

Second Mid-term Business Plan

- FY2010 to FY2014 -

- Creation and transformation toward a new stage of globalization -

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Masayo Tada, President

February 16, 2010

- ◆ **Guideline of the Second Mid-term Business Plan (2nd MTBP)**
- ◆ **Mid- to Long-term Vision**
- ◆ **Summary of the 1st MTBP**
- ◆ **Initiatives under the 2nd MTBP**
- ◆ **Business Goals**
- ◆ **Basic Strategies of the 2nd MTBP**
- ◆ **Returns to Shareholders**

Guideline of the 2nd MTBP

The 2nd MTBP was formulated based on the following four principles:

- ◆ Ability to realize DSP's management mission and achieve the mid- to long-term vision
- ◆ Continuity and consistency with the action plans for 2009
- ◆ Adoption of the premises of all items that cause uncertainty
- ◆ Participation of all departments in drafting the plan for agreement with its contents

DSP's management mission:

Manage from the patients' perspective, create innovative new drugs, continually maximize corporate value, provide opportunities for employees to increase their creativity and contribute to society as a corporate citizen.

Mid- to Long-term Vision (Drawn Up in 2007)

Envisioning our corporate status for the next 10 years

- ◆ **Establish a solid foundation for our domestic business**
- ◆ **Expand our international business operation**
- ◆ **Enrich our R&D product pipeline to realize our future vision**



Our vision of the next 15 years

- **Become an internationally competitive R&D-oriented pharmaceutical company**
- **Two solid mainstreams of our revenue, from domestic operation and from international operation**

Process to Achieve the Mid- to Long-term Vision (Drawn Up in 2007)

MTBP

First phase

Second phase

Third phase

10 years

**Solid
fundamentals**

Take off

Sustained growth

Focus resources on four
strategic products
Early maximization of
new products

Expand domestic business
foundation

Establish strong
domestic business
foundation

Establish US marketing
organization
Expand US/EU clinical
development organization

Start-up US business in our
own sales organization

Expand sales activities in
US

Strengthen new drug
discovery activities and
in-licensing activities

Expand new product
pipeline

Further expand new
product pipeline

**Achieve
mid- to long-term vision**

Summary of the 1st MTBP (FY 2007 – FY 2009)

FY 2009 business goals

	MTBP Goals	FY2009 Forecast
Net sales	295.0 billion yen →	295.0 billion yen
Operating income	50.0 billion yen →	31.0 billion yen
Net income	30.0 billion yen →	19.0 billion yen
R&D costs	55.0 billion yen →	53.5 billion yen

Impact of government medical costs reduction

Decrease in sales due to expiration of patents

Acquisition of Sepracor

Significant investment in lurasidone, etc.

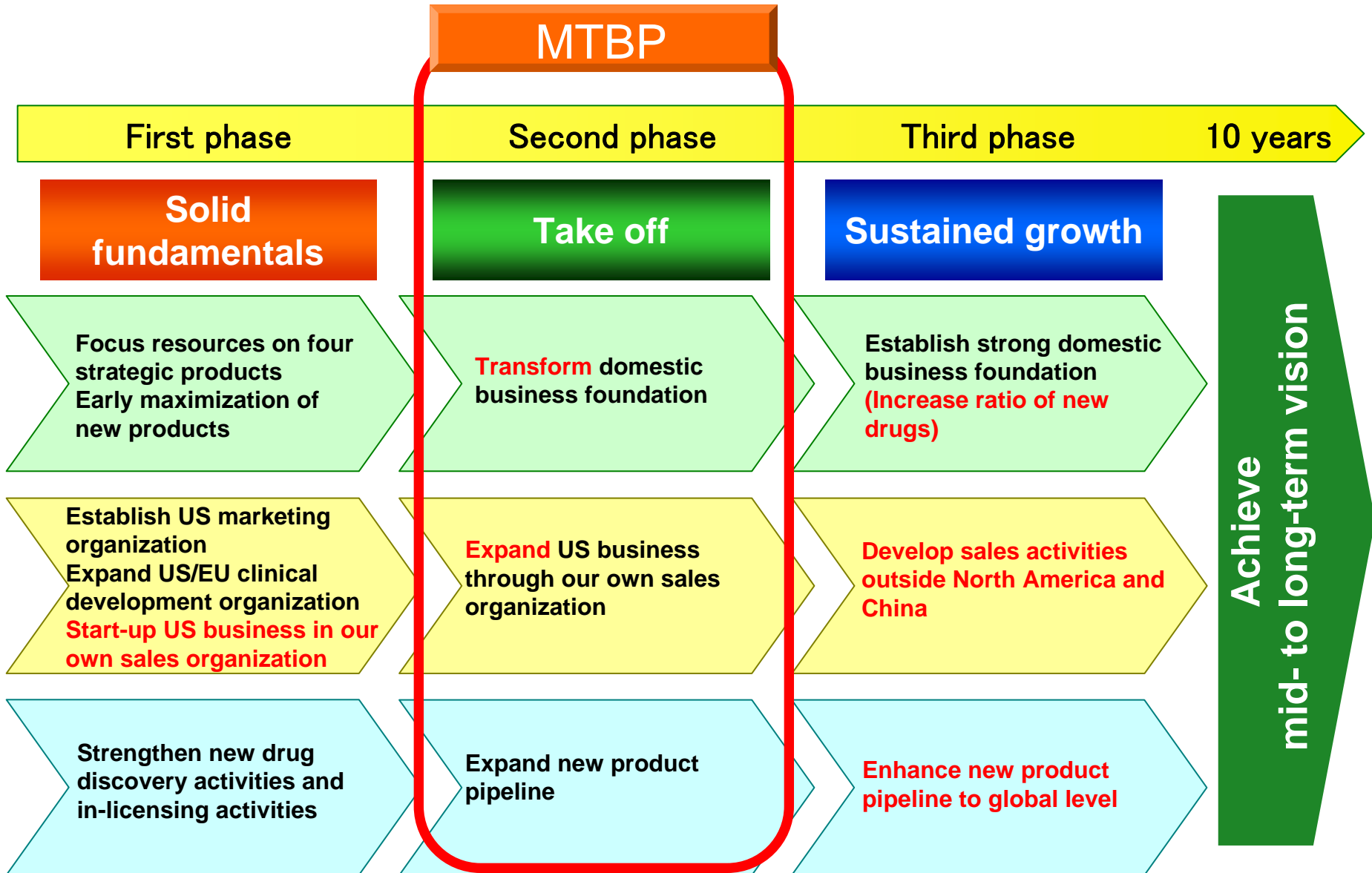
Summary of the 1st MTBP (FY 2007 – FY 2009)

