&D organization for strong flow of the pipeline products
- 3. Preparing international operation structure
- 4. Strengthening strategic partnership
- 5. Striving for efficient management and for efficient and profitable corporate structure
- 6. Establishment of "DSP Management"



### Actions continuing after FY2010

- Strengthening our domestic business foundation
- Striving for efficient management and for efficient and profitable corporate structure
- Preparing international operation structure



- Strengthening our domestic business foundation
- <Strengthening in sales & marketing>
  - Organizational reform of Sales & Marketing Division
  - Introduction of regional profit and loss management system
  - Further advancement in quality and quantity of detailing
- <Strengthening in product>
  - Maximization of values of four strategic products
  - Focused sales & marketing on new product, and accelerated launch of development pipeline
  - Accelerated in-licensing of products under late-stage development



- Striving for efficient management and for efficient and profitable corporate structure
  - Efficient R&D spending based on prioritization
  - Promotion of operation streamlining project in indirect sections
  - Reduction in total cost



- Preparing international operation structure
  - Establishment of US sales organization for lurasidone, possible partnership in US, etc.
  - Pursuing further business development in US following lurasidone
  - Strengthening of business in China
  - Other territories



### Clinical Development of Lurasidone

#### Global studies (ongoing)

- Schizophrenia
  - Phase 3 Placebo-Controlled Clinical Trial (PEARL 1)
    - > Screening started on October 25, 2007.
    - > Recruitment of patients completed as scheduled
  - Phase 3 Placebo- and Active Comparator- Controlled Clinical Trial (PEARL 2)
    - ➤ Screening started on January 31, 2008, dosing underway
  - Long-term Safety Study (PEARL Safety)
    - ➤ Screening started on March 17, 2008, dosing underway
  - Phase 3 Placebo- and Active Comparator- Controlled Clinical Trial (PEARL 3)
    - ➤ IND Amendment submitted to FDA on October 15, 2008.
    - ➤ Screening started on October 27, 2008, dosing underway



### Clinical Development of Lurasidone

#### Global studies (ongoing)

- Bipolar Disorder (Phase 3 studies)
  - IND submitted to FDA on December 17, 2008.
  - Screening started in April, 2009

#### Development for Japanese NDA submission (Pan-Asia study)

- IND for Phase 3 Study (against schizophrenia) in Japan, Taiwan and South Korea
- Dosing underway in Japan, Taiwan and South Korea
- Protocol Synopsis
  - Comparator: Placebo (Reference: risperidone)
  - Target Number of Enrolled Patients: 440
  - Primary Endpoints: PANSS



## Lurasidone Schedule (2009)

- PEARL 1 Trial Results
  - Presentation at APA: 20 May, 2009
  - Analyst Meeting in Tokyo: mid in June, 2009
- PEARL 2 Trial Results: to be received in autumn, 2009
- PREVAIL Trial: Dosing to be started in 1Q, FY2009



## 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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