

*Progressing Towards an Internationally Competitive  
R&D-Oriented Pharmaceutical Company*

## **Dainippon Sumitomo Pharma**

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# 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.

# Company Profile

- **Created from merger of Dainippon Pharmaceutical and Sumitomo Pharmaceuticals in Oct. 2005**
- **FY2010 revenue (forecast) of US\$4 billion\***
- **Pharmaceutical revenue accounts for approx. 90%**
- **No. of employees: 7,513 (consolidated, as of Sep 30, 2010)**
- **Leverage CNS experience globally**
- **Traded in Tokyo and Osaka Stock Exchange**
- **Headquartered in Osaka, Japan**
- **Major Subsidiaries in U.S. (Sunovion) and China**



(\*Exchange rate in this presentation assumed as: 1US\$=¥90)  
FY2010 is a year ending March 31, 2011

# Our Key Strategic Priorities

(Mid-term Business Plan – FY2010 to 2014)

*Expand U.S. business through Sunovion*

*Transform earning structure of Commercial Operations in Japan*

*Expand new product pipeline*



***To become an internationally competitive  
R&D-oriented pharmaceutical company***

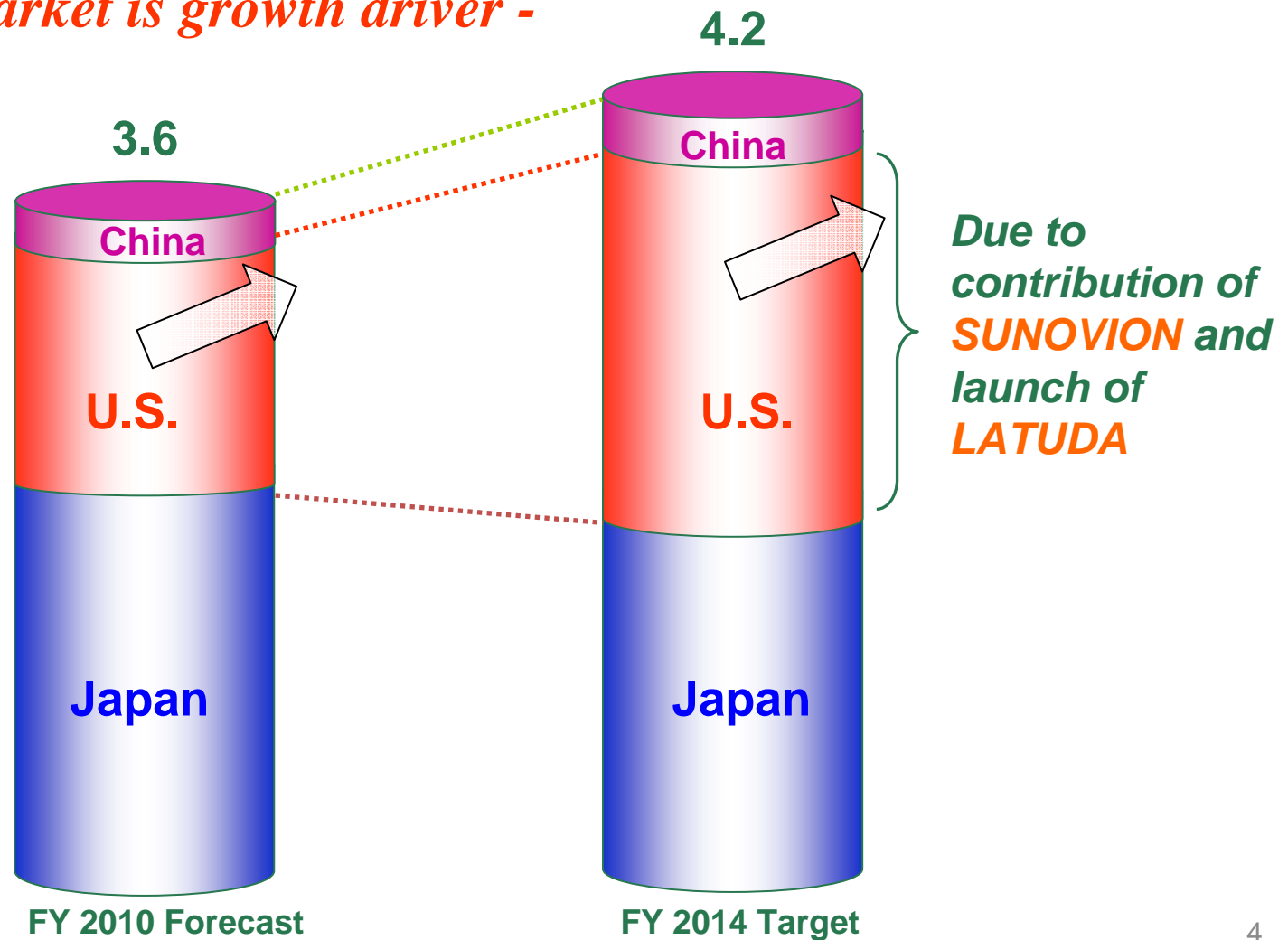
# 1. U.S. Business

*Expand U.S. business through Sunovion*

*- U.S. market is growth driver -*

Sales in  
Pharmaceutical sector

(in Billion US\$)

