

Mitsubishi Tanabe Pharma Corporation Medium-Term Management Plan 16-20



Mitsubishi Tanabe Pharma

Open Up the Future

Masayuki Mitsuka

President and Representative Director

Open Up the Future

The operating environment in the pharmaceutical industry is undergoing dramatic change.

In this setting, we must steer our own course and implement reforms to become a “company that works with a sense of speed and is the first to deliver differentiated value.”

Open Up the Future

In accordance with this key concept, Mitsubishi Tanabe Pharma will open up the future of medicine.

We will continue to contribute to the healthier lives of people around the world through the creation of new pharmaceuticals.

Agenda

▶ Review of Medium-Term Management Plan 11-15

▶ Medium-Term Management Plan 16-20

▶ Overview

▶ Four Strategic Priorities to Open Up the Future

1. Maximizing Pipeline Value
2. Strengthening IKUYAKU* and Marketing
*Drug Fostering and Evolution
3. Accelerating U.S. Business Development
4. Reforming Operational Productivity

▶ Financial Guidance

Review of Medium-Term Management Plan 11-15

Review of Medium-Term Management Plan 11-15

Domestic Business

- ① Growth of Remicade and Simponi: Sales of more than ¥100.0 billion (NHI drug price basis)
- Growth in sales resulting from the launch of new drugs and post-marketing development for existing priority products
- Cost reductions achieved through structural reforms
- ✕ Lower revenues from long-listed drugs due to reevaluation of the NHI drug price system and measures to promote the use of generic drugs
- ✕ Did not reach sales target for the generic drug business the generic drug business

Overseas Business

- ① Substantial growth recorded by Gilenya, INVOKANA
- ✕ Delay in Accelerating U.S. Business Development due to the discontinuation of drug candidates in the field of kidney diseases

Fiscal 2015 Financial Guidance

(Japan GAAP)

	Initial Objectives
	Announced October 2011
Net sales	¥500.0 billion
Operating income	¥100.0 billion

Revised Objectives	Forecasts
Announced April 2014	Announced September 2015
¥410.0 billion	¥418.0 billion
¥65.0 billion	¥82.0 billion



Creating Value through the Launch of New Drugs and IKUYAKU for Existing Priority Products

New *Value Creation*

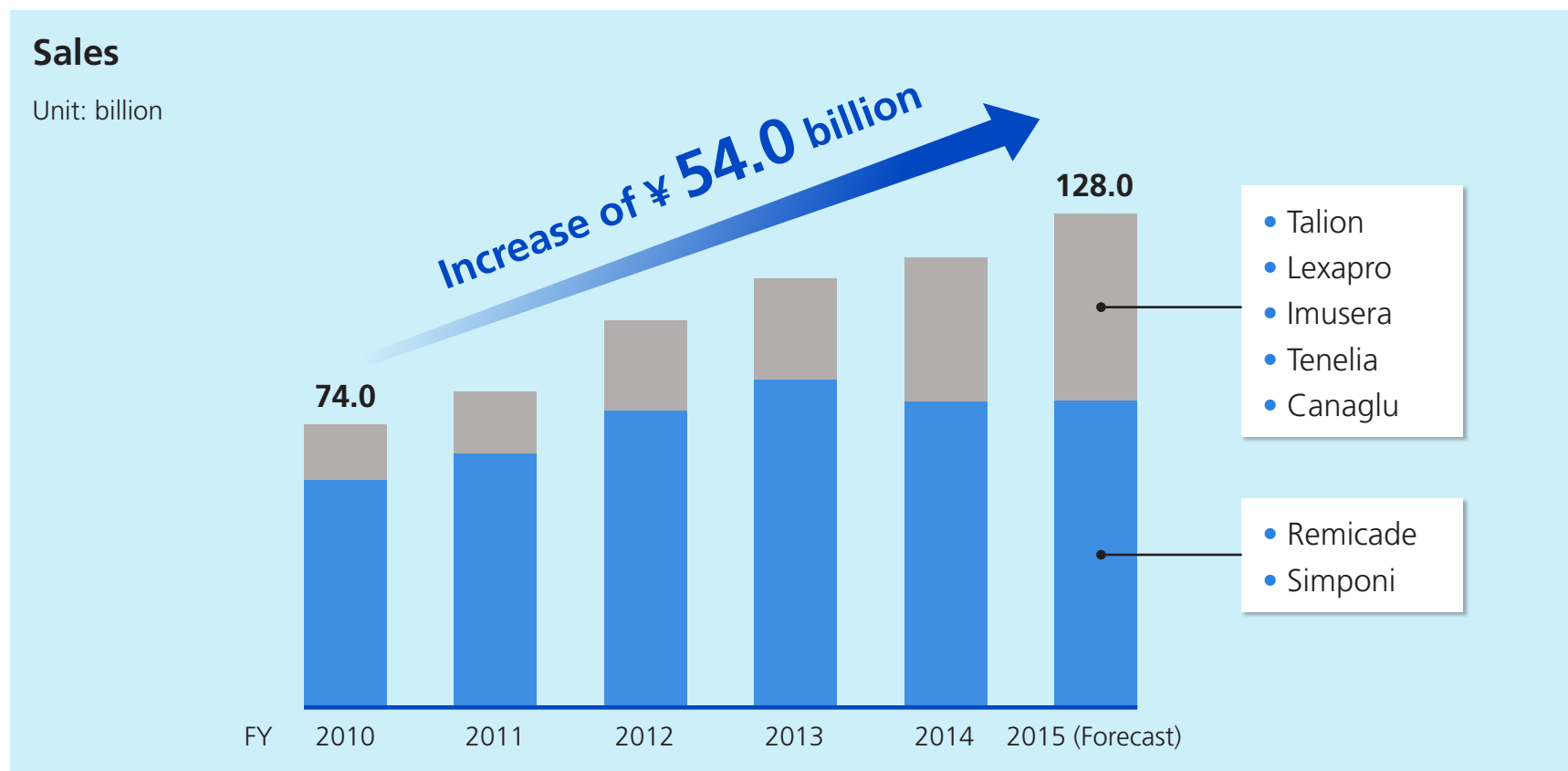
Key results in the launch of new drugs and IKUYAKU

