

Third Mid-term Business Plan - FY2013 to FY2017 -

- Quest for Further Innovation -

February 19, 2013

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Dainippon Sumitomo Pharma Co., Ltd.

Agenda

- ◆ Second Mid-term Business Plan Review (2nd MTBP)
- ◆ Vision and Third Mid-term Business Plan (3rd MTBP)
- ◆ 3rd MTBP Business Goals and Basic Strategies
- ◆ 3rd MTBP Strategies
 - Product Strategy
 - Therapeutic Area Strategy
 - Regional Strategy
 - R&D Strategy
 - Investment/Finance Strategy and Shareholder Returns
- ◆ Non-Pharmaceutical Businesses Strategies
- ◆ Strengthen Business Foundation

Second Mid-term Business Plan Review

Vision (Created in 2007)

Our vision was created at the time of the First Mid Term Business Plan based on a projection of where the company should be in 10 years (2017 Vision)

2017

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

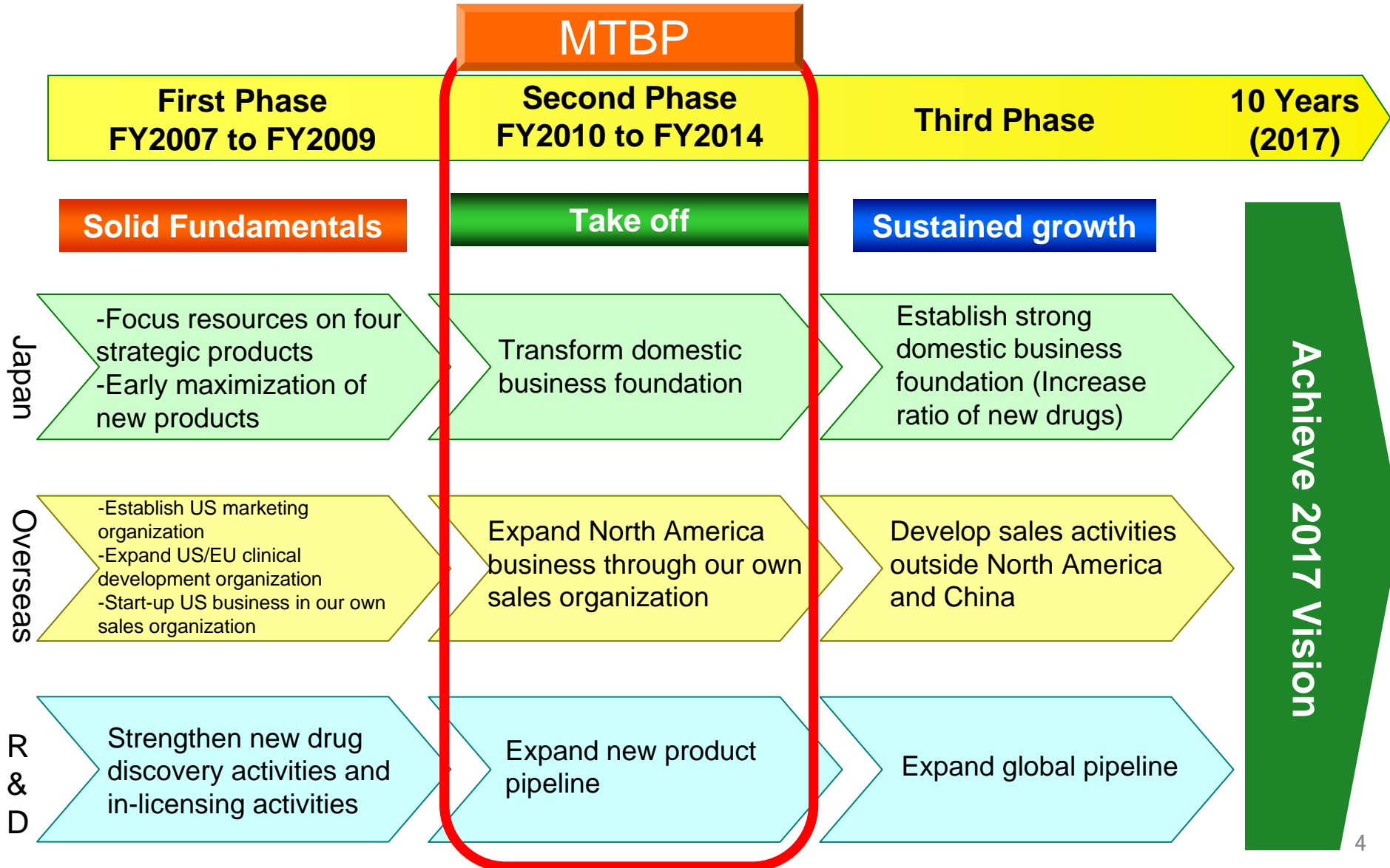


2022

Our vision for the next 15 years

- Become an internationally competitive R&D-oriented pharmaceutical company
- Two solid streams of revenue, from domestic and international operations

2017 Vision and the 2nd MTBP



2nd MTBP Review (Japan)

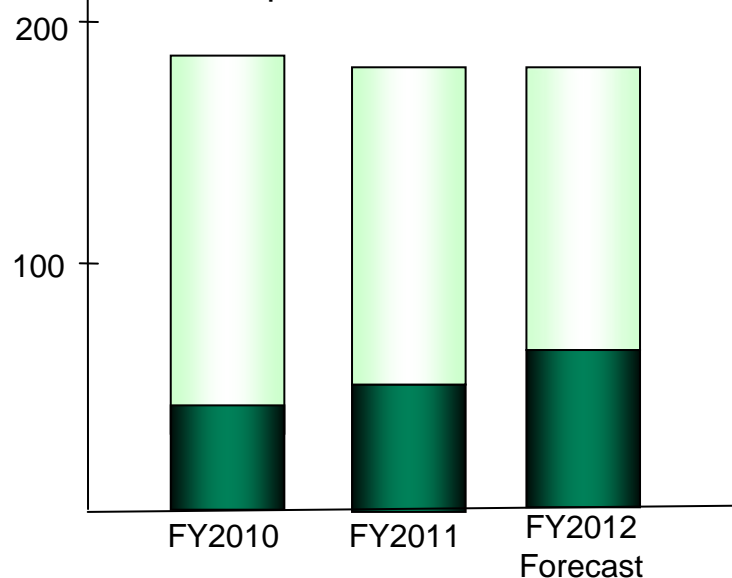
Achievements

- Expanded strategic and new products sales
- Strengthened CNS sales capabilities (independence of CNS business unit, increased specialist reps)
- Strengthened product lineup in cardiovascular area (approval and launch of AIMIX[®] ahead of schedule)

Challenges

- Further growth of LONASEN[®]
- In-licensing of late-stage development pipeline

(Billion Yen) Japan Sales Trend



Absorb long term decline of long-listed products by expanding strategic and new products

Others

Strategic, New Products: (AIMIX[®], AVAPRO[®], LONASEN[®], TRELIEF[®], PRORENAL[®], METGLUCO[®], SUREPOST[®], MILIPLA[®])

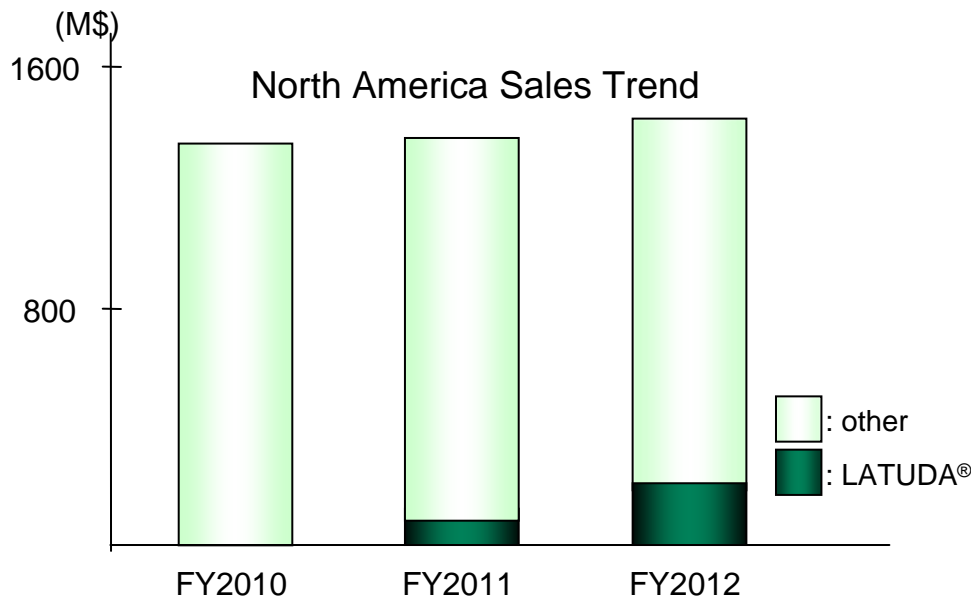
2nd MTBP Review (Overseas)

Achievements (North America: Sunovion)

- Launch and steady growth of LATUDA[®]
- Steady sales growth
- Improved profitability through business structure improvement
- Launch of ZETONNA[®]

Challenges (North America: Sunovion)

- Early launch of STEDESA[™]
- Early expansion of LATUDA[®] sales



North America: Sales increased due to expansion of LATUDA[®] sales and steady sales of existing products.