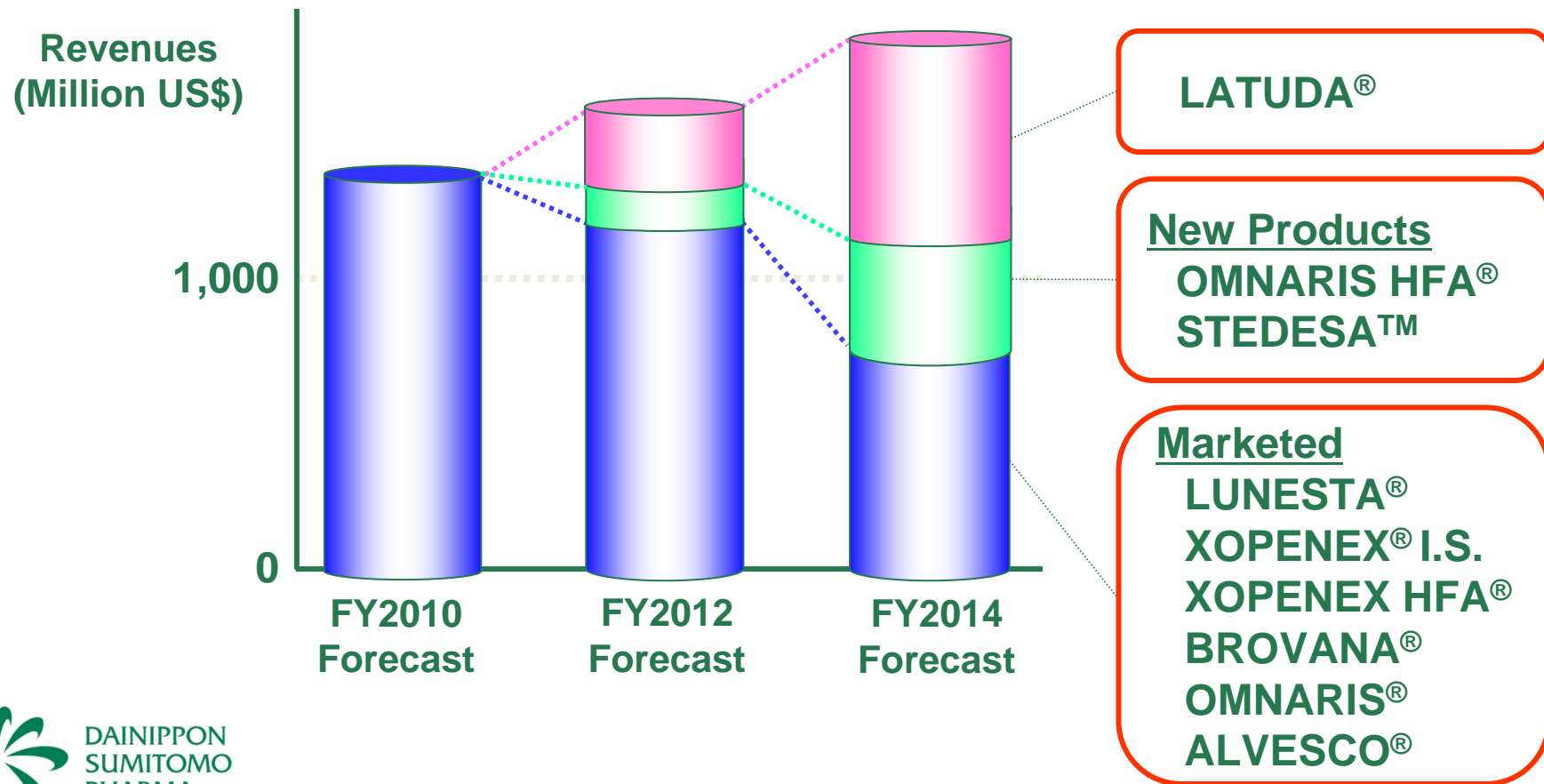


# 1-1. Sunovion Pharmaceuticals Inc.

- **DSP acquired Sunovion (formerly Sepracor Inc.) in Oct. 2009**
  - Name change to Sunovion Pharmaceuticals in Oct. 2010
- **Profile of Sunovion:**
  - Focus in CNS and respiratory disease areas
  - 6 currently marketed products
- **Key priorities**
  - Strengthen franchises in the CNS and respiratory areas
  - Successfully launch new products: LATUDA<sup>®</sup> (lurasidone), OMNARIS<sup>®</sup> (ciclesonide) HFA, STEDESA<sup>™</sup> (eslicarbazepine acetate)
  - Maintain strong financial performance

# 1-2. Sunovion's Mid-term Revenue Forecast

*(Latuda is an engine for growth)*



# 1-3. LATUDA<sup>®</sup> (lurasidone HCl) Tablets – Overview

*(Growth Driver in U.S.)*

- **Regulatory Timeline:**
  - October 28, 2010 – First Cycle FDA Approval; 10 month review
- **Indication:**
  - Treatment of patients with schizophrenia
- **Dosage and Administration:**
  - The recommended starting dose is 40 mg once daily with food
  - The maximum recommended dose is 80 mg/day.
- **Contraindications / Warnings**
  - Not approved for the treatment of people with dementia-related psychosis
  - Metabolic section includes data up to 52 weeks for glucose, lipids and weight (including olanzapine)
  - Prolactin data includes data up to 52 weeks
- **Efficacy Data for 4 Studies Included in Label**
  - Phase 2 Study (006): Lurasidone at 40 and 120 mg/d
  - Phase 2 Study (196): Lurasidone at 80 mg/d
  - PEARL 1 (229): Lurasidone at 80 mg/d
  - PEARL 2 (231): Lurasidone at 40 and 120 mg/d and olanzapine