Major achievement during the 1st MTBP

- ◆ **NDA submission of lurasidone and acquisition of marketing organization ahead of schedule**
(NDA submitted at end of 2009, launch targeted for 2011)
- ◆ **Established and expanded business platform and R&D facilities in North America through acquisition of Sepracor**
- ◆ **Introduced regional headquarters in the Sales & Marketing Division**
(Regionally based, customer-oriented sales and marketing, transfer of responsibility and improved profitability)
- ◆ **Achieved launch targets for the first MTBP**

- **Start up for lurasidone and increase potential to maximize lurasidone business**
 - ▶ Substantially reduce time and costs for building a sales network
 - ▶ Synergy with existing products in CNS area
- **Establishment of business platform in North America**
 - ▶ Enter the North American market and gain superior ability to generate cash
 - ▶ Leverage accumulated business know-how and experience to reduce business development risks
 - Quality assurance, pharmaceutical affairs, intellectual property, marketing strategy, etc.
- **Further enhancement of development pipeline**
 - ▶ Seamless pipeline from initial to final stage of development
 - ▶ Increase in R&D costs and improved productivity
 - ▶ Synergies among main research areas
(CNS, respiratory and inflammation/allergies)

Process to Achieve the Mid- to Long-term Vision (Revised in 2010)



Initiatives under the 2nd MTBP

- Creation and transformation toward a new stage of globalization -

Expand
lurasidone sales

Expand earnings
in North America

Transform the
domestic business
structure

Pursue greater
management
efficiency

Aggressive investment for future growth

Enhance pipeline

Strategic alliances
and in-licensing

Develop and enhance
human resources

Become a internationally
competitive R&D-oriented company

Two solid mainstreams of our revenue,
from domestic operation and from
international operation

Business Goals



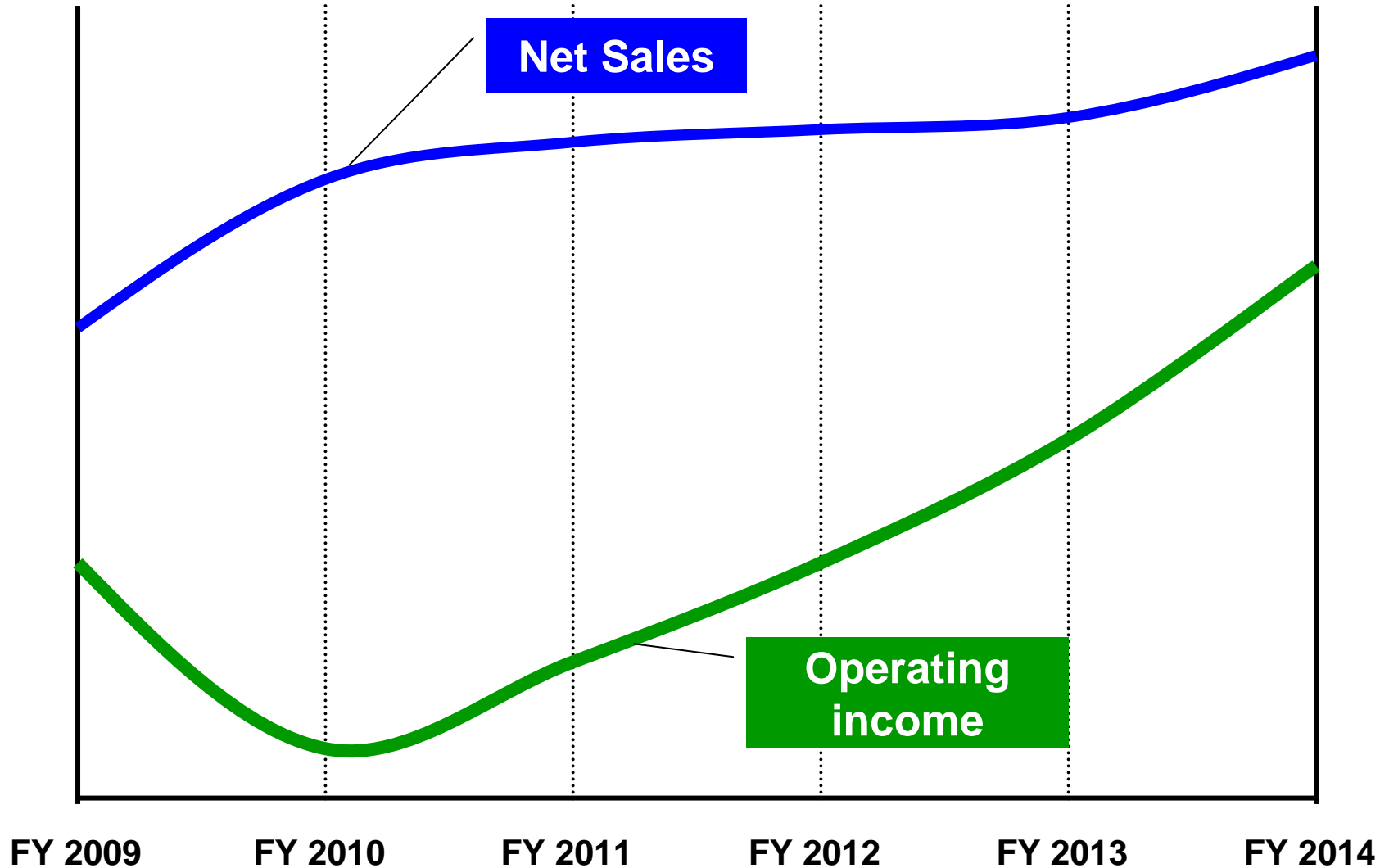
Note: Exchange rate: 90 yen/\$
Billions of yen

	FY 2009 Forecast	FY 2014 (Goals)	FY 2012 (Reference)
Net sales	^{*2} 295.0	440.0	400.0
Pharmaceuticals	236.0	375.0	340.0
Operating income	31.0	70.0	30.0
EBITDA ^{*1}	53.0	90.0	70.0
R&D costs	53.5	70.0	65.0