Other regions:

China - Consistent growth

UK - Preparing its own sales organization

Southeast Asia: Subsidiary established

2nd MTBP Review (R&D)

Achievements

- Acquired Boston Biomedical Inc. (BBI)
- Established DSP Cancer Institute
- Started Phase3 for BBI608
- Obtained option rights for SB623
- Acquired SUN-101
- Eight compounds started clinical studies during 3 years
- Accomplished key launch targets during 3 years
- In-licensed distinctive compounds in early development
- Proactively utilized leading-edge science in drug discovery

} *Full-scale entry into oncology R&D*

} *Multiple Post-LATUDA[®] candidates*

Challenges

- Lack of late-stage development pipeline

Summary of 2nd MTBP Progress

2nd MTBP Business Goals - Progress

Billions of Yen

	FY2012		Change	Exchange Impact
	Forecast	MTBP Goal		
Net sales	348	380	- 32.0	- 14.8
Operating Income	28	30	- 2.0	1.1

[Exchange Rates]
Revision: 1\$=79.8 JPY
MTBP: 1\$=90 JPY

Although Japan is on track both in sales and profit, the risk of losing profitability from long-listed products is increasing rapidly

Even though sales are growing in North America, new products are below midterm target

- Delay in the launch of STEDESA™
- Shortfall in key products, change of market environment
- Increase in sales expenses for LATUDA®

Entered into the oncology field (BBI acquisition, etc.)

Create the 3rd MTBP

Towards 2014

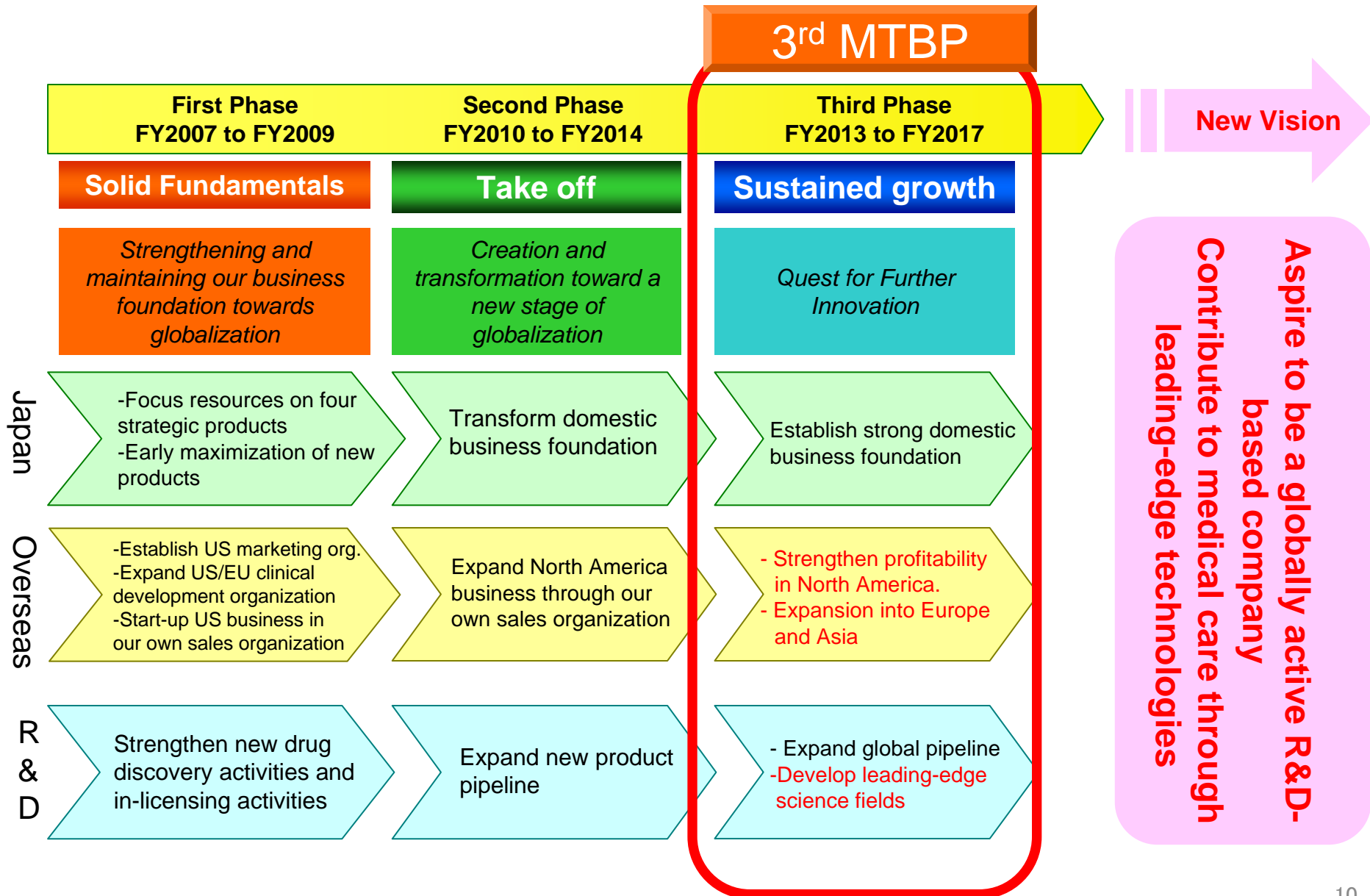
Must accelerate earnings structural reform

Challenges achieving targets

Significant changes in business structure

Vision and Third Mid-term Business Plan

Vision for the 3rd MTBP



3rd MTBP Business Goals and Basic Strategies

Business Goals

Note: Exchange rate: 1\$ = 80yen
Billions of yen

	FY2012 Forecast	FY2015 (Reference)	FY2017 (Goals)
Net Sales	348.0	350.0	450.0
Pharmaceuticals	309.2	300.0	400.0
Operating income	28.0	30.0	80.0
EBITDA	63.0	50.0	110.0
R&D costs	59.2	65.0	80.0

3rd MTBP Basic Strategies

- Quest for Further Innovation -

1. Establish a robust revenue base in Japan
2. Further expand overseas business and maximize earnings
3. Expand global pipeline
4. Continuously pursue operational efficiency and CSR
5. Build an active corporate culture and develop talent

3rd MTBP Strategies

3rd MTBP Strategies

- Quest for Further Innovation -

Product Strategy

Regional Strategy

Investment Strategy

Therapeutic Area
Strategy

R&D Strategy

Finance Strategy



**Aspire to be a globally active R&D-based company
Contribute to medical care through leading-edge technologies**

Product Strategy (1)

Maximize LATUDA[®] (lurasidone) business

Successful development of new oncology product (BBI608/BBI503)

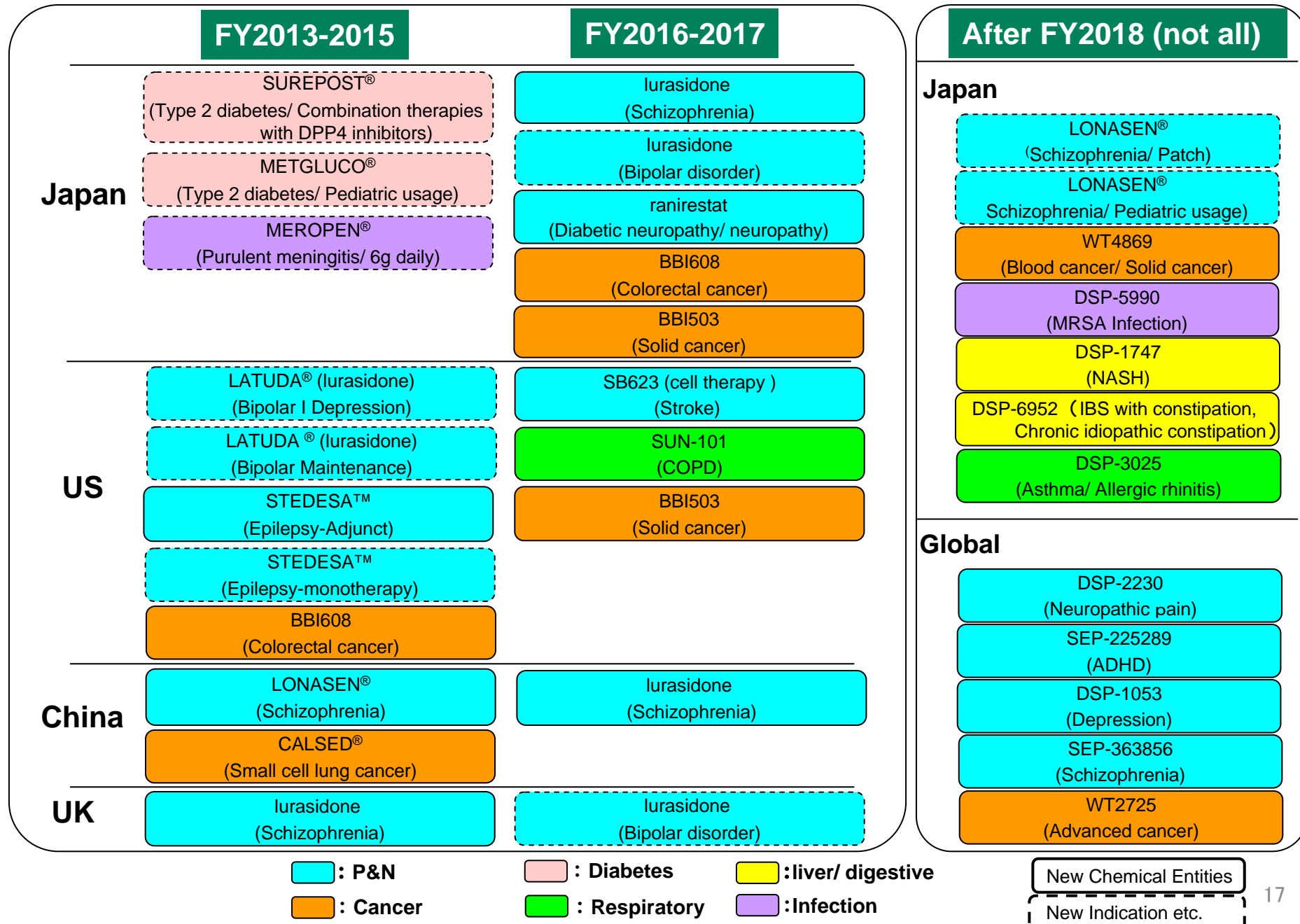
Successful development of post-LATUDA[®] candidates