# 1-4. PEARL Studies: Program to Evaluate the Antipsychotic Response to Lurasidone

## PEARL 1 and 2 Results

(Double-blind, placebo-controlled, 6-week trials with an acute exacerbation of schizophrenia )

### PEARL 1

- 80 mg/d dose significantly separated from placebo on PANSS total and CGI-S

### PEARL 2

- 40 and 120 mg/d dose groups significantly separated from placebo on PANSS total and CGI-S
- Active Comparator: olanzapine

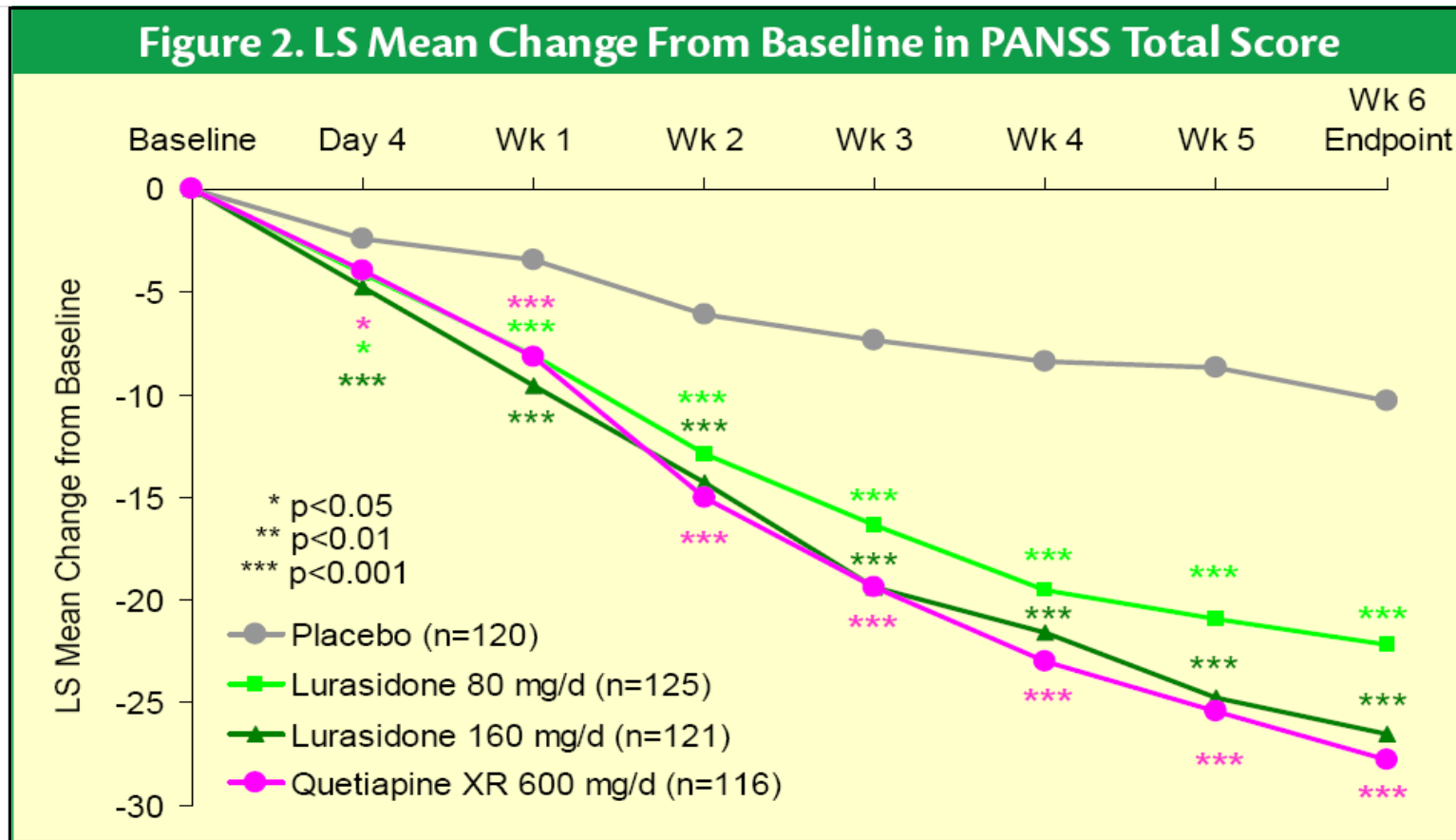
### Summary of results

- 40, 80, 120 mg given once daily demonstrated efficacy versus placebo
- LATUDA was well-tolerated and associated with limited weight gain or changes in metabolic parameters.
- Most common adverse events were: somnolence, akathisia, nausea, parkinsonism, and agitation