	Product name	Indication	(FY)	Overseas licensee
Launch of New Drugs <div>Joint sales</div>	Imusera	Multiple sclerosis (MS)	(2011)	Gilenya: Novartis (launched in the U.S. in 2010)
	Simponi	Rheumatoid arthritis (RA)	(2011)	
	Tenelia	Type 2 diabetes mellitus	(2012)	
	Canaglu	Type 2 diabetes mellitus	(2014)	INVOKANA: Janssen Pharmaceuticals (launched in the U.S. in 2013)
	Tetrabik	Combined vaccine for four diseases	(2012)	
	Lexapro	Depression Social anxiety disorder (SAD)	(2011) (2015)	
Integrated Value Development	Remicade	Change in dosage for Crohn's disease	(2011)	
		Reduction in IV administration time	(2012)	
		Change in dosage for psoriasis	(2015)	
		Behcet's disease with special lesions	(2015)	
	Maintate	Heart failure Atrial fibrillation	(2011) (2013)	
	Talion	Pediatric allergic disease	(2015)	
	Radicut	Amyotrophic lateral sclerosis (ALS)	(2015)	

Growth in Priority Products in Japan

Favorable growth in domestic sales of priority products (7 products)

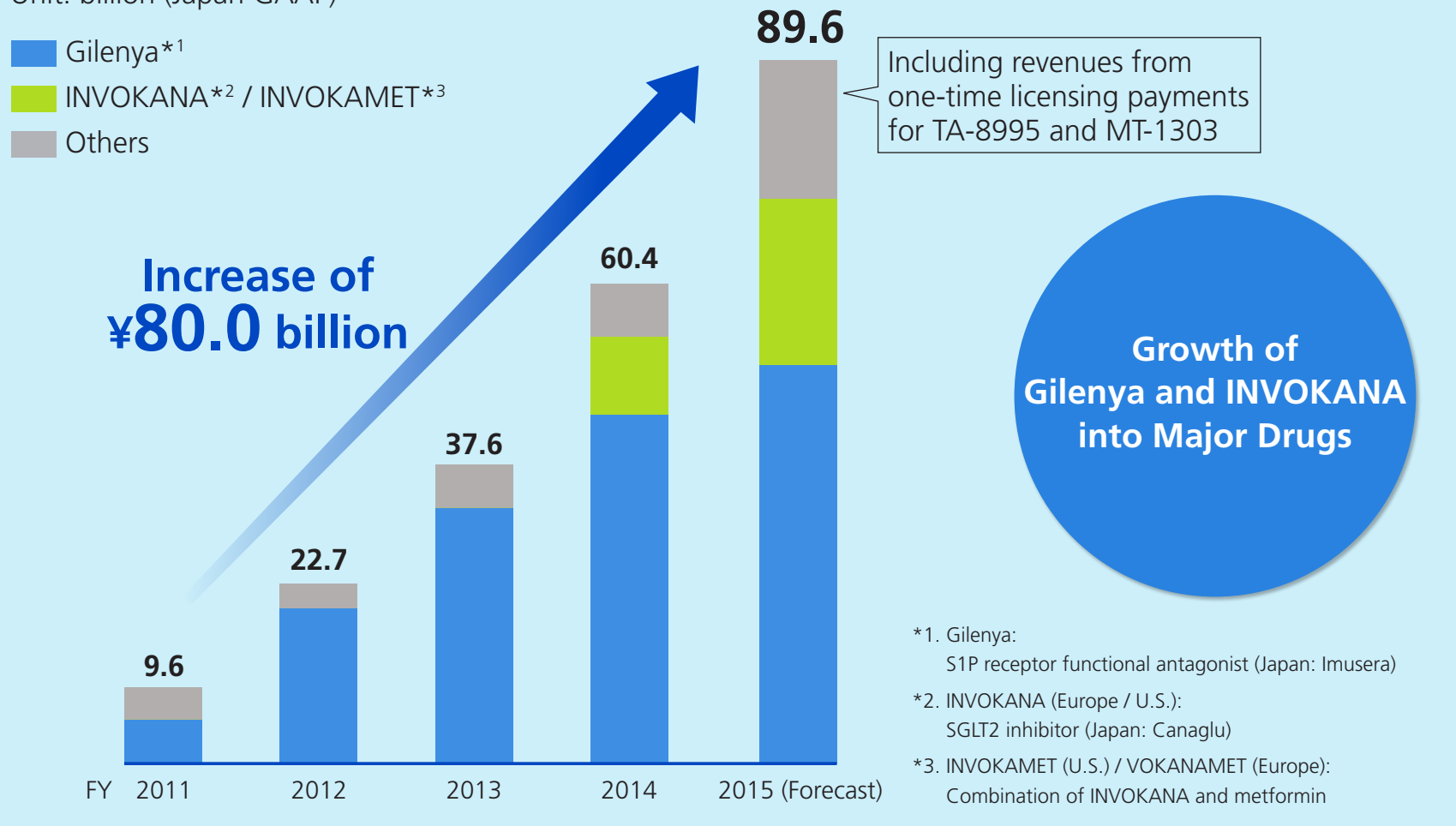
- ▶ Remicade and Simponi: Sales of more than ¥100.0 billion (NHI drug price basis)
- ▶ Growth in sales resulting from the launch of new drugs and IKUYAKU