Proactively promote in-licensing and strategic alliances



Globally grow businesses driven by new medicines

Product Strategy (2): Product Launch Plan

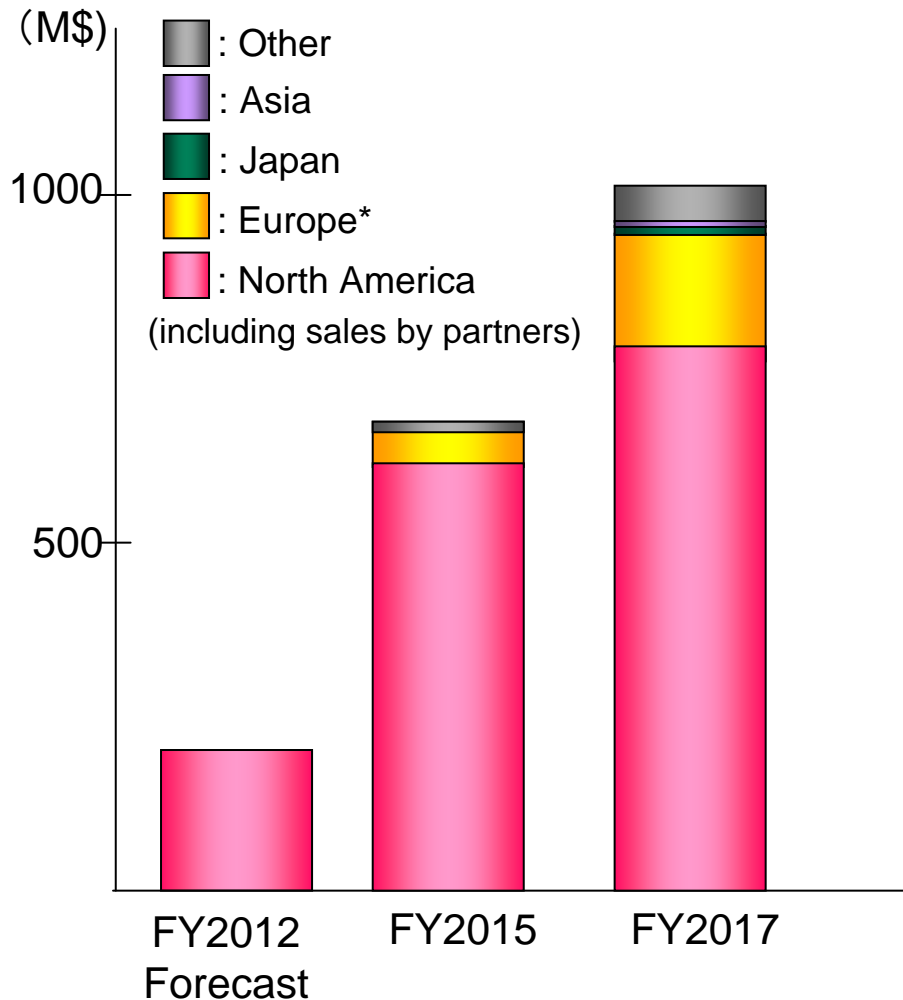


 : P&N
 : Diabetes
 : liver/ digestive
 : Cancer
 : Respiratory
 : Infection

New Chemical Entities
New Indication etc.

Product Strategy (3): Maximize LATUDA® (lurasidone) Business

LATUDA®: Globally and consistently grow to be a blockbuster



- NA: Expand sales by adding indication (bipolar I depression)
- EU: Establish sales & marketing structure in UK
- JP: Expand indication to bipolar disorder in addition to schizophrenia (Phase3)
- Quick launch in China, Australia and South East Asia.

Expand sales regions including alliances

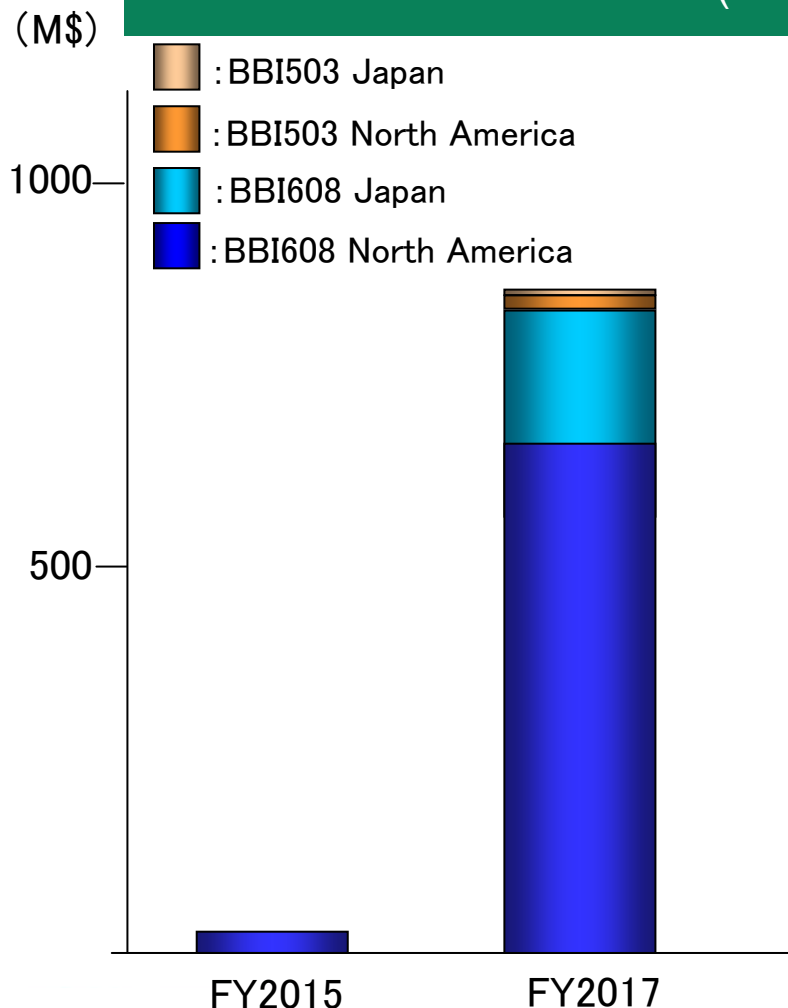


Maintain LATUDA® business after loss of exclusivity in US

* Sales by partner in Europe (excl. UK) was estimated by DSP

Product Strategy (4): Launch BBI608, BBI503 and Build Oncology Business

Achieve fastest launch of BBI608/BBI503 to become the global leader in CSC (Cancer Stem Cell) areas



Profile of BBI608 and BBI503

- First-in class, molecular target drug (small molecular compound, oral agent)
- Inhibits the growth of tumor cells and cancer stem cells to induce apoptosis

- MOAs are different for each compound

Development Phase

- BBI608: colorectal cancer (2nd/3rd line, monotherapy: Phase3)

- BBI503: Phase1

Launch Plan

- BBI608: Launch in North America in FY2015 and Japan in FY2016

- BBI503: Launch in North America and Japan in FY2017

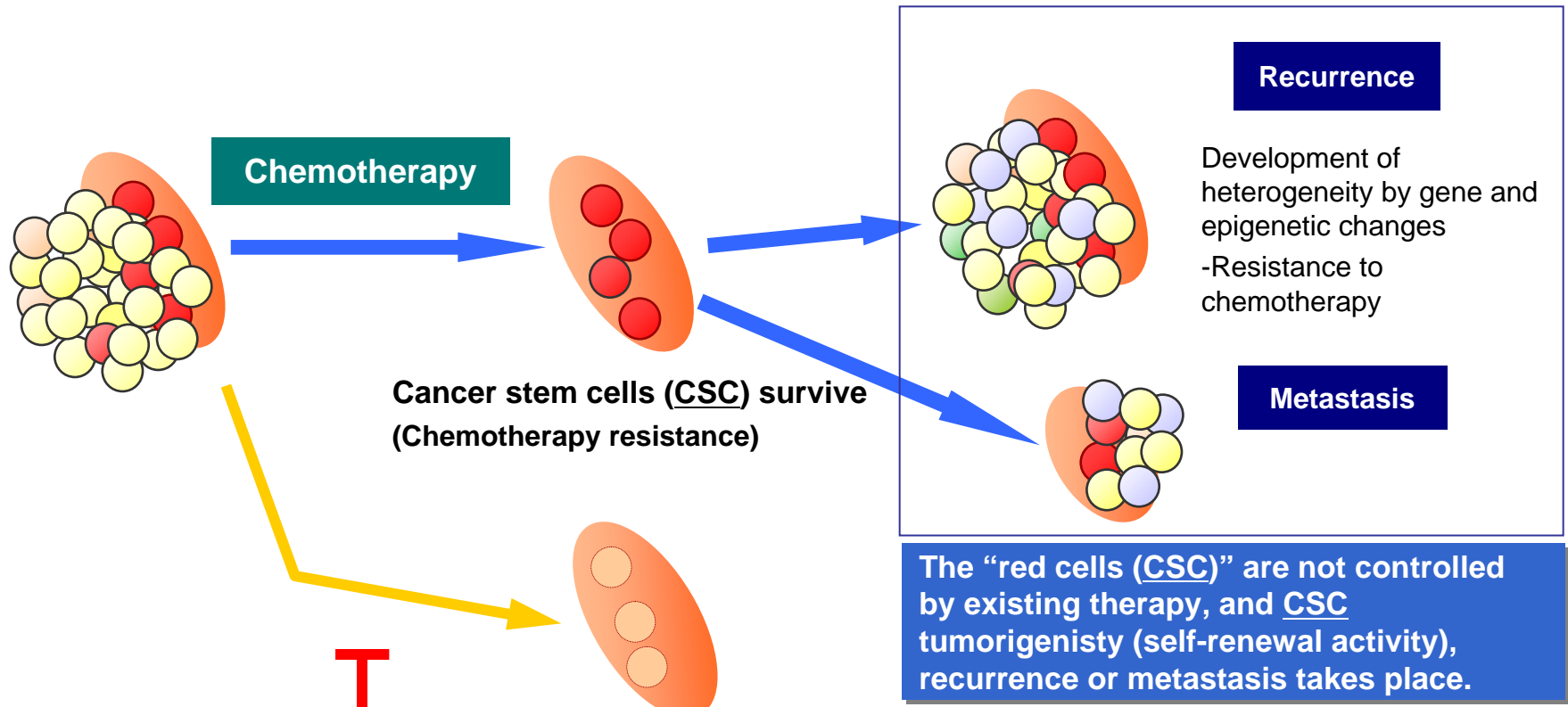
Build oncology sales & marketing structure