# 1-5. PEARL 3 Results

## Third Study in PEARL Clinical Program

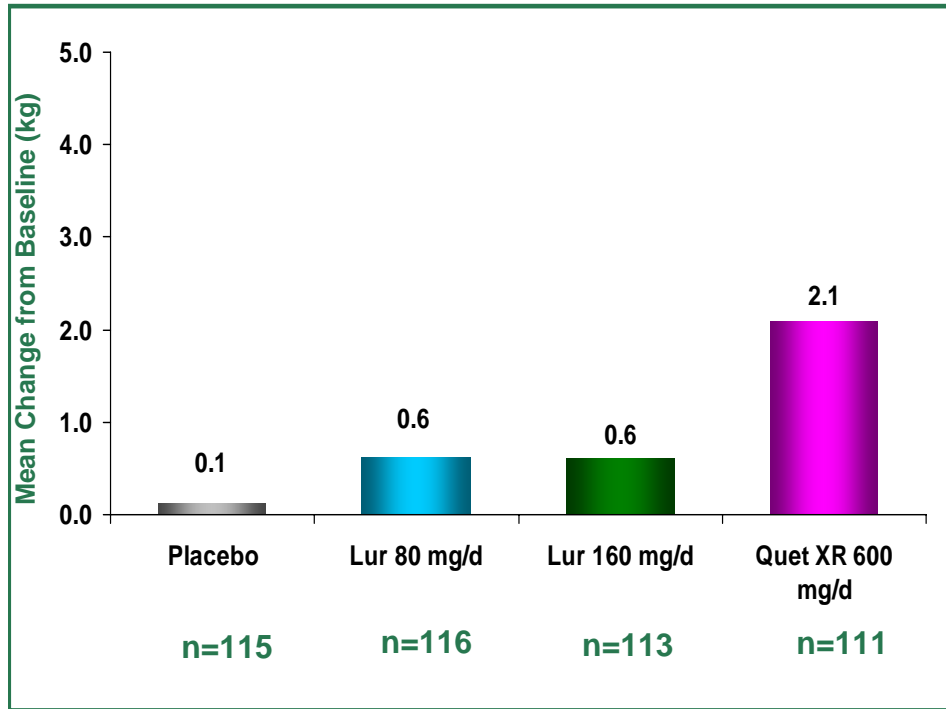
- 6-week, placebo-controlled study
- Two fixed-doses of lurasidone: 80 and 160 mg/day
- Active comparator: quetiapine XR – 600 mg/day



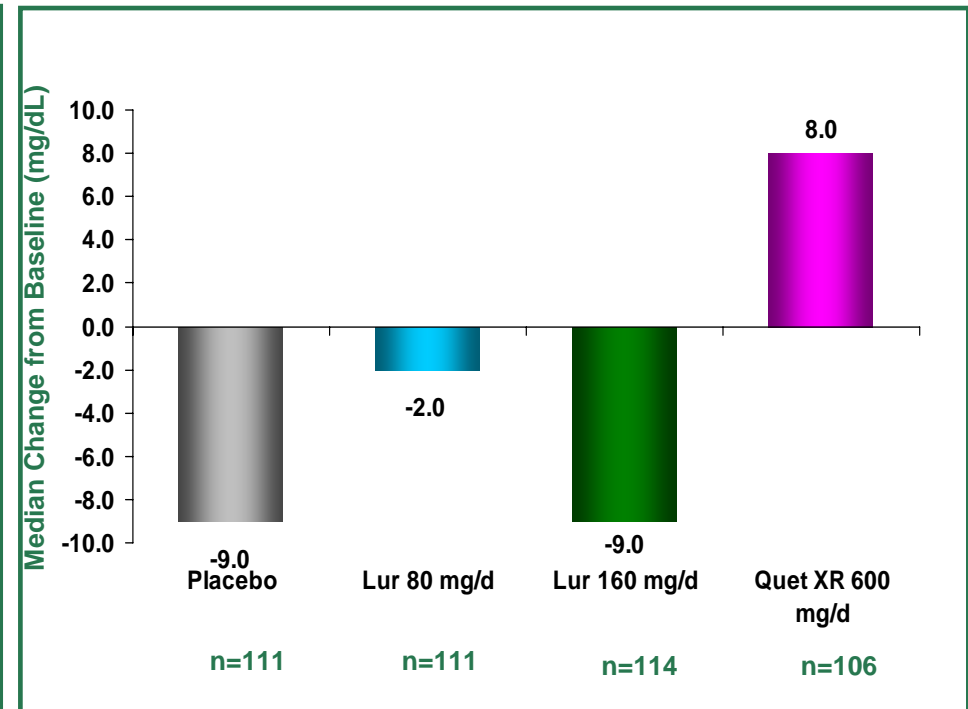
Note: The data for 160 mg/day dose of lurasidone has not been submitted at this point in time.

# 1-6. PEARL 3 Metabolic Results

## PEARL 3: Weight Change (LOCF)



## PEARL 3: Triglycerides



- Lurasidone 160 mg/day dose has not been submitted at this point in time.
- The use of quetiapine XR in the study was for the purpose of establishing assay sensitivity.