Continuously Discovering New Products that Are Used around the World

Revenues from Running Royalties and Milestone payments (RR / MS)

Unit: billion (Japan GAAP)

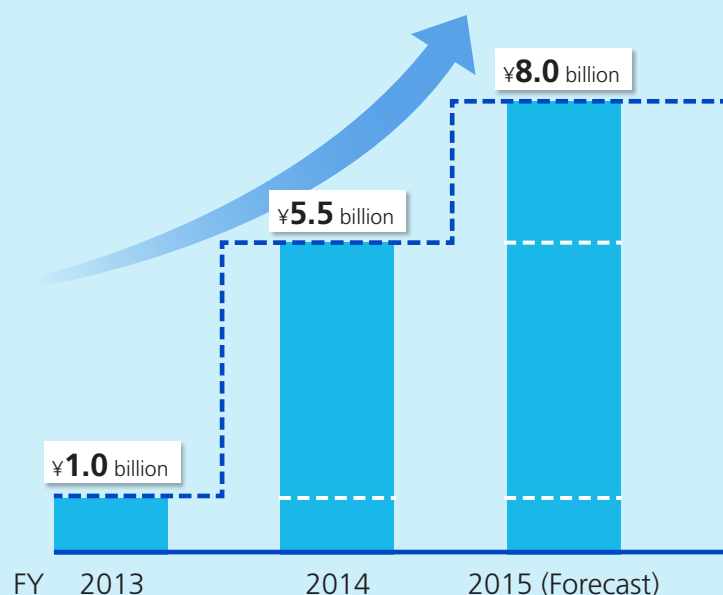


Progress of Structural Reforms

Forecasting ¥8.0 billion in cost reductions in FY 2015 as a result of structural reforms.

Progress of Cost Reductions

Benchmark: FY 2012 expenses



Concentration on core business

- ▶ Transfer of Plasma fractionation (FY 2012)
- ▶ Transfer of Fine chemical operations (FY 2012)
- ▶ Transfer of Intravenous solution operations in China (FY 2014)

Consolidation of domestic manufacturing bases

- ▶ Transfer of Ashikaga Plant (FY 2014)
- ▶ Transfer of Kashima Plant (FY 2015)

Consolidation of discovery research bases

- ▶ Closure of Kazusa Office (FY 2015)

Rebuilding purchasing system, reevaluating departmental administrative processes

- ▶ ¥4.0 billion in cost reductions in FY 2014

Medium-Term Management Plan 16-20



Challenges That Will Be Faced During the Medium-Term Management Plan 16-20

Domestic Business

- ▶ Reevaluation of NHI drug price system
- ▶ Progress of measures to promote use of generics (target: 80%)

Overseas Business

- ▶ Advance into the U.S., the largest growth market (growth rate: 5% - 8%)
- ▶ Gilenya cliff

*Source: IMS Global Outlook for Medicines Through 2018 (Nov 2014)



With the domestic business environment becoming increasingly severe and competition to acquire new drug candidates intensifying around the world, we must overcome the Gilenya cliff and record growth centered on the U.S.

Overview of Medium-Term Management Plan 16-20

▶ Key Concept

Open Up the Future

▶ Period

April 2016 - March 2021

▶ Objectives to be achieved during the plan

1. Invest ¥400.0 billion in R&D, launch new drugs with the potential for worldwide roll-out
2. Domestic pharmaceutical sales of ¥300.0 billion
New drugs and priority products sales ratio of 75% (ethical pharmaceuticals)
3. Full-scale roll-out of U.S. business, overseas sales of ¥200.0 billion
(Overseas sales ratio of 40%, including running royalties and milestone payments)
4. Consolidated domestic workforce of 5,000 employees*, Cost of sales, SG&A expenses reduced by ¥20.0 billion

*As of the end of September 2015: 6,176 employees

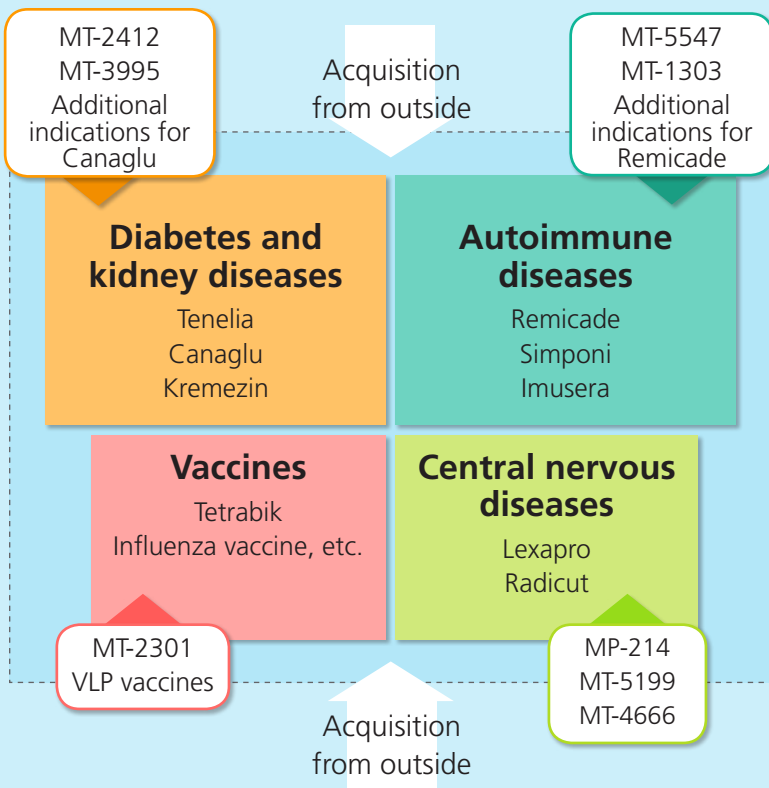
▶ Financial Guidance (IFRS)