- Build commercial/medical functions with over 100 staff for BBI608 launch in US

- The organizational structure will be decided before BBI608 NDA submission in North America

(Reference) Mechanisms of Action of BBI608 and BBI503

Inhibits mechanism for maintaining characteristics of cancer stem cells causing cell apoptosis



BBI-608 and BBI-503
Anti-Cancer Stem Cell drugs

Drugs Targeting cancer stem cells are expected to offer significant advances over current therapies.

(Reference) BBI608 Development Status

■ Development Status

Brand name/ Product code	Generic name	Proposed indication	Development location	Development Stage
BBI608	TBD	Colorectal Cancer (2nd/3rd line) (Monotherapy)	US/Canada	Phase 3
		Colorectal Cancer (3rd/4th line) (Combination therapy)	US/Canada	Phase 2
		Solid Cancer (2nd/3rd line) (Combination therapy with paclitaxel)	US/Canada	Phase 1/2

■ Outline of North America Phase 3 Study

- Phase 3 study initiated in January 2013, drug administration scheduled to begin in spring
- International multi-center, double-blind, randomized Phase 3 clinical trial compared with best supportive care in patients with advanced, unresectable, refractory colorectal cancer, for whom no further standard anticancer therapy is available or appropriate.
- Estimated Enrollment: 650 (2 arms of 325)

■ Development Schedule in Japan

- Plan to initiate Phase 1 in FY2012 (IND submission)
- After Phase 1, Japanese clinical sites will participate in the global Phase 3 study aiming for the earliest approval possible.

(Reference) Market Opportunity for BBI608

- **Oncology is a therapeutic area with very high unmet medical needs (especially for recurrence and metastasis after therapy)**
- **Market is growing rapidly with many blockbusters**
- **Treatment strategy targeting Cancer Stem Cells is a concept drawing attention and BBI608 is the most advanced candidate in the world**

■ **BBI608 Phase 1 Study Initial Results Presented at the 2010 AACR**

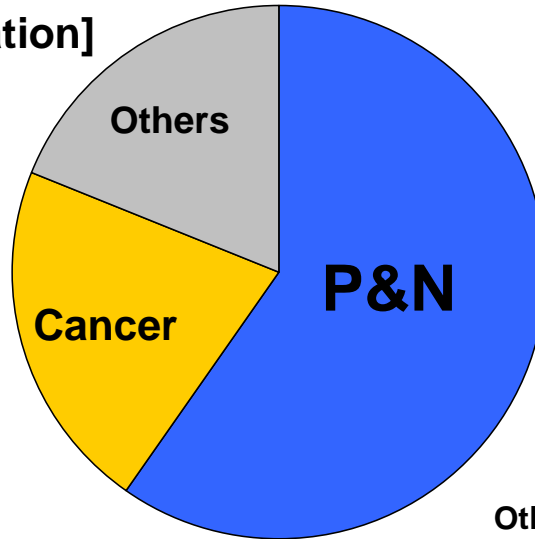
- In the results of the Phase 1 study, dose-limiting toxicity was not observed, and high tolerability was confirmed.
- In various refractory patients with solid tumors, there was a trend of 50% tumor regression and progression-free survival was prolonged by 12 weeks.

**Presentation of results at a scientific meeting in FY2013
(U.S./Europe) under consideration**

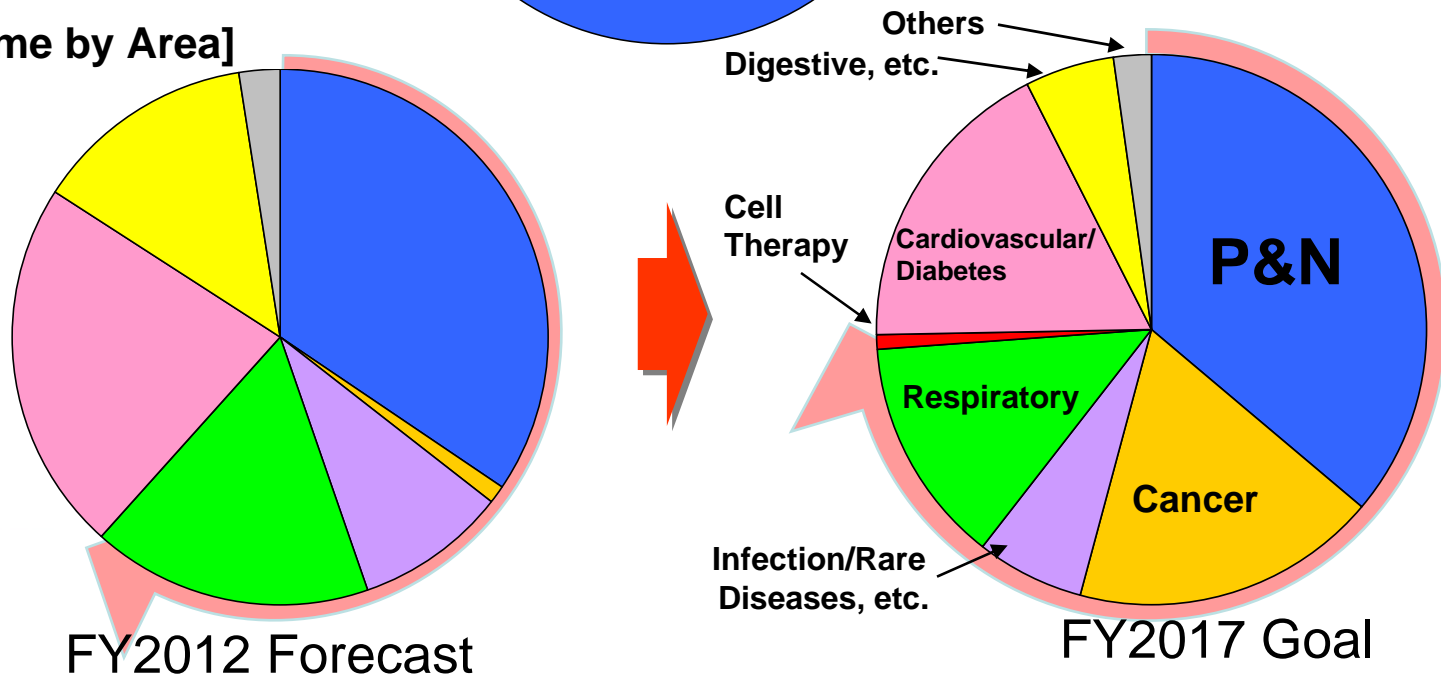
Therapeutic Area Strategy

Shifting from PCP to specialist areas

[R&D Resource Allocation]
(FY2013 Plan)



[Sales Volume by Area]



Regional Strategy (1): Expand Business Deployment Regions

— By 2017

EU

Launch of UK business while expanding into other countries in Europe

North America

- Maximize profit during the culminating period of LATUDA®
- Launch oncology business led by BBI & quickly expand business
- Continue investment to ensure Sunovion business expansion

China

Ensure launch of product currently under development

Japan

- Focus resources on growth products
- Launch global product in JP
- Promote in-licensing and alliance