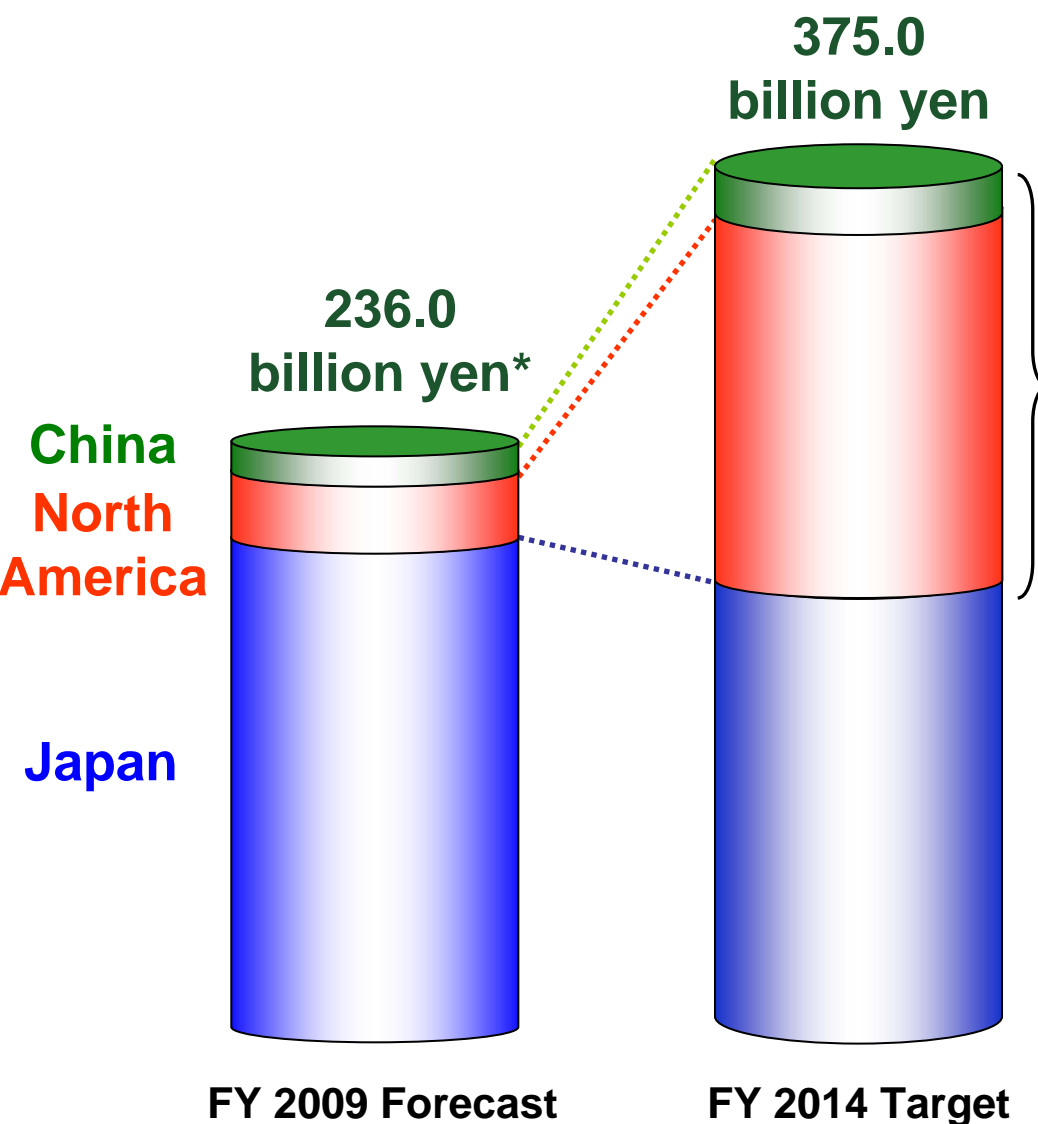
*1. Earnings before interest, taxes, depreciation and amortization

*2. 387.0 billion yen including the net contribution from Sepracor for FY 2009

Net Sales and Operating Income (conceptual graph)



Sales Targets in Pharmaceutical Business (by Region)



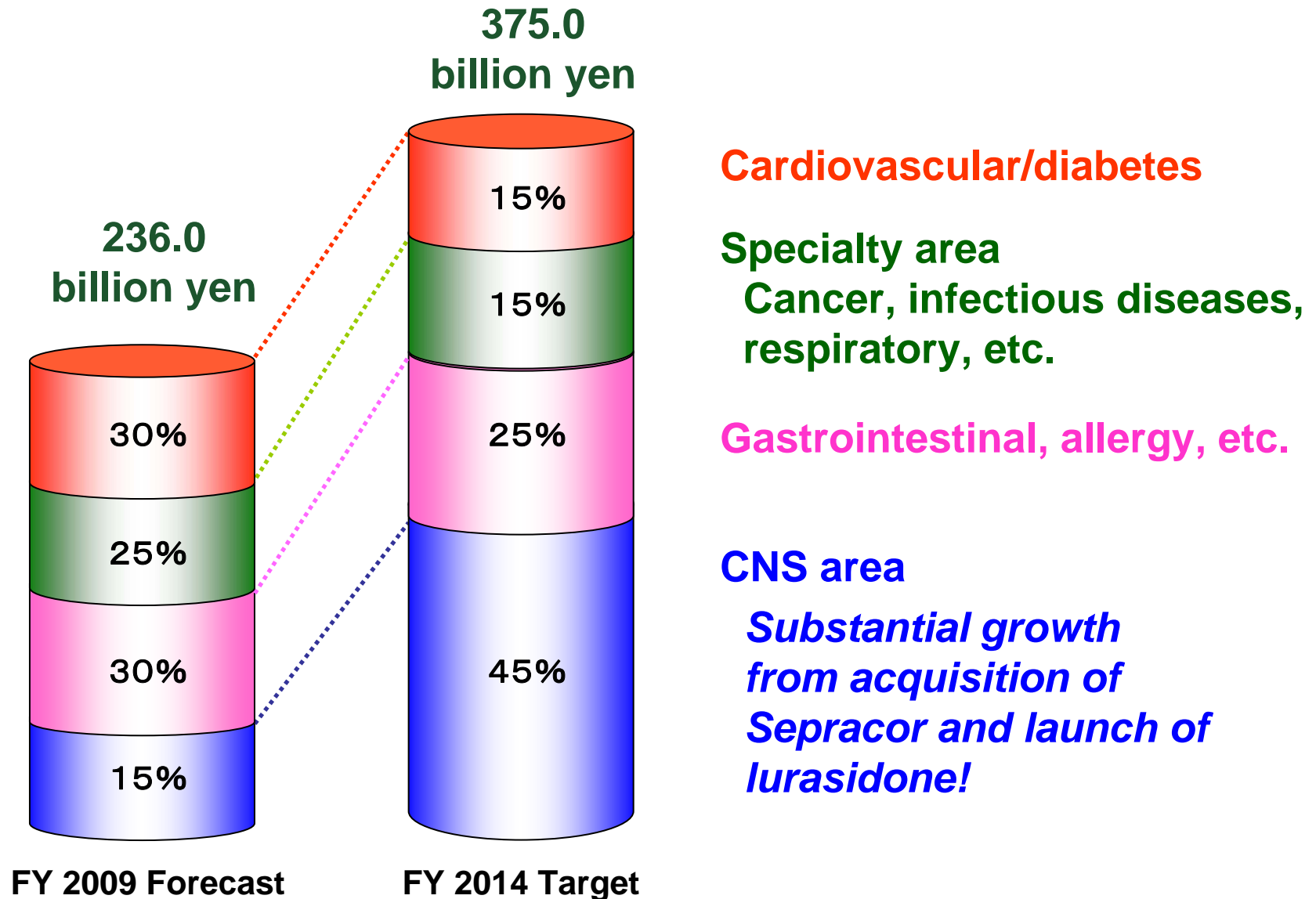
Establish two solid mainstreams of our revenue from domestic operation and from international operation!!