	Fiscal 2020
Net sales	¥500.0 billion
Core earnings	¥100.0 billion

Business Strategies for 2020

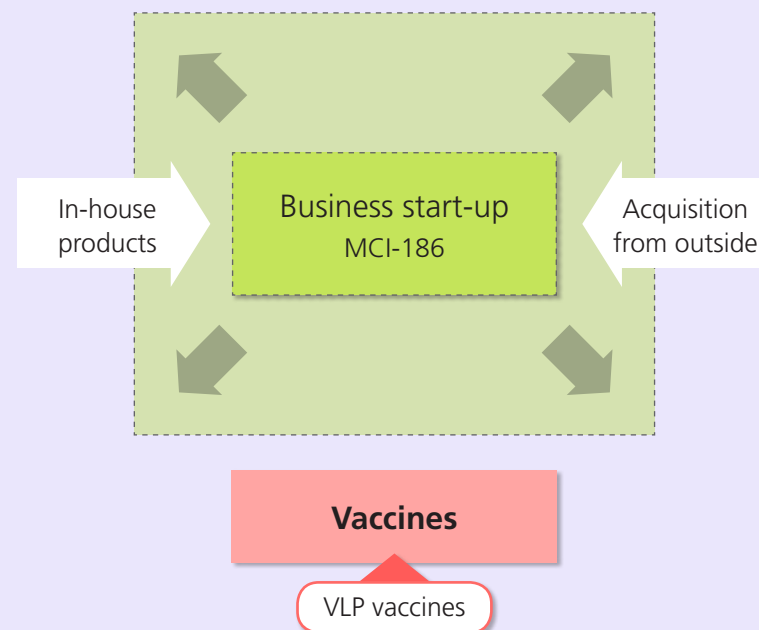
Japan

We will strengthen our business in four disease areas through the launch of new drugs and the acquisition of additional indications and evidence for existing drugs.



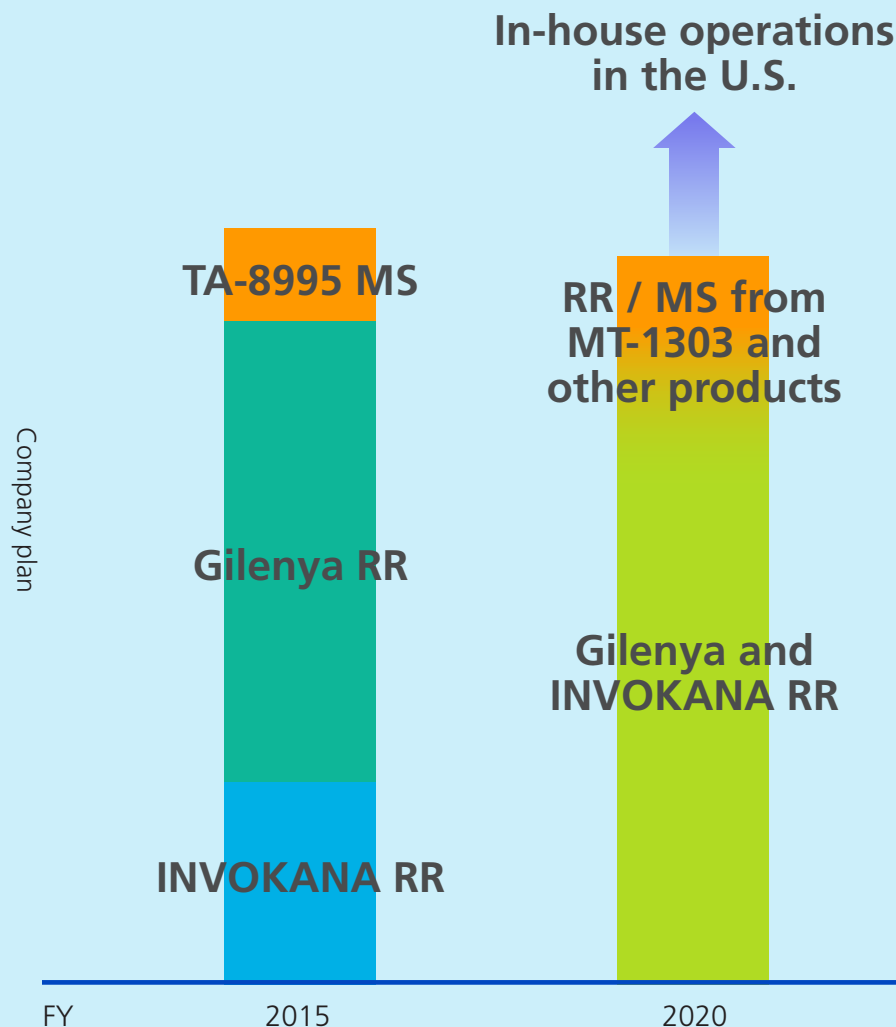
U.S.

Establish a presence in specialized fields by rapidly starting up our own business in the U.S.



Overcoming the Gilenya Cliff

- ▶ Anticipating favorable growth in INVOKANA running royalties
- ▶ In regard to the decline in running royalties due to Gilenya going off patent in the U.S., we will secure revenues through running royalties and milestone payments for other out-licensed products
- ▶ Contribution to revenues from full-scale operations in the U.S.