ASEAN/Oceania

Launch business in South East Asia to expand business into Oceania region

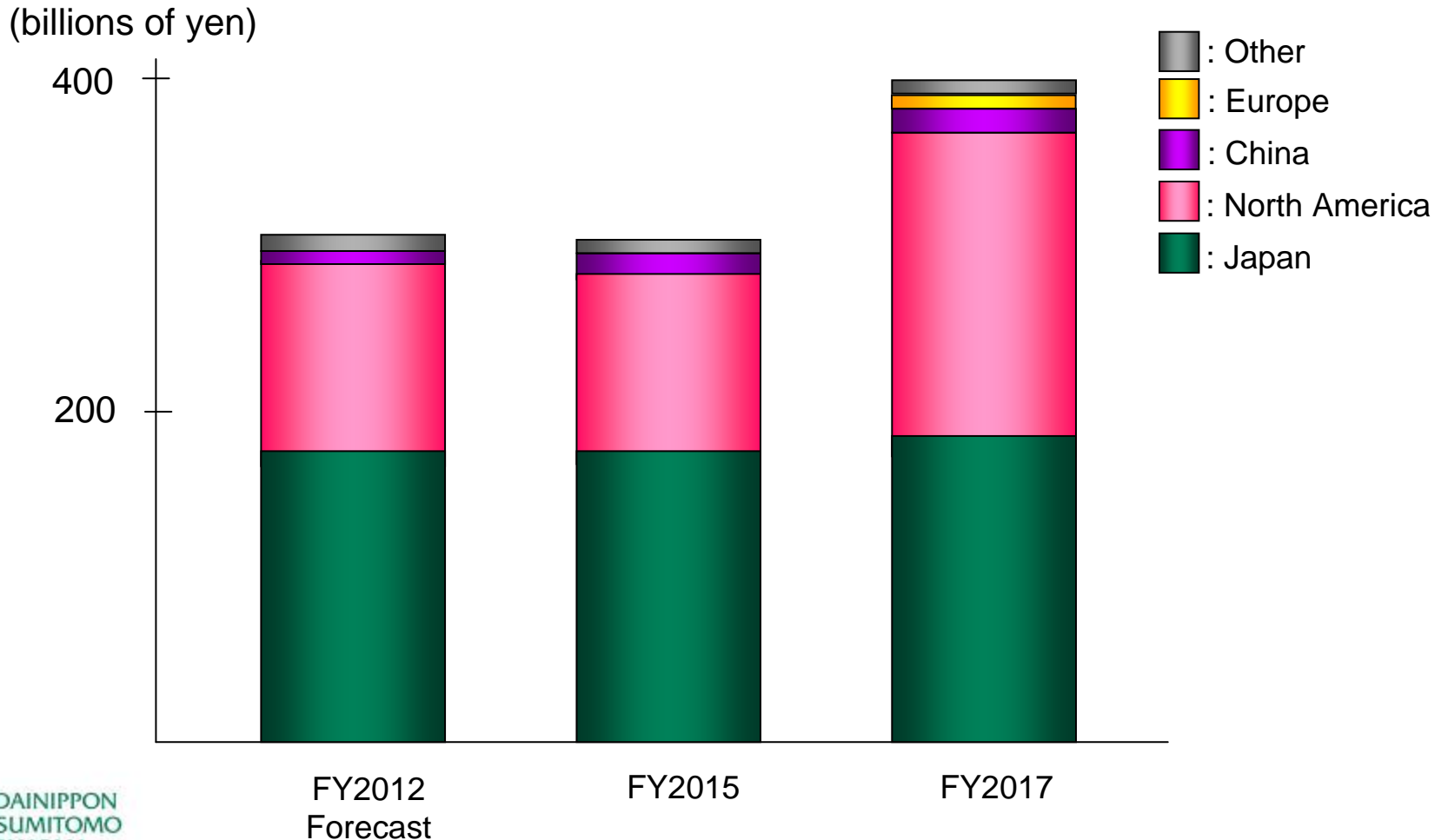
Central/South America

Promote out-licensing and alliance

Regional Strategy (2): Sales Target by Region

North America: Grow LATUDA[®], Launch and expand BBI608

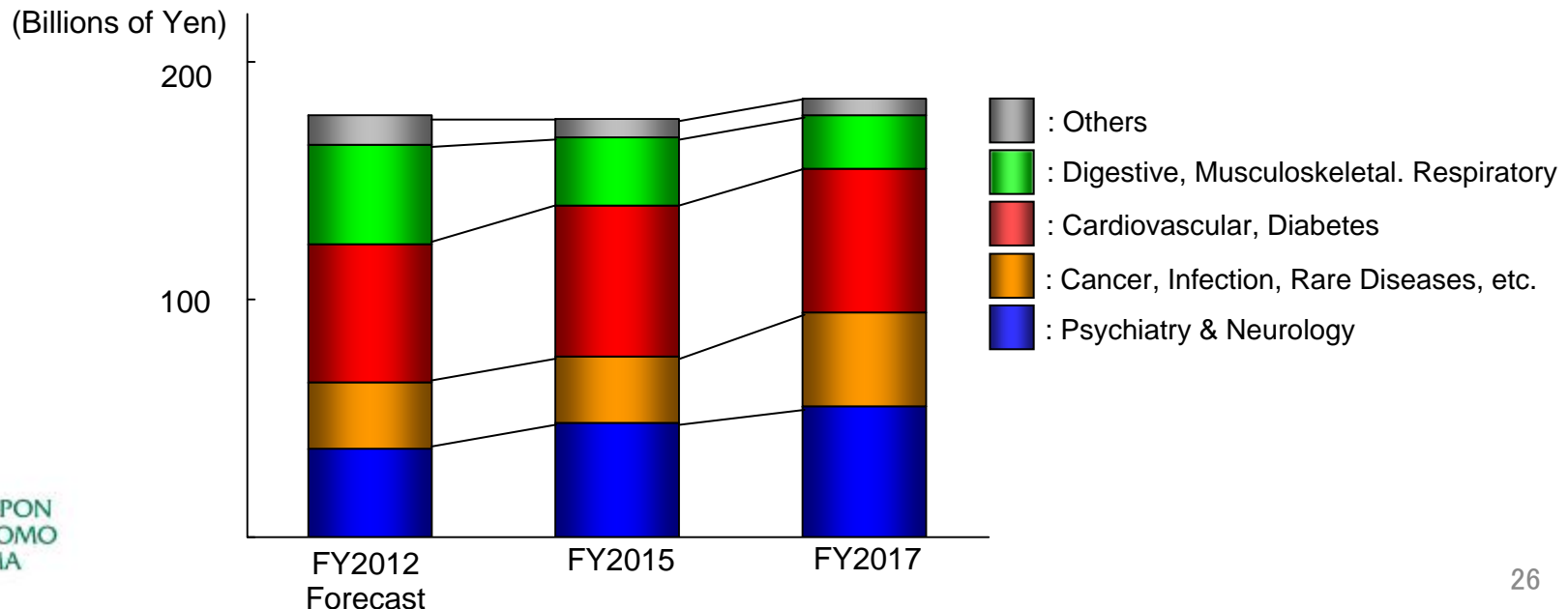
Japan: Expand new products to offset revenue drop of long-listed brands



Regional Strategy (3): Japan Business - 1

Growth led by Global Products

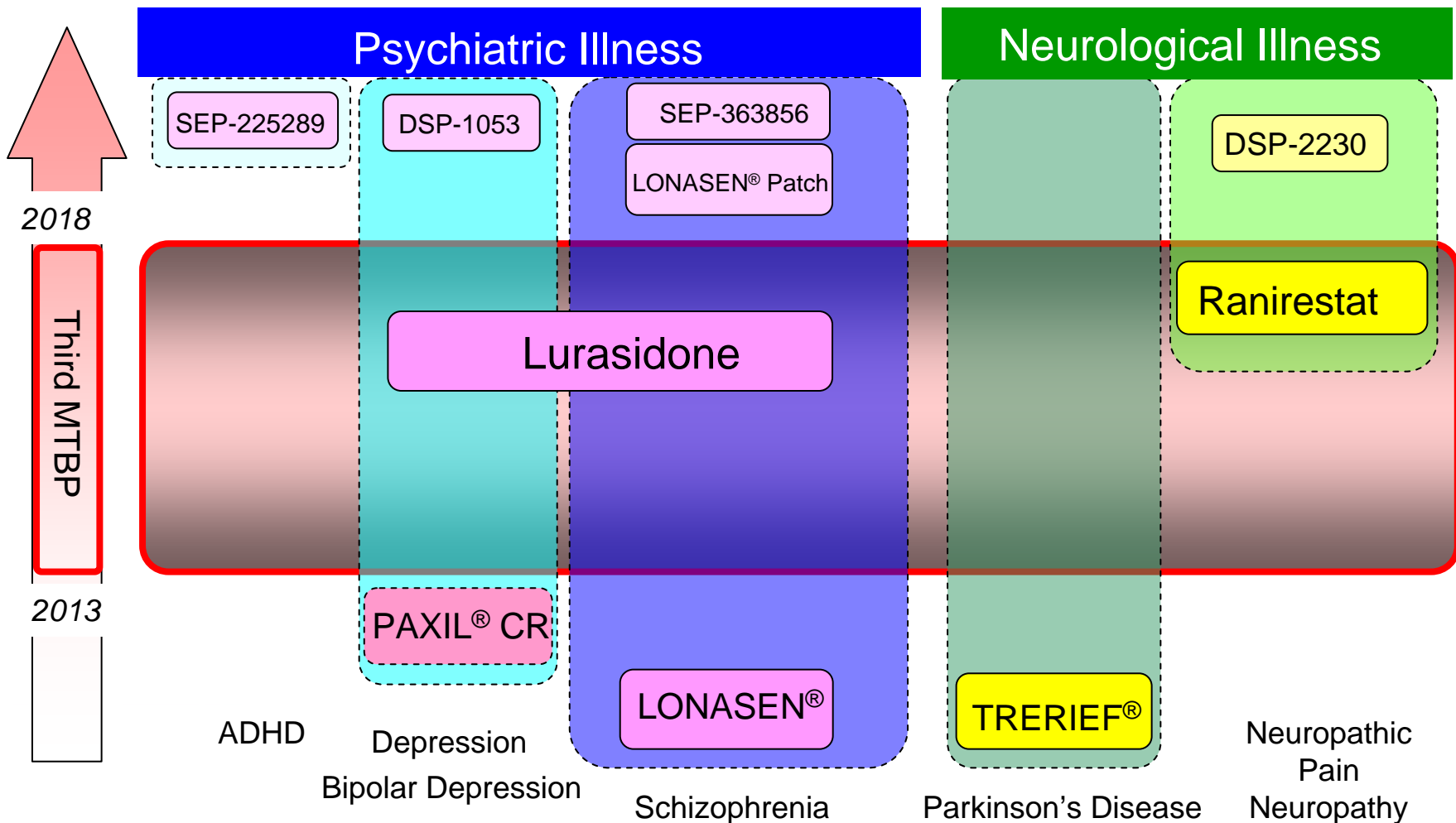
- Focus resources on growth products to increase sales
 - Cardiovascular: Maintain business scale by focusing on AIMIX®
 - Diabetes: Steady growth from METGLUCO® and SUREPOST®
 - Psychiatry & Neurology: Build a key revenue stream for Japan by maximizing LONASEN® and TRERIEF®
- Accelerating growth through the launch of global products
 - Accelerate the launch and maximize the indications for lurasidone
 - Establish a presence in the oncology market through the launch of BBI608
- Offer sales activities that address diverse needs of our customers
- Expand the pipeline through in-licensing and alliances