# 1-7. Latuda Ongoing Studies/Post-Marketing Commitments in Schizophrenia

## Ongoing

- **Switch Study in Schizophrenia**

- Initiated in Q3 2010

## Post Marketing Commitments

- **Schizophrenia Maintenance Study**

- Planned Start Q3 2011

- **Low-dose Schizophrenia Study with 20 mg/d**

- Planned Start Q2 2012

- **Pediatric (13 – 17 yrs) PK Study**

- Planned Start Q3 2011

- **Pediatric (13 – 17 yrs) Efficacy Study**

- Planned Start Q2 2012

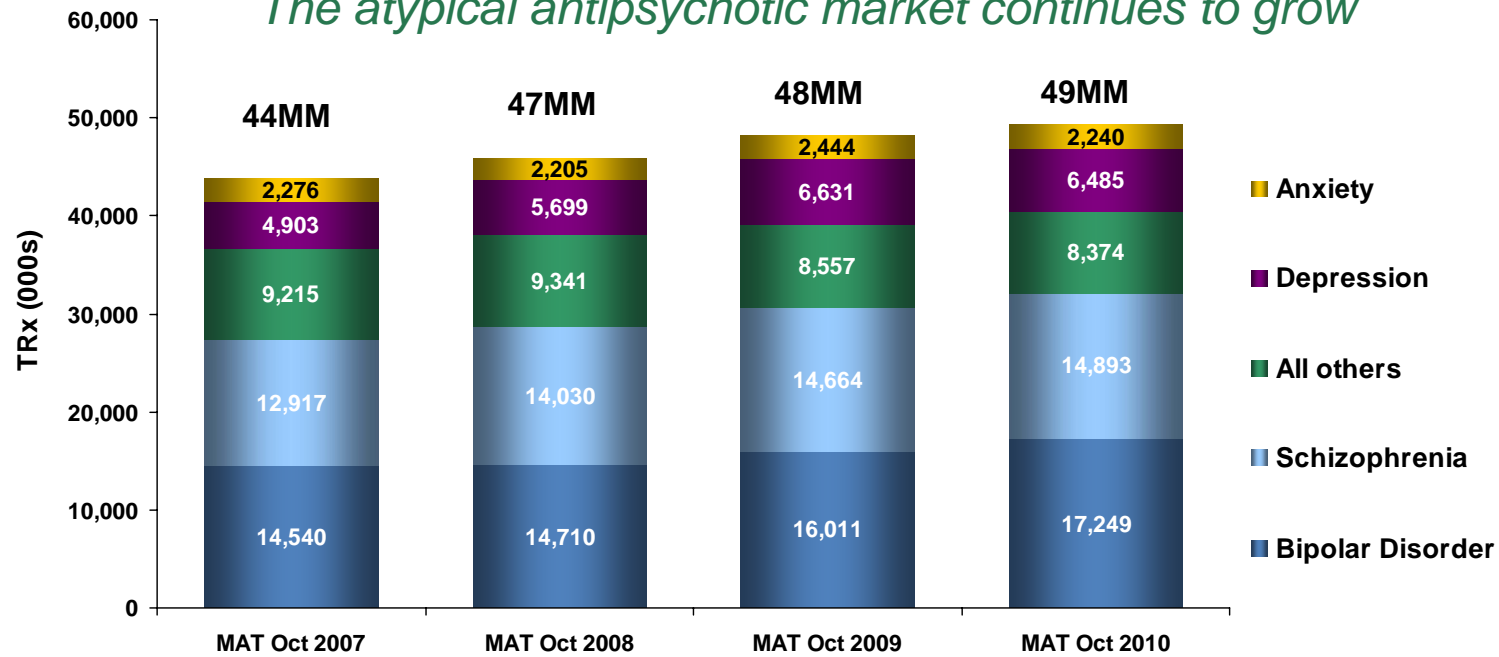
## 1-8. Bipolar Depression Development Plan: PREVAIL Studies

- PREVAIL: PRogram to Evaluate Antidepressant Impact of Lurasidone
- Ongoing global clinical trials for lurasidone in Bipolar Depression will evaluate effectiveness of lurasidone as:
  - Monotherapy
  - Adjunct therapy
  - Maintenance therapy
- Lower, flexible dose range of lurasidone – 20 to 120 mg/day
- Short-term 6 weeks and 24 weeks in an open-label extension
- sNDA planned for 1H/2012

Study Detail	Timing
PREVAIL 1 - Add-on Therapy Added to treatment with lithium or Divalproex	Initiated in April 2009. Estimated completion: Q4 2011
PREVAIL 2 - Monotherapy	Initiated in April 2009. Estimated completion: Q4 2011
PREVAIL 3 - Add-on Therapy Added to treatment with lithium or Divalproex	Initiated in December 2010
PREVAIL Extension	PREVAIL 1, 2, 3 trial participants to enter into 24 week open-label extension
PREVAIL Maintenance Add-on Therapy	To be initiated in Q2 2011

# 1-9. Market Overview

*The atypical antipsychotic market continues to grow*



Source: IMS NPA Data, and SDI PDDA

## Unmet Needs

### Schizophrenia

- 74% of patients discontinue treatment within 18 months due to lack of efficacy or intolerable side effects, CATIE schizophrenia study
- Better efficacy with balance of side effect burden (cardiometabolic)
- Need for new treatment option

## Unmet Needs

### Bipolar Disorder

- More uniformly effective for depressed phase - only one atypical currently approved for bipolar depression
- Fewer side effects (cardiometabolic)
- Drugs that work alone to treat all stages
- 50% remain undiagnosed, untreated

# 1-10. Latuda Commercialization Plan

- Expected Launch: February 2011
- Field Force Resources: 300 Sales Professionals
- WAC Price: US\$14.00
- Key Marketing Strategic Imperatives for Launch
  - Focus on psychiatrists treating schizophrenia
  - Expedite Managed Care acceptance
  - Maintain competitive share of voice across multiple channels
- Continue development plan for additional indications