Bring overseas sales to 50% of total

Substantial contributions to earnings from launch of lurasidone and acquisition of Sepracor

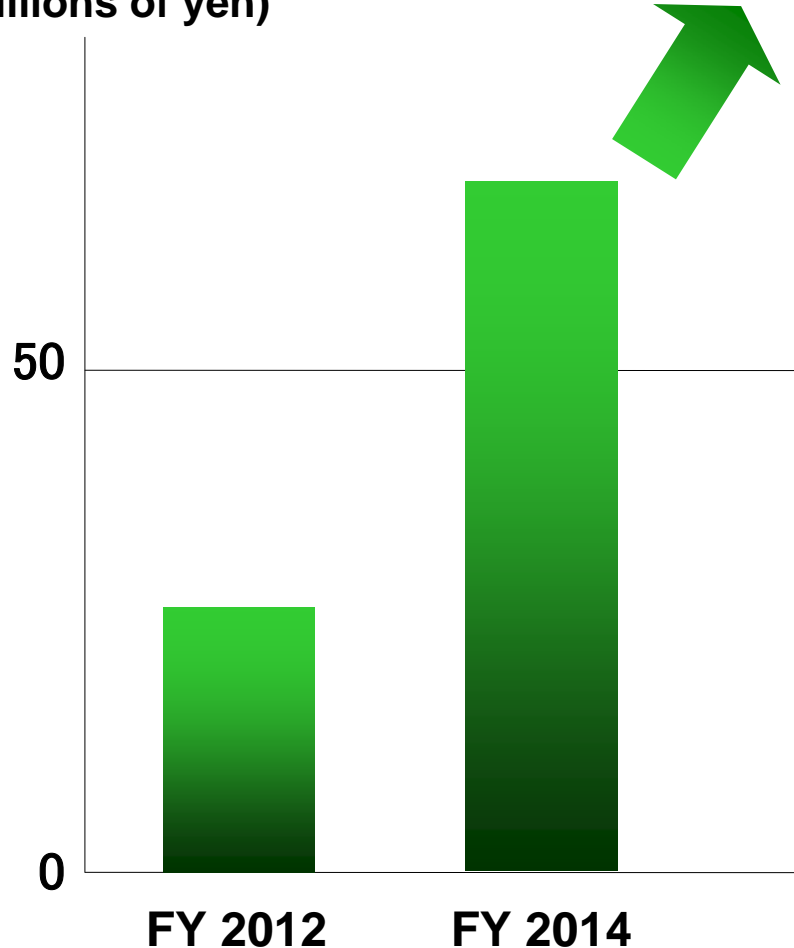
* 328.0 billion yen including the net contribution from Sepracor for 2009

Sales Targets in Pharmaceutical Business (by Therapeutic Area)



Lurasidone projected sales in the U.S.

Revenues
(Billions of yen)



Synergies from Sepracor acquisition

Sales synergies:

- Quick market penetration and sales expansion through use of Sepracor's franchise in the CNS area

Cost synergies:

- Avoid investment in creating a new organization
- Large-scale savings in costs for employing new MRs →
Use of Sepracor MRs in marketing to general practitioners and specialists

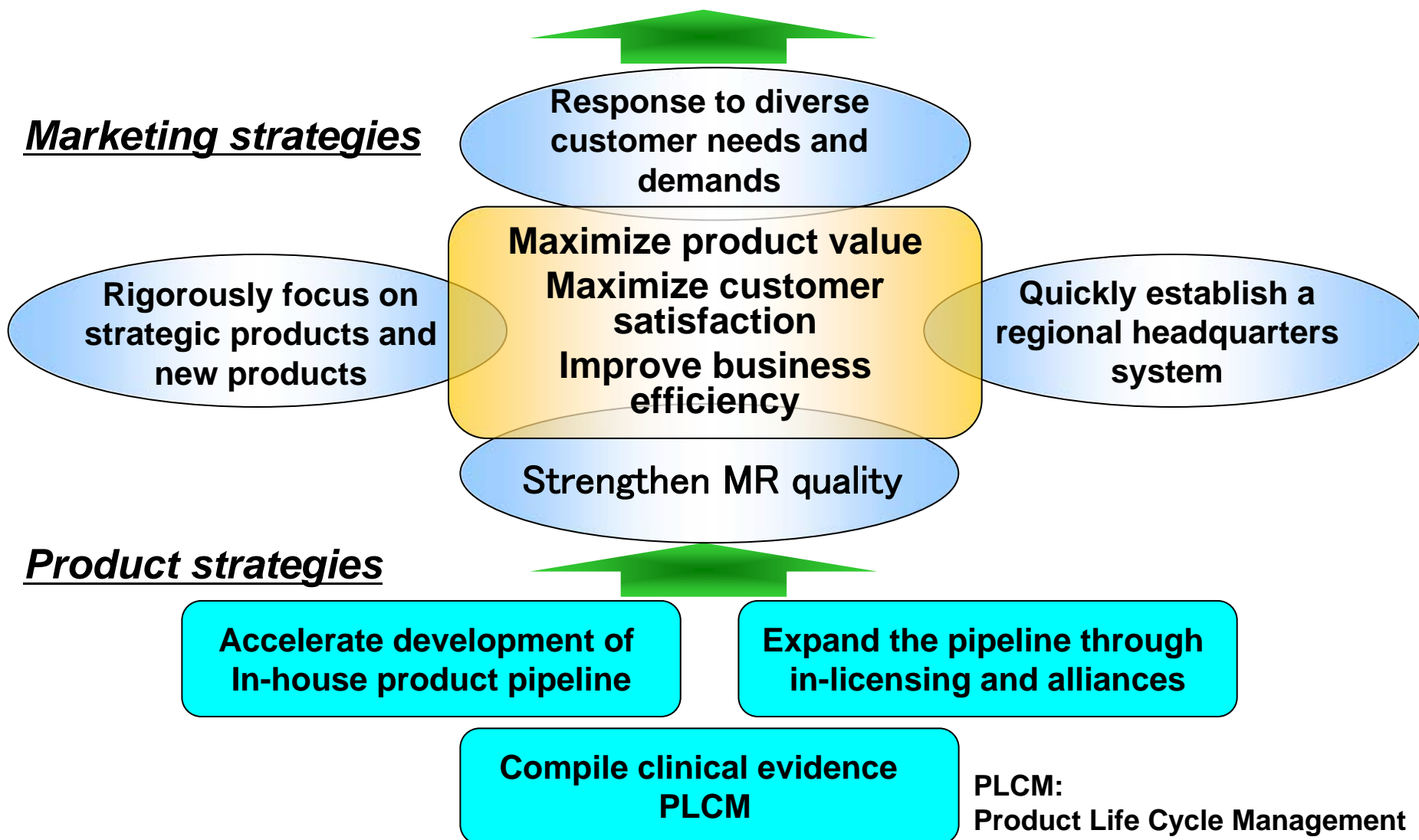
Subject to FDA approval; 2011/1Q potential launch for schizophrenia only
(2014 sales include potential additional indication for bipolar depression, if approved by FDA; Phase III clinical trials under way as treatment for bipolar disorder)