Four Strategic Priorities to Open Up the Future





Four Strategic Priorities to Open Up the Future

1

Maximizing Pipeline Value

- Late-stage drug candidate objectives
10 candidates (including in-licensed candidates)
- Investment in R&D
More than ¥400.0 billion

2

Strengthening IKUYAKU and Marketing

- Domestic sales objective
¥300.0 billion (FY 2020)
New drugs and priority products sales ratio: 75%
- Priority disease areas
Autoimmune diseases, diabetes and kidney, central nervous system, vaccines

Investment

Earnings

3

Accelerating U.S. Business Development

- U.S. sales objective
¥80.0 billion (FY 2020)
- U.S. strategic investment
More than ¥200.0 billion

4

Reforming Operational Productivity

- Cost of sales / SG&A expenses reduction objective ¥20.0 billion (FY 2020, in comparison with FY 2015)
 - Number of employees
Consolidated domestic workforce: 5,000 employees*
- *As of the end of September 2015: 6,176 employees

1

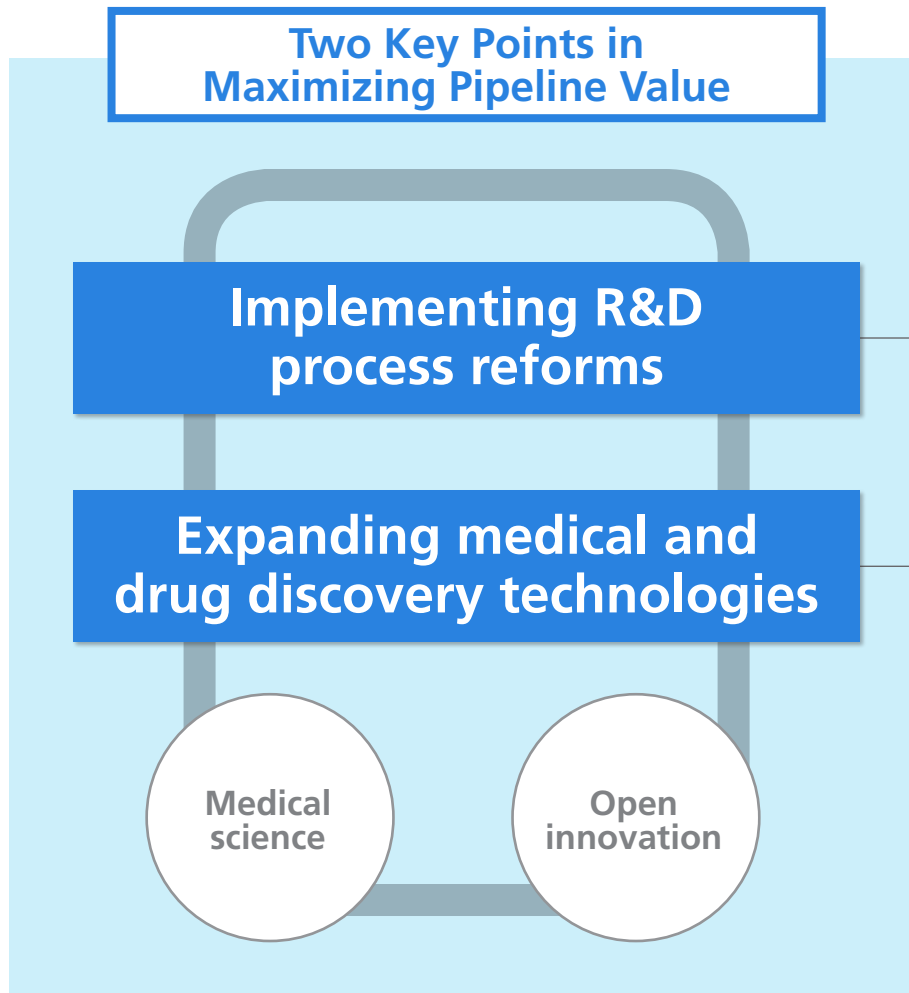
Maximizing Pipeline Value

Open Up the Future of Pharmaceuticals



**Creating differentiated value
as rapidly as possible**

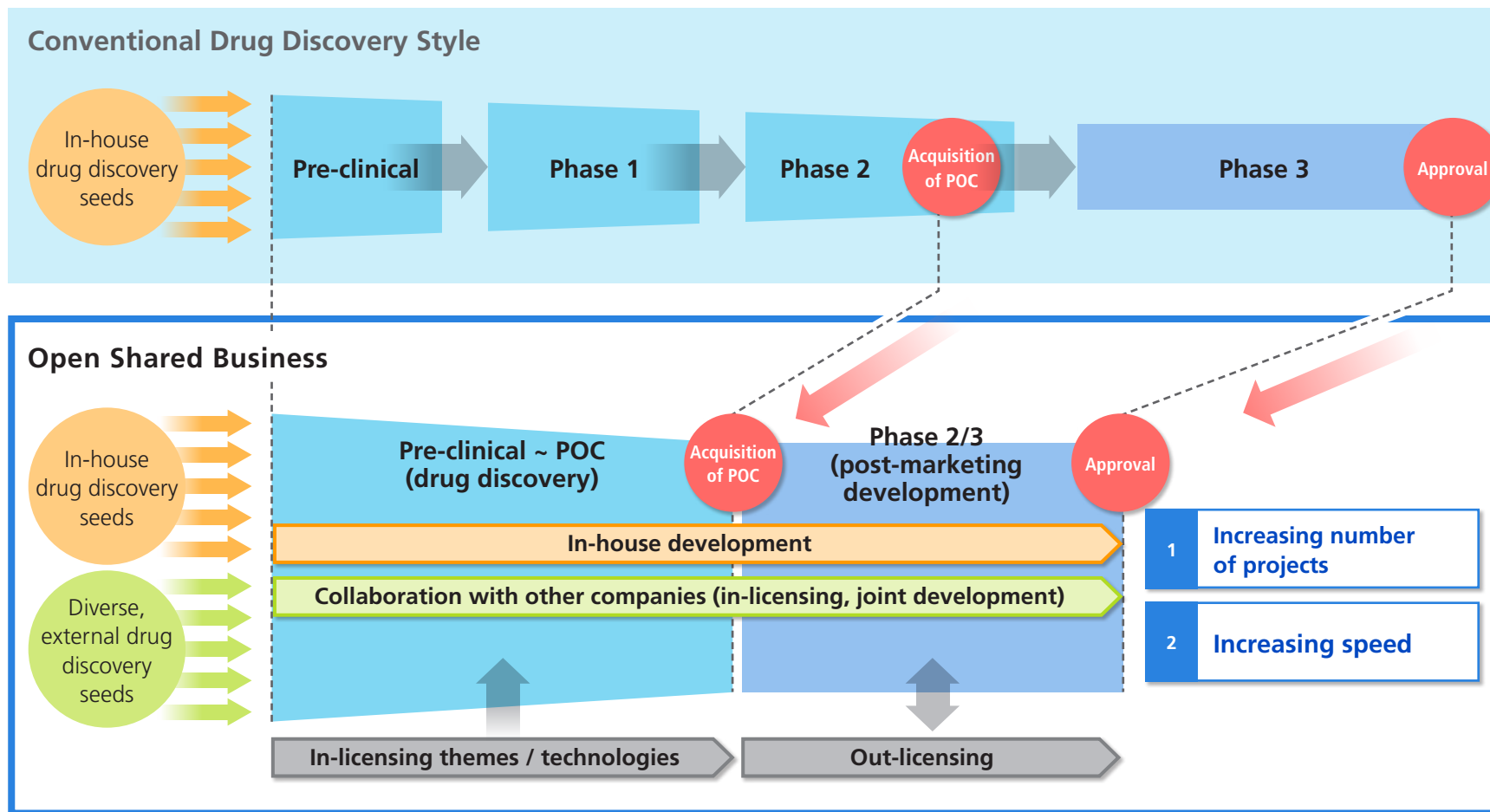
Basic Policies



- Increasing R&D speed and doubling the number of projects
- Anticipating the future of medicine and strictly selecting discovery targets and indications with the potential for worldwide roll-out
- Discovering pharmaceuticals using diverse discovery technology approaches

Implementing R&D Process Reforms

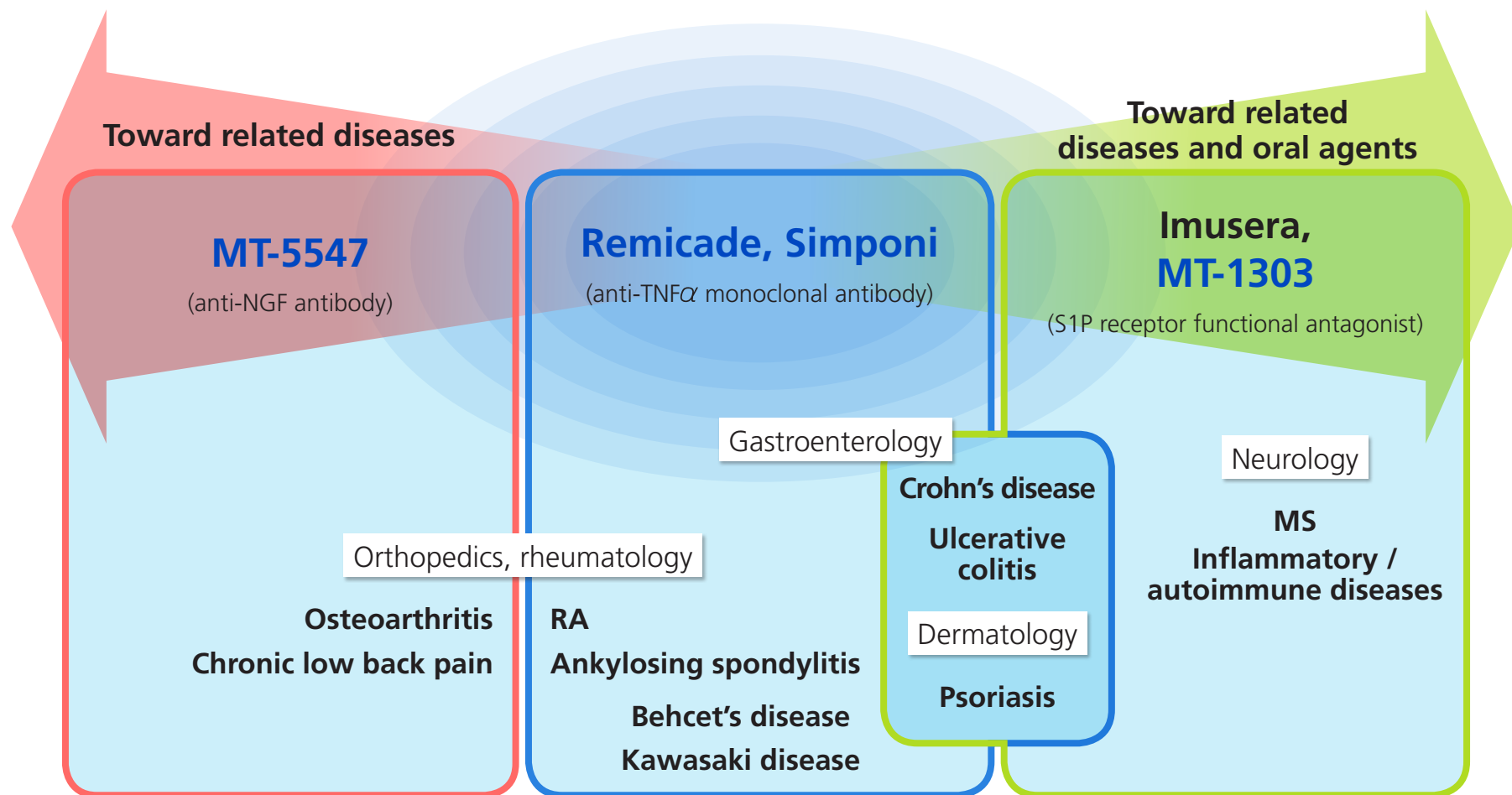
Leverage open shared business to create **10 late-stage drug candidates**