## 2. Domestic Business in Japan

### Overview

- Approx. 1400\* sales professionals
- FY2010 revenue (forecast) of approx. US\$2 billion
- 3 Core therapeutic areas

<b>CNS</b>	<ul style="list-style-type: none"><li>• Strong expertise in both R&amp;D and commercialization</li><li>• Many in-house assets in Schizophrenia &amp; epilepsy</li><li>• 200 CNS - specialty sales professionals</li></ul>
<b>Cardiovasculars &amp; Diabetes</b>	<ul style="list-style-type: none"><li>• Cardiovascular - Strong franchise in hypertension</li><li>• Diabetes – Strong franchise for type II diabetes</li></ul>
<b>Cancer &amp; Infectious Diseases</b>	<ul style="list-style-type: none"><li>• Solid presence in serious infections and systemic fungal infections</li><li>• Focused activities in research in oncology</li></ul>

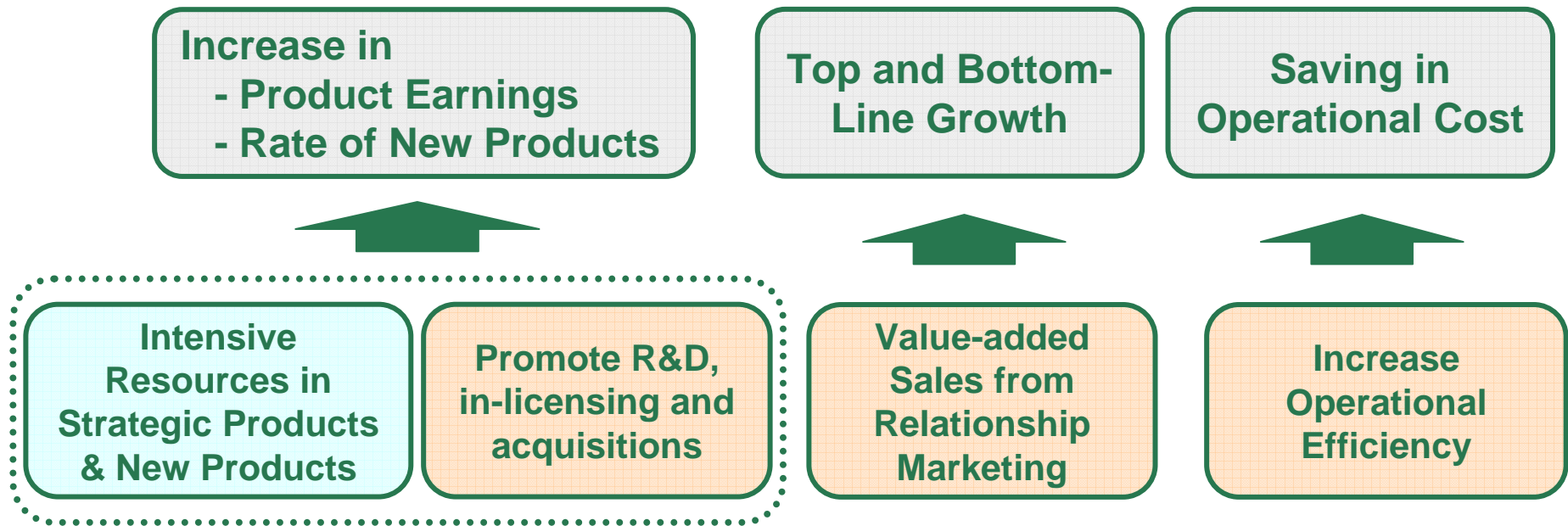
### Industry Landscape & Our Challenges

- Solid market growth is no longer expected
- Facing challenges – NHI Price Cut, Genericization, etc



# 2-1. Initiatives taken in Japan operations

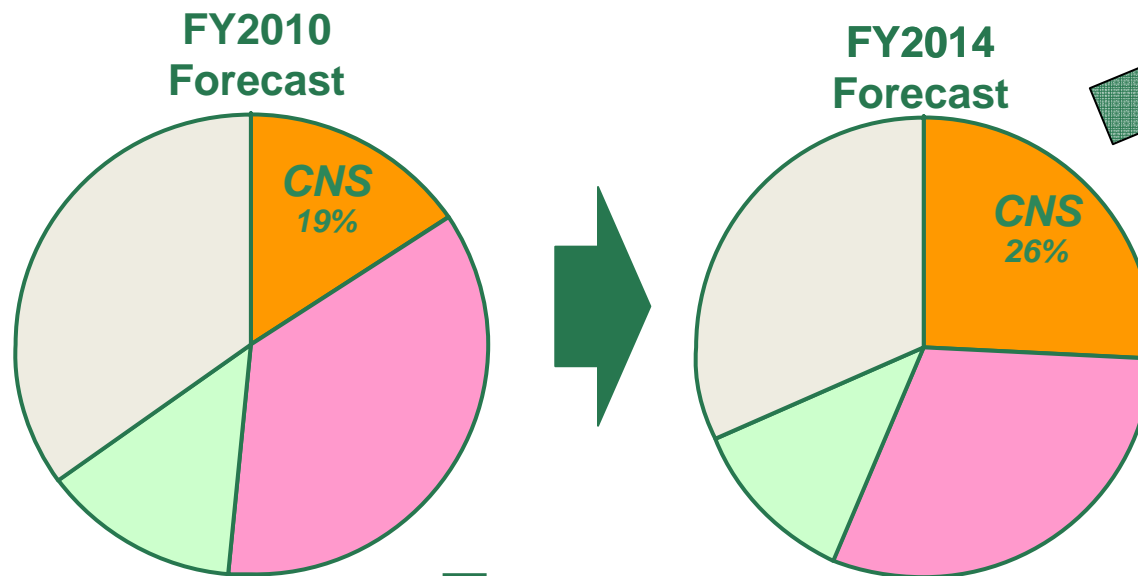
*Strategic Priority: Transform earning structure of Commercial Operations in Japan*