- Creation and transformation toward a new stage of globalization -

- 1. Transform the earnings structure in Japan**
- 2. Expand overseas operation and maximize earnings**
- 3. Expand the pipeline for continuous new drug creation**
- 4. Promote CSR management and continuous increases in management efficiency**
- 5. Establish a challenging corporate culture and cultivate human resources**

1. Transform the Earnings Business Structure in Japan

Continuous growth as a R&D-oriented Pharmaceutical Company



1-1. Domestic Pharmaceuticals: Focus Marketing Areas and Products



Focus marketing areas:

Cardiovascular and diabetes

CNS

Cancer and infectious diseases

Strategic products: AVAPRO[®], LONASEN[®], PRORENAL[®]

New products: TRERIEF[®], MIRIPLA[®], METGLUCO[®], repaglinide, AMLODIN[®]/AVAPRO[®] comb.

Focus products: AMLODIN[®], GASMOTIN[®], AmBisome[®], etc.

1-2. Domestic Pharmaceuticals: Strategies by Product

AVAPRO®

- Intensive investment in e-promotion
- Cultivate MRs with cardiovascular specialization

FY 2014 target: 15 billion yen

LONASEN®

- Compile clinical evidence/PLCM
- Strengthen CNS specialist MRs

FY 2014 target: 22 billion yen

PRORENAL®

- Increase awareness of lumbar spinal canal stenosis
- Further improve recognition of the brand name
- Compile clinical evidence

FY 2014 target: 18 billion yen

Note: Product sales figures before adjustment for rebates

1-3. Domestic Pharmaceuticals: Sales by Product Type

(Billions of yen)

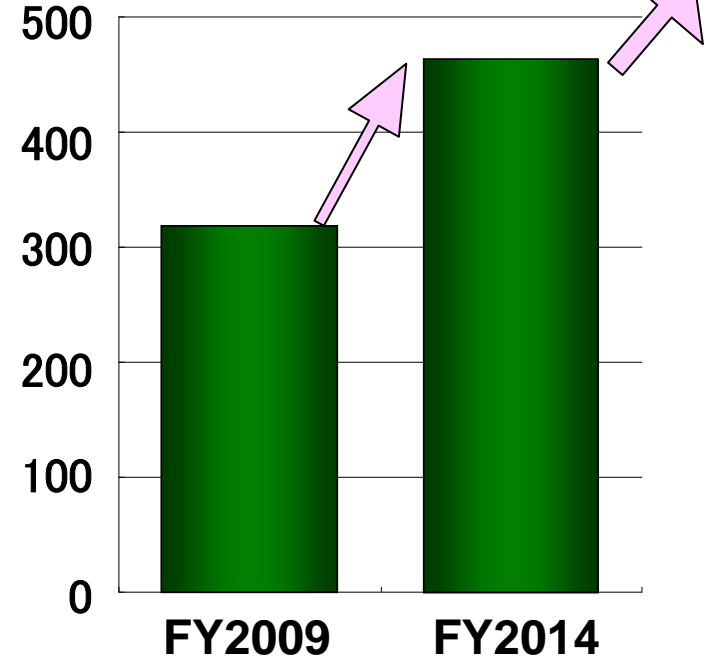
	FY 2009 Forecast	FY 2014 (Projected)	Changes
Strategic products	26.0	55.0	29.0
New products	5.0	23.0	18.0
Focus products	108.0	54.0	-54.0
(AMLODIN [®] , GASMOTIN [®] , MEROPEN [®])	(87.0)	(36.0)	(-51.0)

1-4. Increase Our Presence in the CNS Area

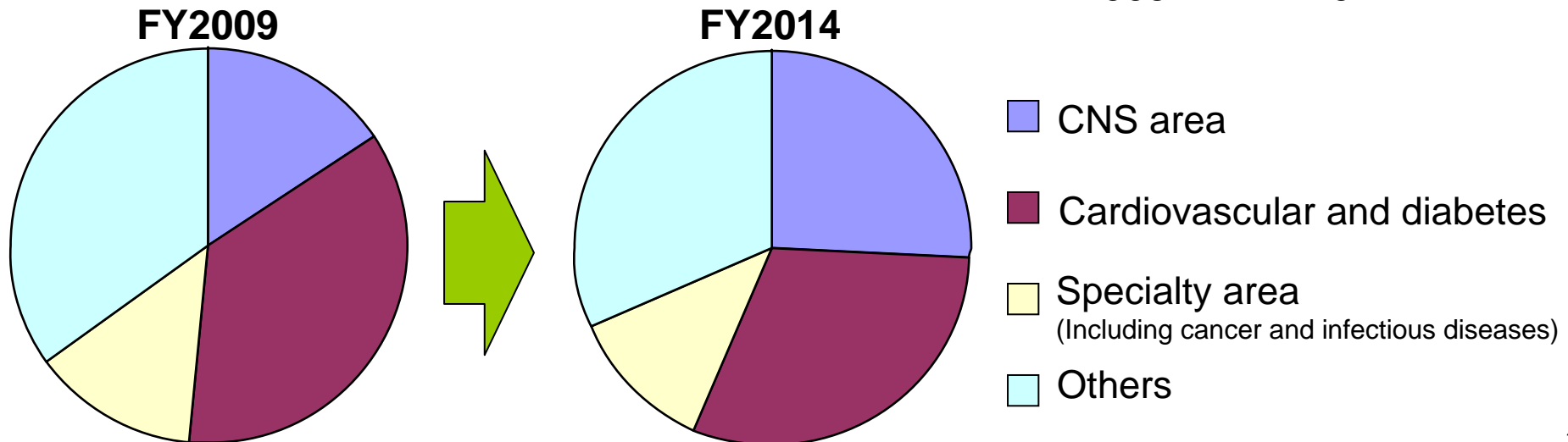
- Further increase number of CNS specialist MRs
- Increase sales of LONASEN[®] and TRERIEF[®]
- Develop lurasidone and Sepracor's compounds in Japan

CNS Area Domestic Sales (projected)

(Billions of yen)