Regional Strategy (3): Japan Business - 2

- Strengthening Psychiatry & Neurology -

- LONASEN® and TRERIEF® : Focus on building clinical evidence in Japan
- Lurasidone: Use global evidence and quickly expand indications
- Pipeline Expansion: Start clinical studies in Japan for global development compounds and proactively seek for alliances and in-licensing opportunities



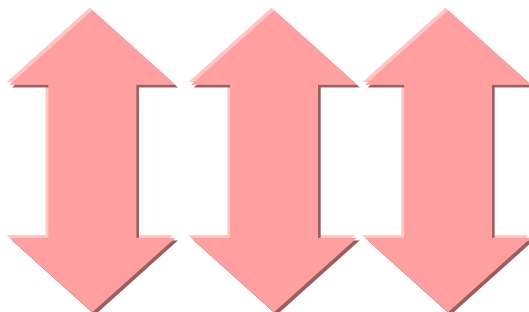
Regional Strategy (3): Japan Business - 3

Offer customer-oriented information and roll-out hybrid marketing activities

Diverse needs and values of customers

“DSP AMBITION”

Sales activities from the patient’s point of view



“Hybrid Marketing”

Combination of personal detailing and e-detailing

Personal Detailing

Optimal placement of general sales reps and effective use of specialist sales reps



e-Detailing

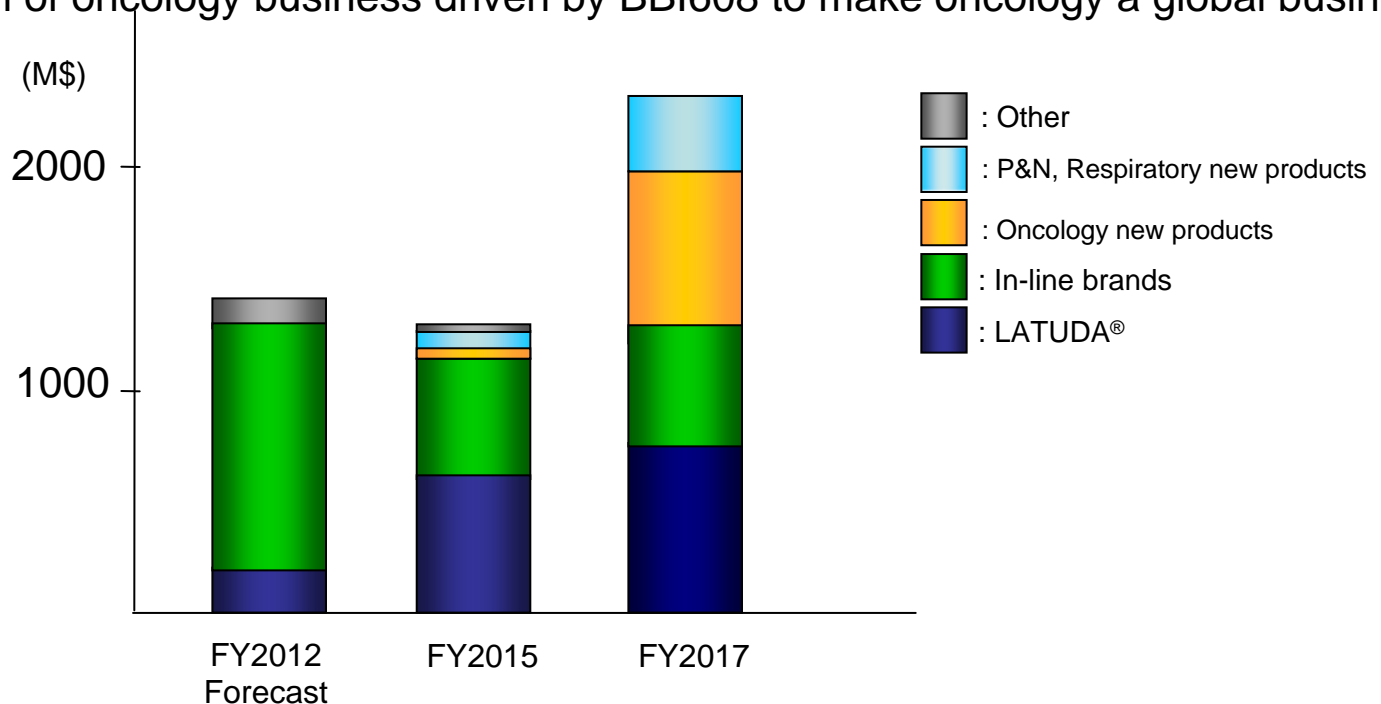
A variety of marketing techniques (with or without sales reps)

Enhance Medical Affairs functions

Regional Strategy (4): North America

Expand profit from LATUDA® and new products

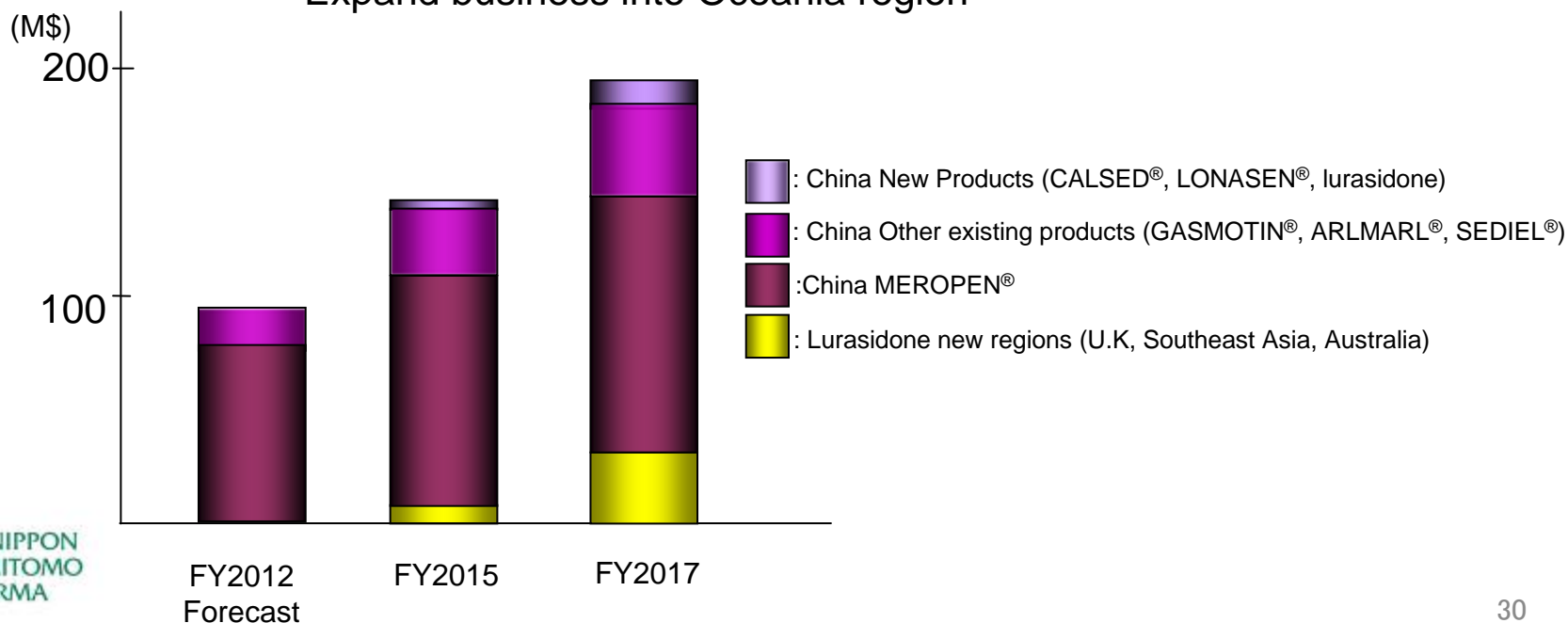
- Maximize profit from LATUDA® in North America
- Further promote operational efficiency at Sunovion
- Expand Sunovion businesses
 - Establish cell therapy business from the successful launch of SB623
 - Strengthen business foundations in Psychiatry & Neurology, Respiratory and other specialty areas through acquiring development pipeline
- Develop business in the oncology area
 - Launch of oncology business driven by BBI608 to make oncology a global business



Regional Strategy (5): China, Europe, Southeast Asia

Regional expansion driven by lurasidone

- China:
 - Efficiently increase profit from existing 4 products (including alliances)
 - Ensure launch of new products (CALSED[®], LONASEN[®], lurasidone)
- Europe:
 - Launch our own sales organization in the UK for lurasidone, Expand business into other European countries
- Southeast Asia:
 - Pursue lurasidone business with our Singapore subsidiary as a base
 - Expand business into Oceania region



R&D Strategy (1)

[Focus Therapeutic Areas]

- Psychiatry & Neurology
- Oncology

[Explore new business fields]

- Cell Therapy/Regenerative Medicine



■ Psychiatry & Neurology

- Psychiatric illnesses (schizophrenia, depression, cognitive dysfunction): focusing on areas of high unmet medical needs
- Alzheimer's disease, neuropathic pain, developmental disorders, neurodegenerative disorders

■ Oncology

- Continually create leading-edge, breakthrough products under the strong collaboration between BBI (US) and the DSP Cancer Institute (Japan)

■ Cell Therapy / Regenerative Medicine

- R&D for clinical application to intractable diseases

R&D Strategy (2)