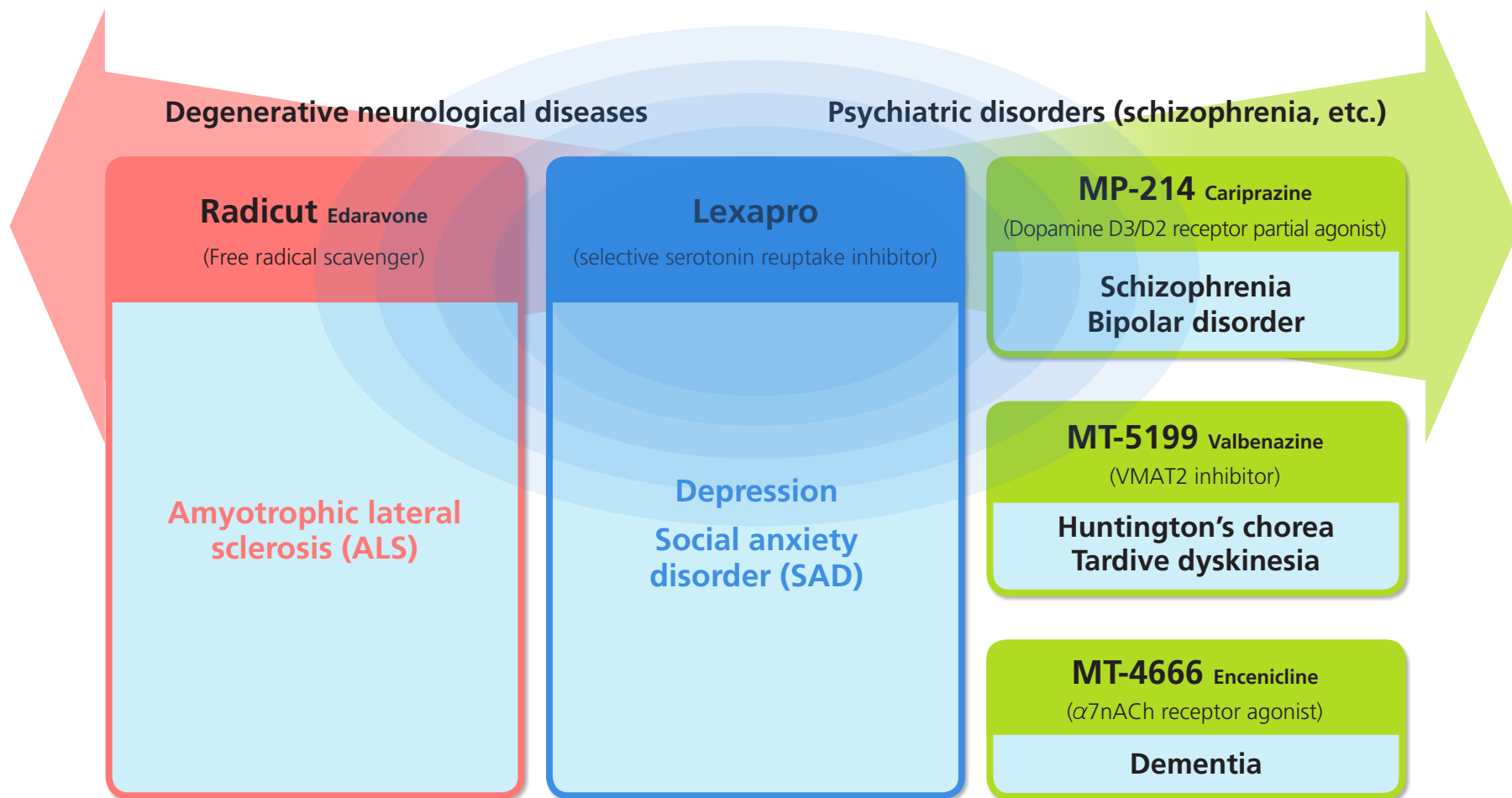
Expanding in the Autoimmune Diseases Area

Discover new drugs that can provide new treatment opportunities, provide wide-ranging coverage of autoimmune diseases area