Domestic Sales by Therapeutic Area



- **Promote product development, in-licensing and acquisitions**
- **Respond to government requirements on drug-lag issues**
- **Refine marketing strategies and distribution policies**
- **Deal with long-listed products**
 - ▶ **Provide information for proper use, compile clinical evidence, provide advanced scientific data, draw up new PLCM strategy**
 - ▶ **Examine possible frameworks for low-cost operation of less-profitable products**

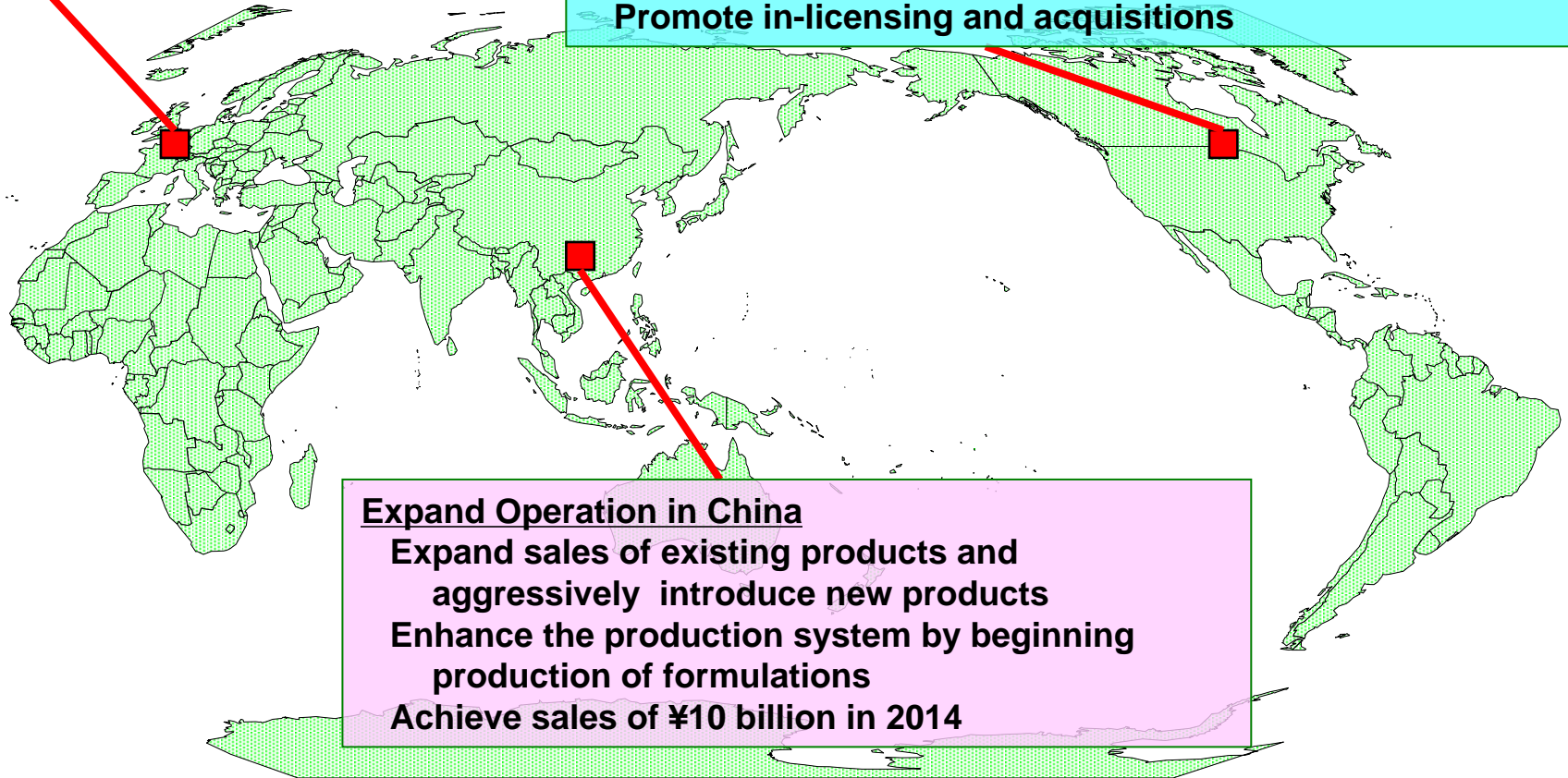


Increase the ratio of new drugs through continuous launches

2. Expand Overseas Operation and Maximize Earnings

Promote Alliances in the EU
Proceed with lurasidone alliances

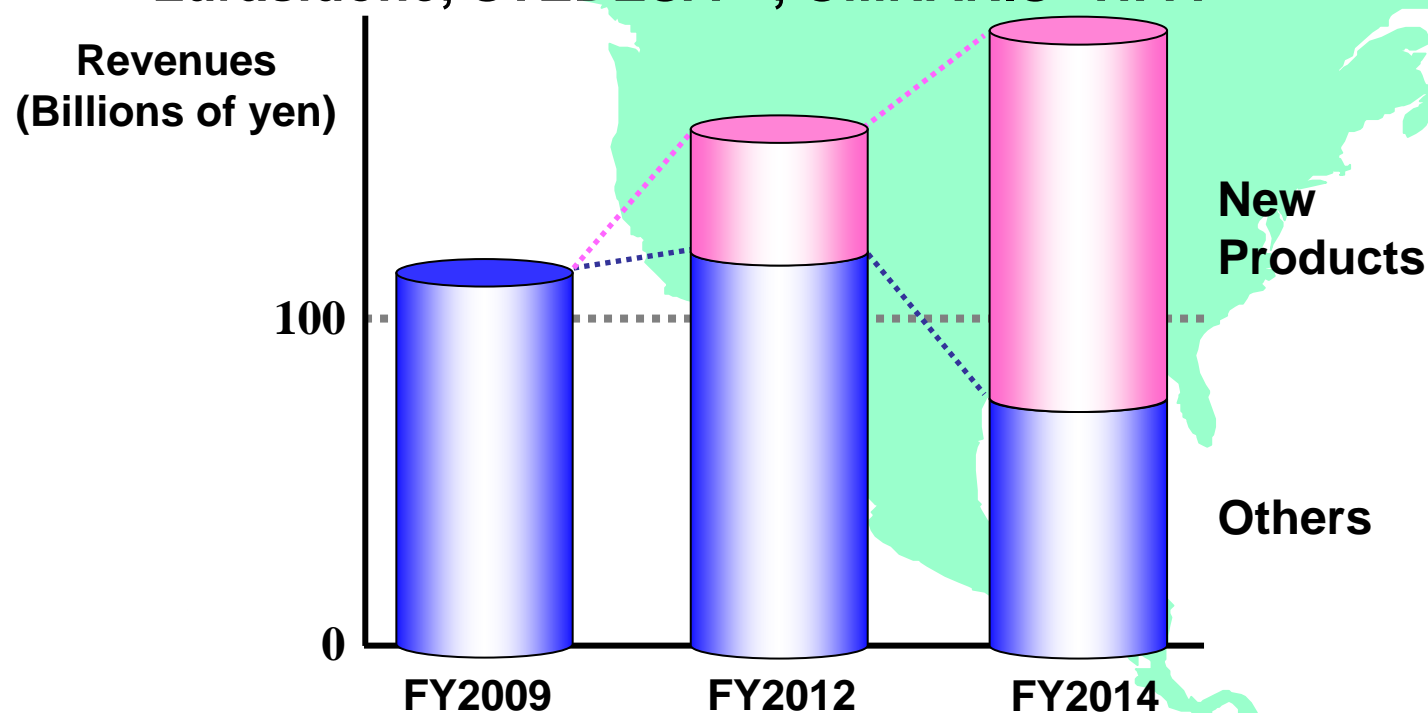
Expand Operation in North America Centered on Sepracor
Maximize lurasidone revenue potential
Quickly launch STEDESA™ and OMNARIS® HFA
Promote in-licensing and acquisitions