Strengthen capability to generate globally competitive new medicines

Increase speed and improve efficiency for R&D

- Transform the R&D system to create innovative medicines
- Establish an efficient global development structure
- Invest in high priority products to accelerate development
- Proactively use leading-edge science in drug discovery including iPS cells
- Promote collaborative research with academia

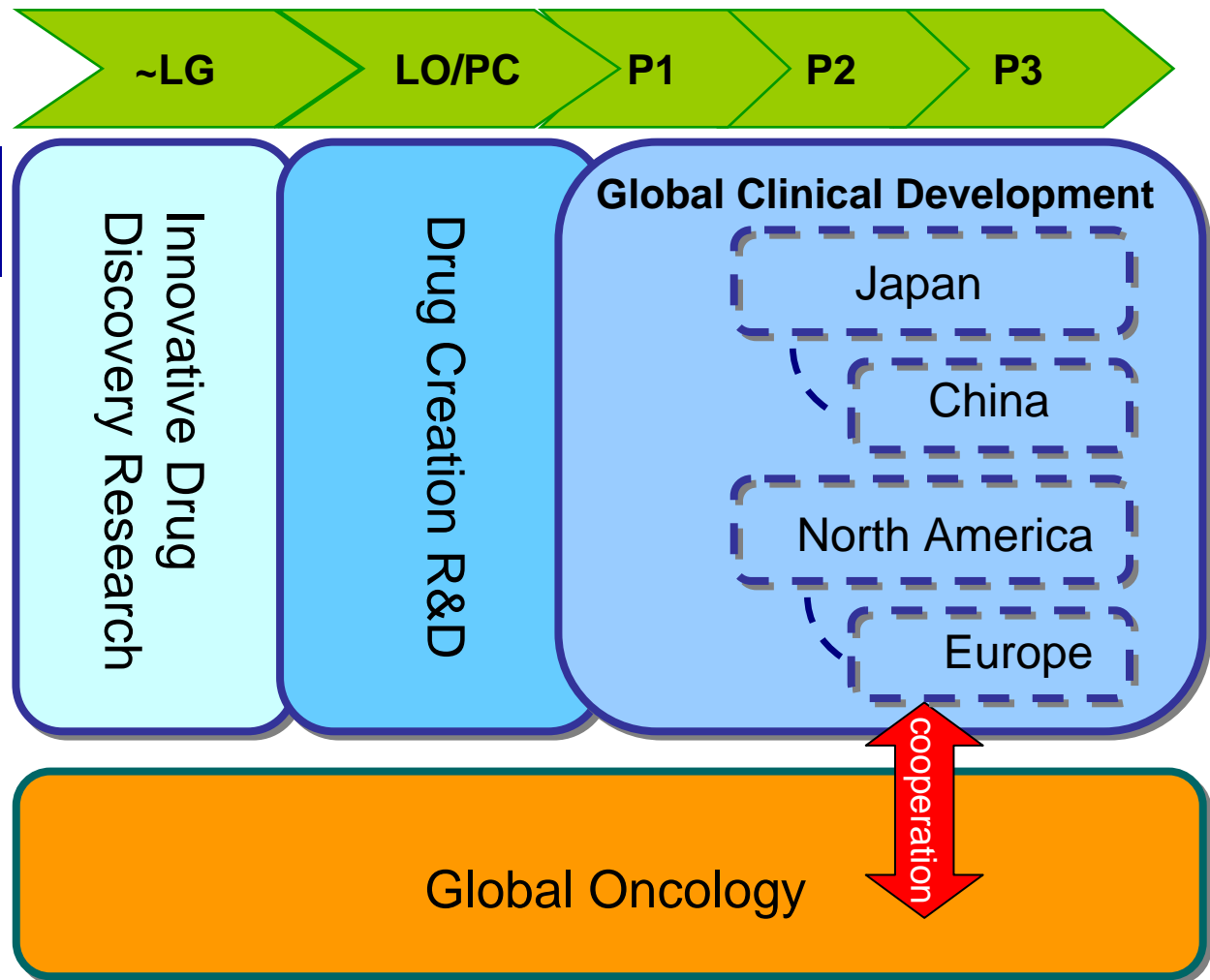


- Non-oncology areas (including Psychiatry & Neurology):
 - Ten compounds to start clinical studies by FY2017
 - One compound to obtain PoC every year
- Oncology:
 - Eight compounds to start clinical studies by FY2017

R&D Strategy (3)

New R&D structure (tentative)

- By therapeutic area, by development stage -



Psychiatry & Neurology
Other Specialty

- ✓ Focus on innovation in early stage
- ✓ Efficient operation and decision making at each stage

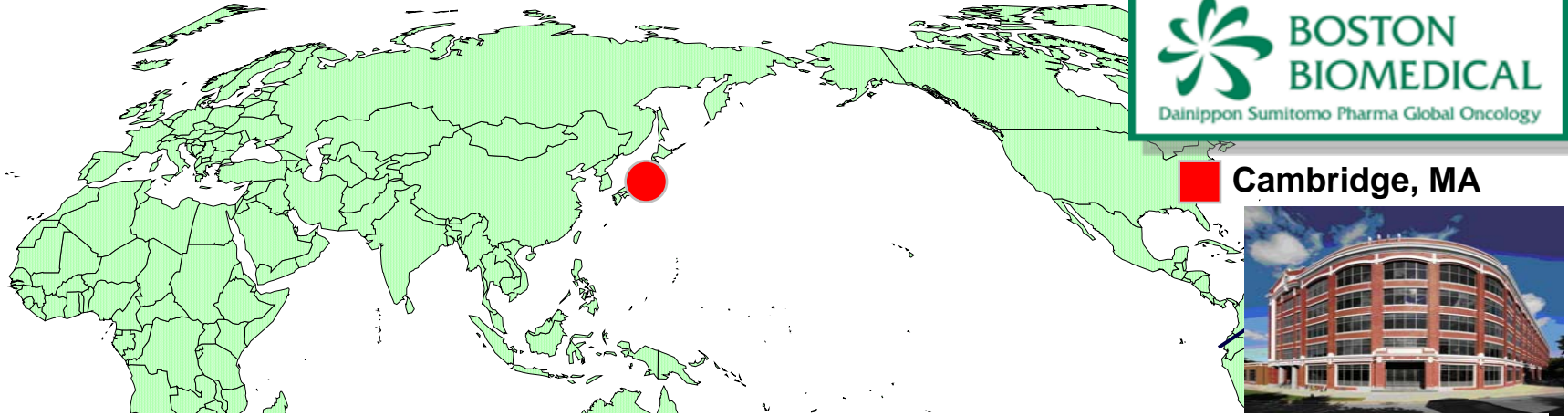
Oncology

- ✓ Independent operation
- ✓ Streamlined and seamless operation

* LG: Lead Generation LO: Lead Optimization

R&D Strategy (4)

DSP Global Oncology



Japan

North America

R&D
-Create infrastructure
-Establish organization

- Research: Osaka (DSP Cancer Institute)
- Development: Osaka, Tokyo
- Management: Global Oncology Office

- BBI to be the core of Global Oncology R&D
- Increase staff to 100 (R&D)

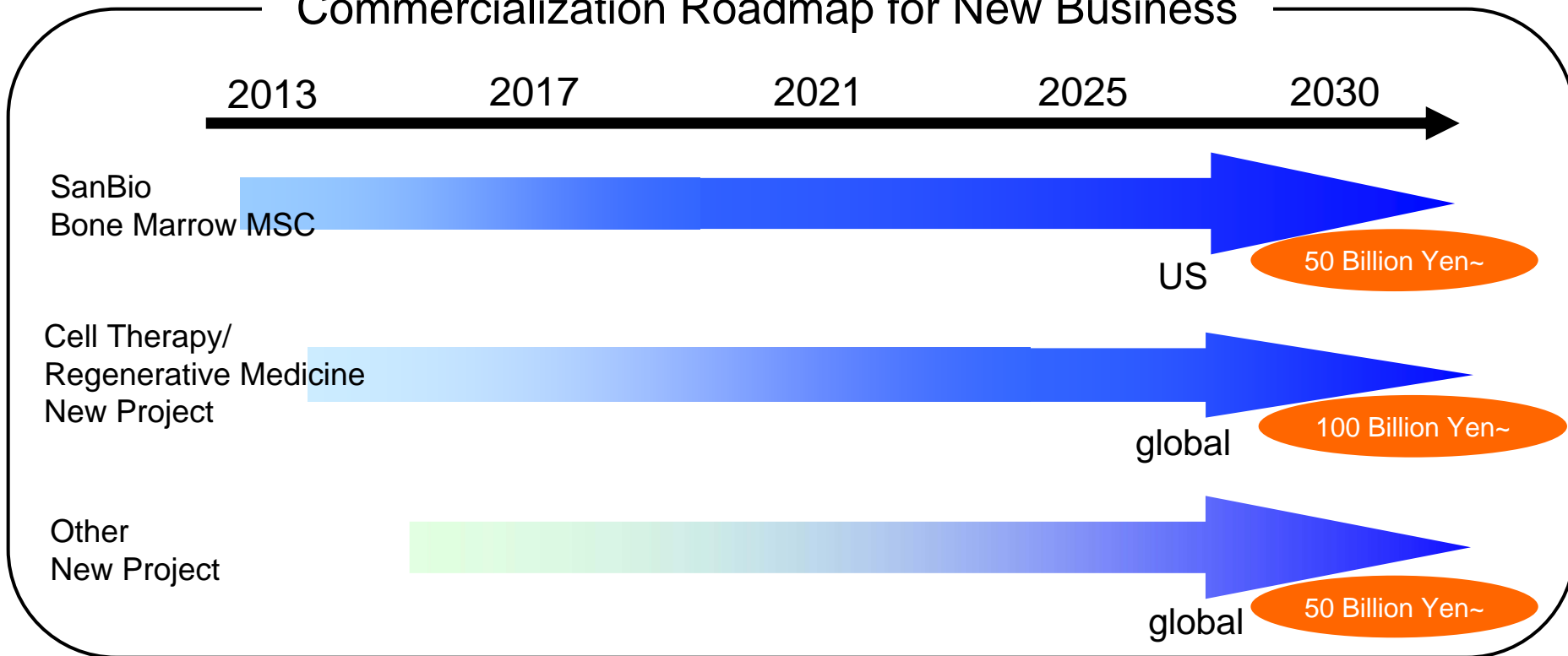
R&D Strategy

- Global Leader in cancer stem cell research
BBI608(P3) : Target FY2015 US approval and FY2016 Japan approval
BBI503(P1) : Approval target in US/Japan in FY2017
- Drug discovery based on cancer immunotherapy and new concepts
WT2725/4869(P1) : Establish PoC in FY2015
- Expand global oncology pipeline
Eight compounds to start clinical studies by FY2017