## 2-2. Increasing Earnings from CNS

- Sales of Lonasen<sup>®</sup> (blonanserin), our new in-house antipsychotic agent, is expected to grow
- CNS revenue in 2014 up by 30% from FY2010 forecast

### Shifting more to CNS



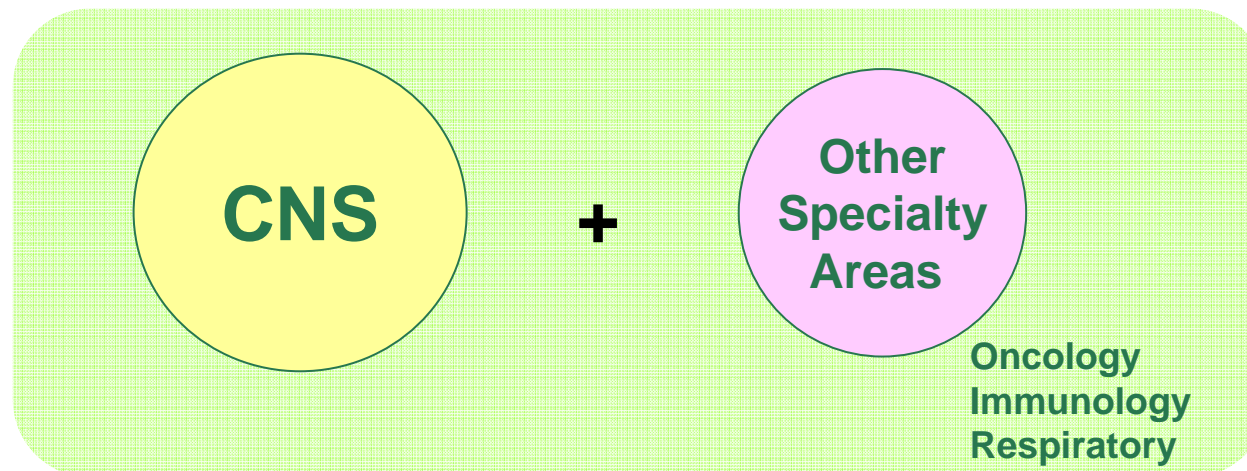
With expected launches of new products including Latuda, our CNS revenue after FY 2014 will substantially expand

### 3. Expand new products pipeline

#### Status of R&D

- R&D professionals: approx. 1,500  
- 1,100 (Japan), 400 (U.S.), 20 (China)
- R&D costs: approx. US\$750 Million (FY2010 forecast)
- R&D facilities: Osaka (Japan), Massachusetts, New Jersey, London, Suzhou (China)