Expand Operation in China
Expand sales of existing products and aggressively introduce new products
Enhance the production system by beginning production of formulations
Achieve sales of ¥10 billion in 2014

Also enter countries other than
North America, China and the EU

- **Increase profitability by optimizing the North American business organization**
 - ▶ Earlier completion of PMI and start up new business organization
 - ▶ Build a sales organization for lurasidone and strengthen franchises in the CNS and respiratory areas
- **Successfully launch new products**
 - ▶ Lurasidone, STEDESA™, OMNARIS® HFA



- Upgrade R&D organization, etc.
 - ▶ Organic alliances in the DSP Group
- Seek licensing opportunities
 - ▶ Centered on CNS and respiratory areas
- Group portfolio management



3. Expand the Pipeline for Continuous New Drug Creation

R&D Areas in a Mid- to Long-Term

Focus therapeutic area: CNS area

Challenge therapeutic area: Specialty area*

*Diseases with high unmet medical needs, and highly specialized research, development and management are required

■ Existing products in clinical development

- ▶ Rapid POC confirmation, rapid NDA filing and approval

■ New R&D program

- ▶ Prioritize products in focus area and challenge area
- ▶ Evaluate other areas based on product potential, development scale and competitive conditions

Overall R&D strategy

- **Prioritize investment in establishing POC for next strategic candidates**
- **Enhance overseas development function as a basic strategy for global development**
- **Seek out various measures to expedite R&D**

Progress targets for each stage

- **Ensure fulfillment of approval targets**
- **Enhance early-stage research activities**
 - ▶ **Establish POC for one product every year**
 - ▶ **Start PI for two products every year**

3-2. Striving in Alliances and In-licensing through Strategic Investment

Late Stage

Aggressively invest in products with early launch potential

- ▶ In-licence products that can leverage the domestic business foundation in areas such as CNS
- ▶ Acquire late-stage development products by applying Sepracor's information network and in-licensing know-how

Early Stage

Expand the development pipeline

- ▶ Emphasize the focus area and challenge area

Discovery

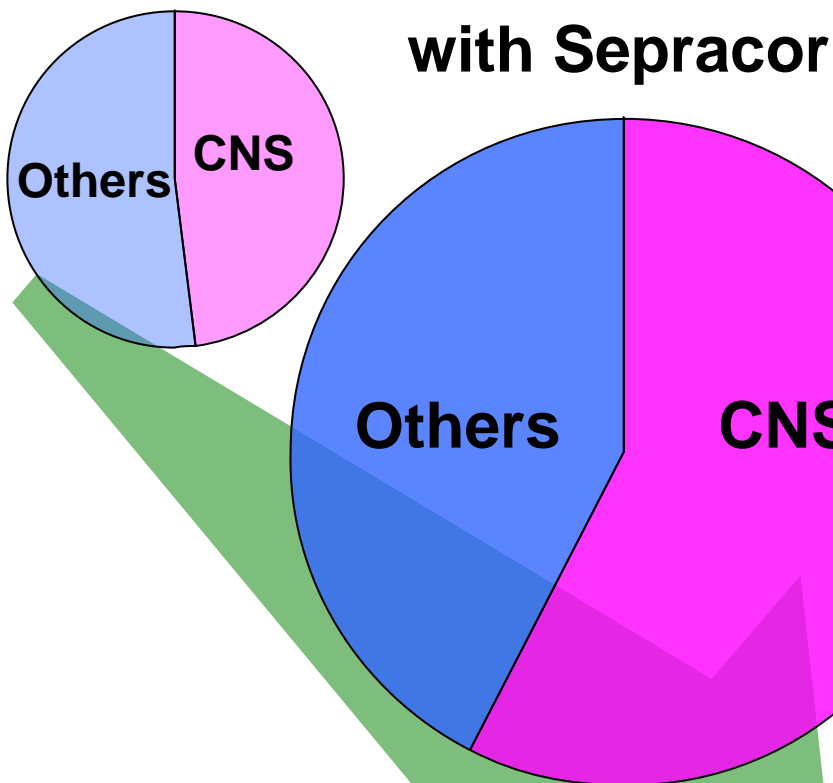
Promote alliances and collaborations for the continuous new drug creation

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

3-3. Strengthen Research in CNS Area (conceptual graph)