R&D Strategy (5)

Explore New Business Fields

Commercialization Roadmap for New Business



Become a company that contributes to health outcomes by commercializing cell therapy/regenerative medicine and through full-scale initiatives in preventative care such as vaccines and diagnostics

Investment/Financial Strategy and Shareholder Returns

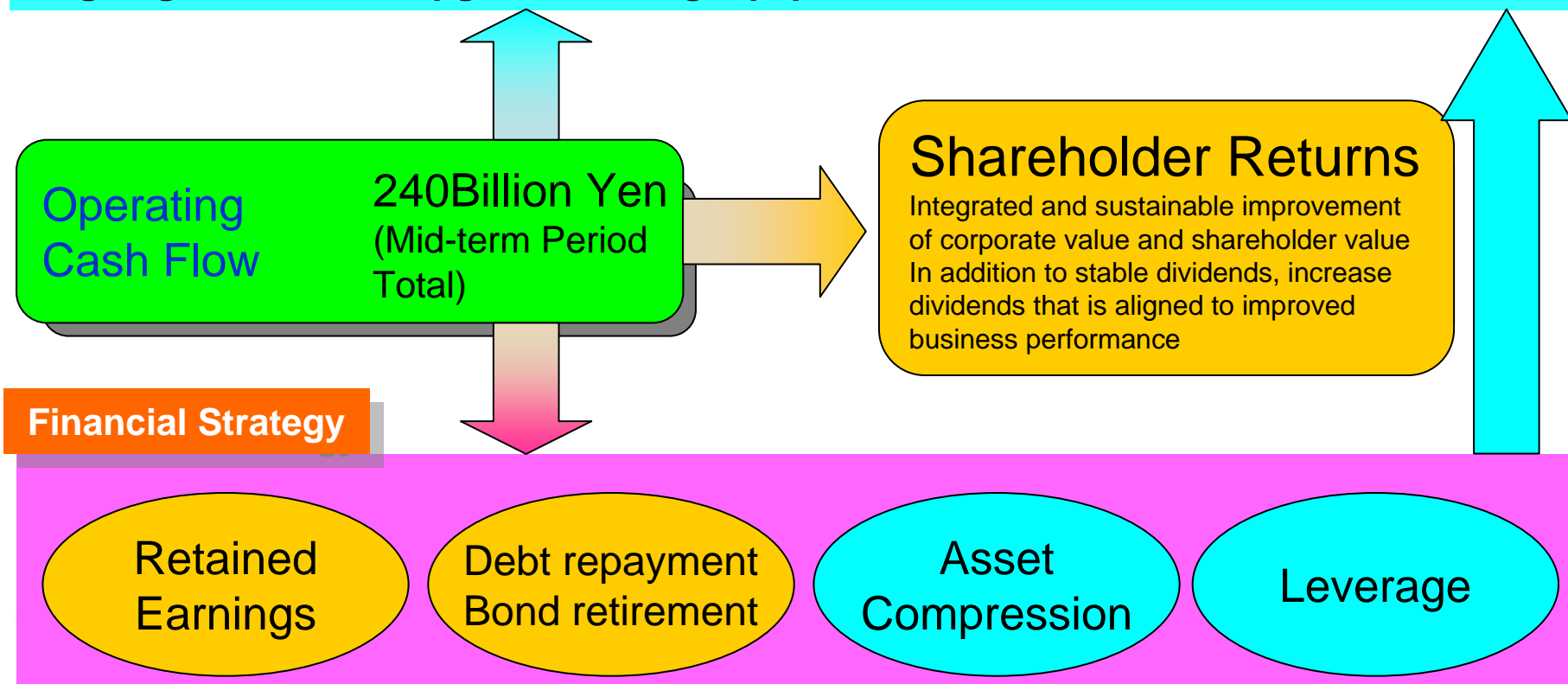
Investment Strategy

New
Investment

Japan: Augment pipeline to ensure expansion of business (in-license, alliances, etc)
North America: Enhance pipeline to offset LATUDA® loss of exclusivity (in-license, acquisitions, etc)
New Business: Cell Therapy/Regenerative Medicine/Vaccines/Diagnostics
Europe: Establish and expand business foundations (alliances, acquisitions, etc)

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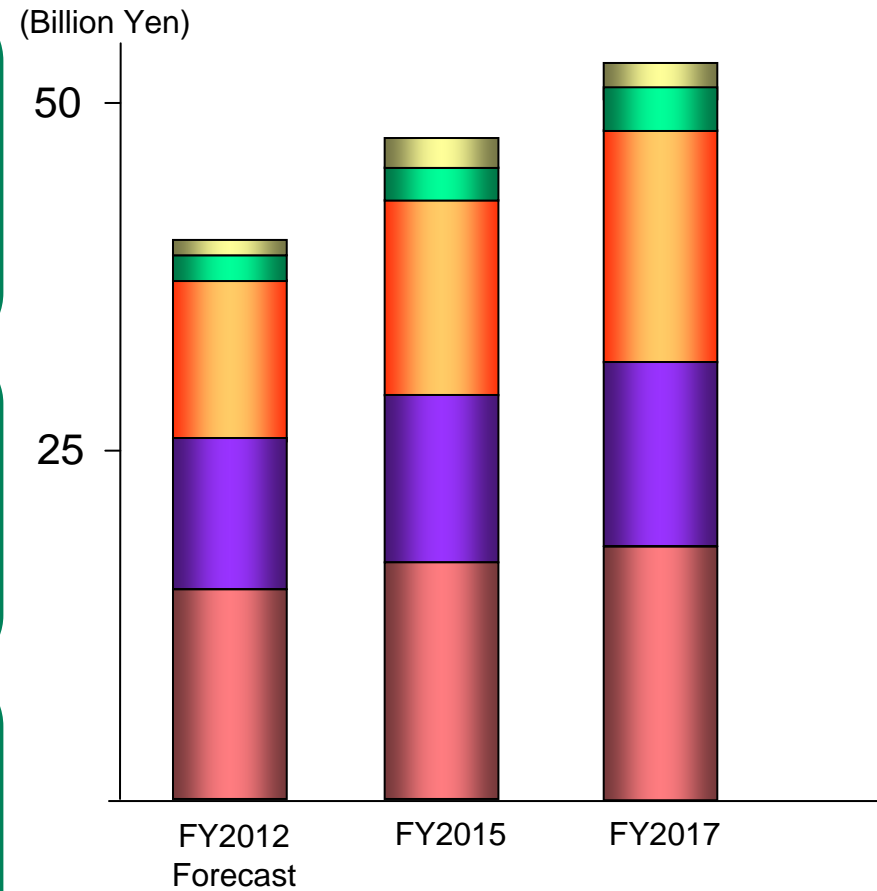
Ongoing investment: Upgrade existing equipment and facilities, etc.



Non-Pharmaceutical Business Strategy

Non-Pharmaceutical Business Strategy (1)

Achieve over 50 billion yen in sales by quickly expanding new products



Non-Pharmaceutical Business Strategy (2)

Food Ingredients and Chemicals

DSP Gokyo Food & Chemical Co., Ltd.

- Maximize the corporate value that integrates profile as a R&D focused manufacturer with trading firm functions in order to increase business value
- Build a foothold for overseas expansion by accelerating the creation and discovery of new business and new products
- Shift resources to growth areas in food business. In chemical business, further strengthen and improve business foundation through alliance with leading partners

Veterinary Medicines

DS Pharma Animal Health Co., Ltd.

- Expand sales in small animal business by promoting PLCM for in-line products and by launching new products
- Maximize product value by building and penetrating new evidence and also through marketing initiatives that emphasize product profile
- Enrich pipeline based on product portfolio strategy and focus on early launch

Diagnostic Agents, Research Materials

DS Pharma Biomedical Co., Ltd.

- Promote biomarker development that generates synergies with the pharmaceutical business
- Strengthen the development pipeline, while ensuring early launches of new products
- Promote measures to maximize sales from existing products including overseas expansion

Strengthen Business Foundation

Strengthen Business Foundation (1)

- Towards a leaner corporate structure -

Establish a robust business management structure that can respond flexibly to changes in the business environment

In Pursuit of Management Efficiency

- Decrease SG&A costs and increase efficiency of assets
- Optimize personnel
- Promote relocation of sites
- Accelerate efficiency in decision-making processes and the execution of operations
- Streamline organization

Strengthen Business Foundation (2)

- Towards a leaner corporate structure -

Create Strong Corporate Culture

- Emphasize corporate culture that encourages willingness to take on a challenge
- Establish differentiated personnel evaluation system
- Further develop global talent

Promote CSR Management

- Further penetrate Corporate Mission, Management Mission and Declaration of Conduct
- Strengthen our corporate governance globally
- Promote social contribution activities in and out of Japan and improve the vitality of employees
- Promote communication with various stakeholders

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