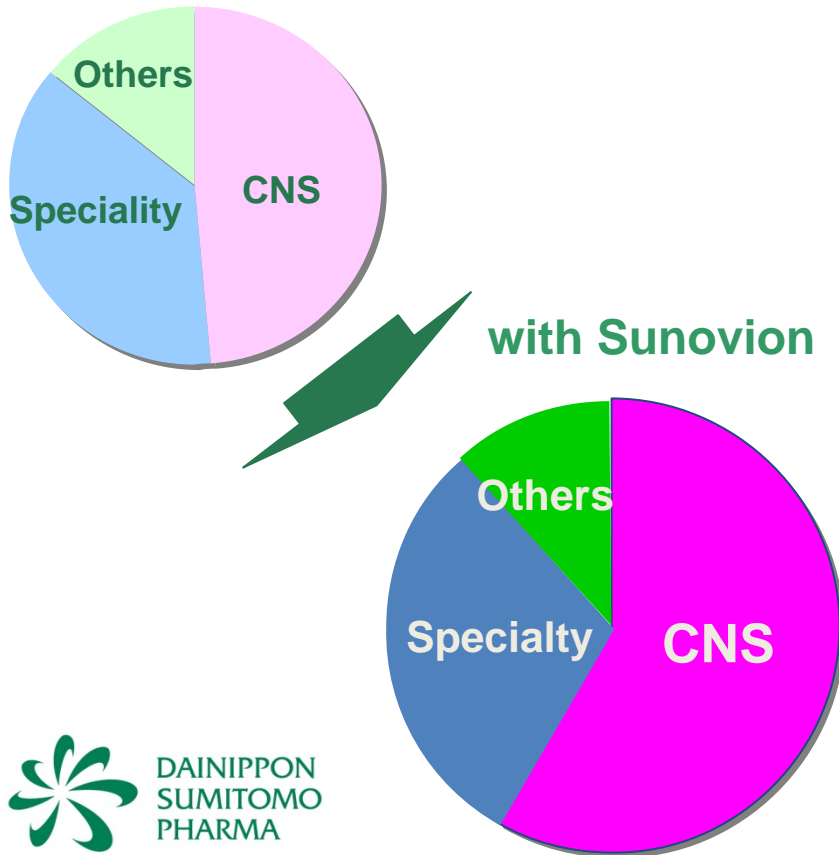
#### Therapeutic Strategy



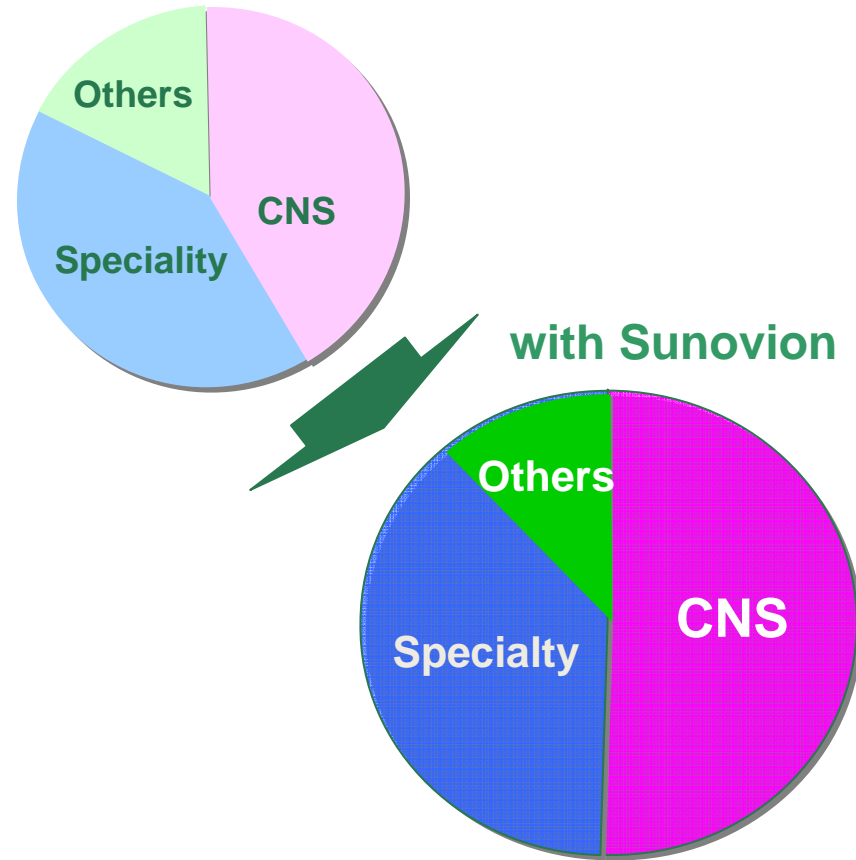
# 3-1. Strengthen Research in CNS Area

*Combined Strength from DSP and Sunovion*

**Ratio of Research Programs**



**Allocation of Researchers**



## 3-2. Striving in Business Development and In-licensing through Strategic Investment

Late Stage

**Primary focus is on products with early launch potential**

- In-license products that can leverage the established domestic commercial base in areas such as CNS
- Acquire late-stage development products by leveraging Sunovion's expertise in Business Development

Early Stage

**Expand the development pipeline**

- Focus on CNS and other Specialty areas

Discovery

**Promote strategic alliances for the continuous new drug creation**

- Alliances and collaborations with biotech companies and academia
- Research in oligo nucleotides and antibodies

# 3-3 Collaborating Partners - DSP & Sunovion



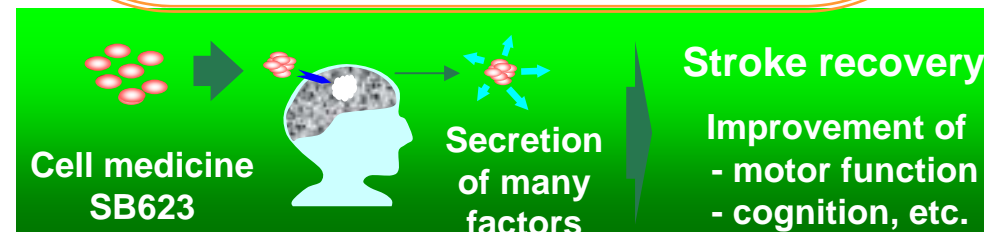
## 3-4 Recent Partnerships

### Joint Development of WT4869 with Chugai Pharmaceutical

- | WT4869 is a therapeutic peptide cancer vaccine, being developed for the treatment of various cancers under the joint development agreement with Chugai.
- | WT4869 is expected to induce immune responses targeting WT1 (Wilms' tumor gene 1) peptide expressing on the tumors of cancer patients.
- | Phase I clinical study for patients with myelodysplastic syndromes (MDS) will be initiated in Japan with Chugai in January 2011.

### Option Agreement with SanBio for Co-development of SB623

- Challenge for high unmet medical needs with innovative approach
- | Execution of an option for exclusive U.S. and Canadian marketing rights to SB623
- | Innovative drug candidate for disabilities caused by stroke for which there are currently no effective therapies.
- | Excellent efficacy in animal models of stroke disability
- | Be available to supply by vials because of allogeneic cell product
- | Phase 1/2a studies on going



# Our Passion

- We strive to contribute to patients around the world through delivery of innovative medicines.
- As patients experience better quality of life, our sustained corporate growth is attained. We strive to achieve this goal.
- In pursuit of this, we continue our active investment in R&D, most efficiently through close collaborations of our innovative experts in Japan and the U.S.



Healthy bodies, healthy lives