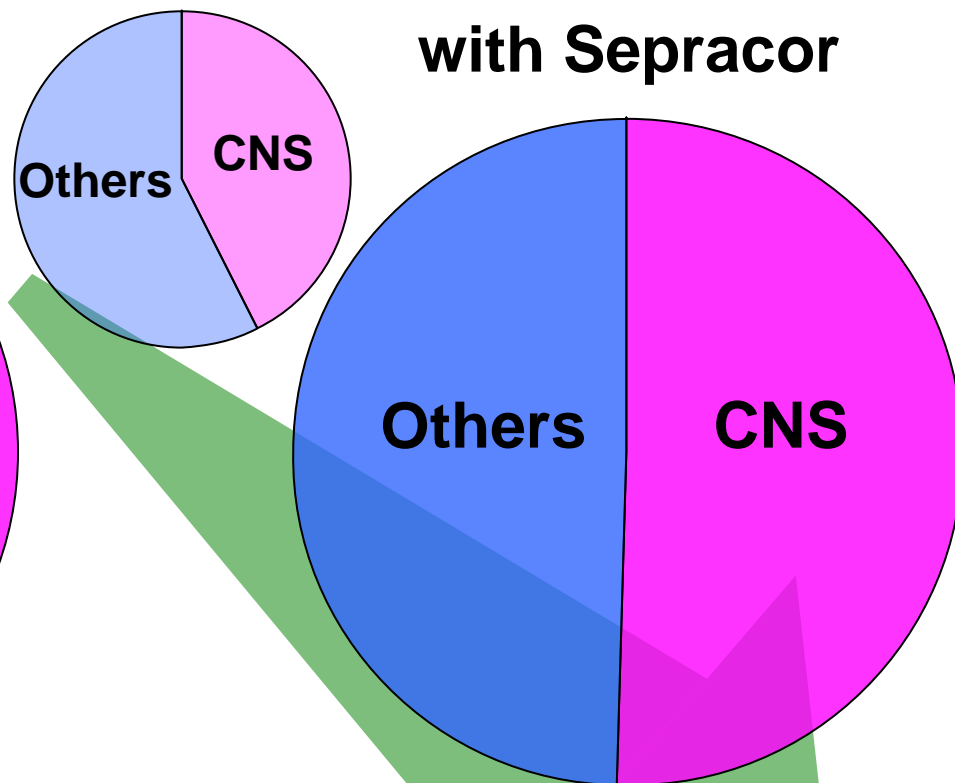
Ratio of Research Programs

Focus on CNS





Allocation of Researchers

Focus on CNS



Bolstered by focusing on CNS and the Sepracor acquisition,
Expand the CNS pipeline by further concentration!

3-4. Development Pipeline

	NDA filed	Phase III	Phase II	Phase I
Japan	<p>SMP-508 (Diabetes)</p>	<p>Lurasidone (Schizophrenia)</p>	<p>AS-3201 (Diabetic neuropathy)</p> <p>DSP-8153 (Hypertension/ Combination product)</p>	<p>SMP-986 (Overactive bladder)</p> <p>DSP-3235 (Diabetes)</p> <p>DSP-3025 (Bronchial asthma / Allergic rhinitis)</p>
Overseas	<p>Lurasidone US (Schizophrenia)</p> <p>STEDESA™ US/Sepracor (Epilepsy-Adjunct)</p>	<p>Lurasidone US, EU etc. (Bipolar disorder)</p> <p>STEDESA™ US/Sepracor (Epilepsy- Adult monotherapy)</p> <p>Amrubicin hydrochloride China (Small cell lung cancer)</p> <p>OMNARIS® HFA Nasal MDI US/Sepracor (Allergic rhinitis)</p> <p>LUNESTA® US/Sepracor (Insomnia-Pediatrics)</p>	<p>SMP-986 US, EU (Overactive bladder)</p> <p>SEP-225289 US/Sepracor (TBD)</p> <p>SEP-227162 US/Sepracor (Major depressive disorder)</p> <p>SEP-227018 US/Sepracor (Insomnia)</p> <p>ALVESCO® HFA US/Sepracor (Asthma-Pediatrics, age range TBD)</p>	<p>SMP-028 US, EU (Bronchial asthma)</p> <p>DSP-7238 EU (Diabetes)</p> <p>DSP-8658 US (Diabetes)</p> <p>SEP-227900 US/Sepracor (Cognition/Pain/AD)</p> <p>SEP-228432 US/Sepracor (ADHD)</p>
	<p> New Chemical Entities</p> <p> New Indication etc.</p>			

3-5. Launch Targets

2nd MTBP

Japan

SMP-508
(Diabetes)

DSP-8153
(Hypertension/
Combination product)

New Chemical Entities

New Indication etc.

Overseas

Lurasidone
US, EU etc.
(Schizophrenia,
Bipolar disorder)

STEDESA™
US/Sepracor
(Epilepsy)

Amrubicin
hydrochloride
China
(Small cell lung cancer)

Blonanserin
China
(Schizophrenia)

OMNARIS®
HFA Nasal MDI
US/Sepracor
(Allergic rhinitis)

LUNESTA®
US/Sepracor
(Insomnia-Pediatrics)

ALVESCO® HFA
US/Sepracor
(Asthma-Pediatrics,
age range TBD)

Potential of Sepracor's pipeline in Japanese market
is under review

3rd MTBP Onward

Lurasidone
JP
(Schizophrenia)

AS-3201
JP
(Diabetic neuropathy)

DSP-3235
JP
(Diabetes)

DSP-3025
JP
(Bronchial asthma /
Allergic rhinitis)

SMP-601
JP
(Life-threatening
infection)

SMP-986
JP, US, EU
(Overactive bladder)

SMP-028
JP, US, EU
(Bronchial asthma)

DSP-7238
EU
(Diabetes)

DSP-8658
JP, US
(Diabetes)

SEP-225289
US/Sepracor
(TBD)

SEP-227162
US/Sepracor
(Major depressive
disorder)

SEP-227900
US/Sepracor
(Cognition/Pain/AD)

SEP-228432
US/Sepracor
(ADHD)

SEP-227018
US/Sepracor
(Insomnia)

AD: Alzheimer's disease

ADHD: Attention-deficit hyperactivity disorder

4. Promote CSR Management and Continuous Increase in Management Efficiency

- **Promote CSR management**
 - ▶ Establish global governance
- **Improve management efficiency through job streamlining and transformation**
 - ▶ Thoroughly promote low-cost operation on all fronts
 - Reduce costs by more than 12 billion yen by 2014
- **Transform the business structure**
- **Expand operations and improve management efficiency by splitting off non pharmaceutical businesses**

DS Pharma Animal Health Co., Ltd.

- ▶ Split off the animal science business
- ▶ Clarify business responsibilities, accelerate decision-making and improve profitability to become a leading company
- ▶ Closely coordinate with DSP's R&D divisions

DSP Gokyo Food & Chemical Co., Ltd.

- ▶ Integrate DSP's food and specialty products business into its subsidiary Gokyo Trading Co., Ltd.
- ▶ Seek to maximize synergy effects as an enterprise combining research, development and sales
- ▶ Strengthen the company's originality and marketing capabilities to become a highly profitable R&D oriented company

5. Establish a Challenging Corporate Culture and Cultivate Human Resources

- **Share and practice the corporate mission and management mission within the DSP Group**
- **Encourage new challenges and establish a corporate culture of speedy response**
- **Promote C&S Campaign**
Activities to improve awareness and conduct, with the mottos
“Change for Challenge!” and “Seek Something New!”
- **Cultivate and energize diverse human resources**
 - ▶ **Cultivate and recruit human resources for global expansion**
 - ▶ **Enhance research specialization**
 - ▶ **Establish and entrench the new personnel system scheduled for introduction in 2010**

■ Dividend Policy

- ▶ Allot appropriate dividends in line with performance while balancing aggressive investment and internal reserves for future growth
- ▶ Also consider stable dividends

■ Dividends Paid

	FY 2006 (Actual)	FY 2007 (Actual)	FY 2008 (Actual)	FY 2009 (Forecast)
Net income	22.6 billion yen	25.6 billion yen	20.0 billion yen	19.0 billion yen
Cash dividends per share	14 yen	18 yen	18 yen	18 yen

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in North America

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efficiency

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Enhance pipeline

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