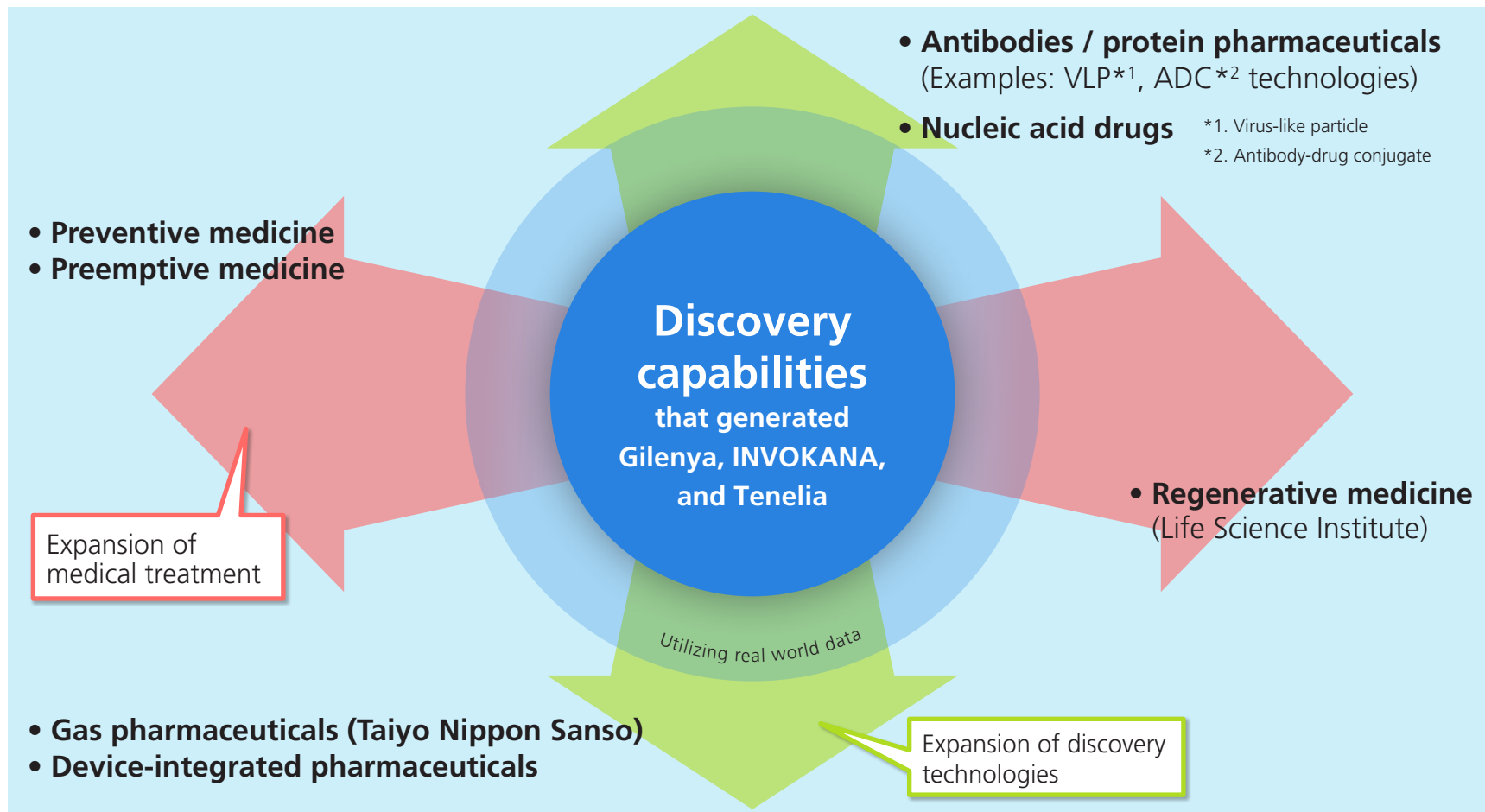
Expanding in the Central Nervous System Diseases Area

Discover new drugs that address unmet medical needs in the areas of degenerative neurological disorders and psychiatric disorders (schizophrenia, etc.)





Expanding to the Drugs of the Future



Collaboration with companies in the Mitsubishi Chemical Holdings Group, establishment of New Value Creation Office, utilization of MPH, a U.S.-based investment company, and TRL, an in-house venture company.


New Initiatives to Open Up the Future of Medicine

Initiatives in regenerative medicine (New Value Creation Office)

- ▶ Collaboration with Life Science Institute, AnGes MG
- ▶ New initiatives in gene therapy and cell therapy aimed at functional regeneration


 Development of new methods of treatment

Rolling out plant-derived VLP technologies (Medicago)

- ▶ (Virus-like particles) VLP
 - Efficiently induce immune response
 - Higher safety than live vaccines
-  Development of new vaccines
- Influenza virus vaccine
 - Rotavirus vaccine

New initiatives in preemptive medicine ("Sohyaku. Innovative Research Division")

- ▶ Accumulating molecular change information using clinical samples (joint research with Johns Hopkins University, Hokkaido University)

 Developing new treatment agents and early diagnostic methods using clinical data analysis

Taking on the challenge of new therapeutic antibodies (TRL)

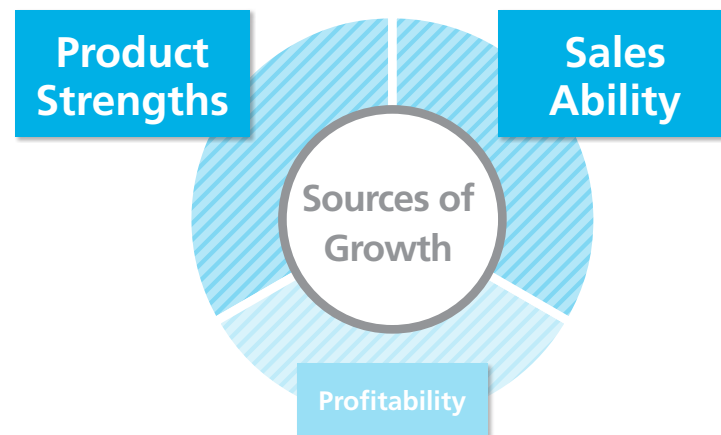
- ▶ Antibody drug conjugates (MedImmune)
- ▶ Bispecific antibody (Covagen)

 Discovering new therapeutic antibodies by drawing on multiple technologies

2

**Strengthening IKUYAKU
and Marketing**

Open Up the Future for Patients



**Delivering differentiated
value to patients**

Basic Policies

Two Key Points in Strengthening IKUYAKU and Marketing

Maximizing product value

Strengthening sales promotions

- Increasing value in the development stage, targeting commercialization
- Increasing product value after launch
- Further enhancing presence in priority disease areas
- Advancing area marketing
- Strengthening information provision for high-value products

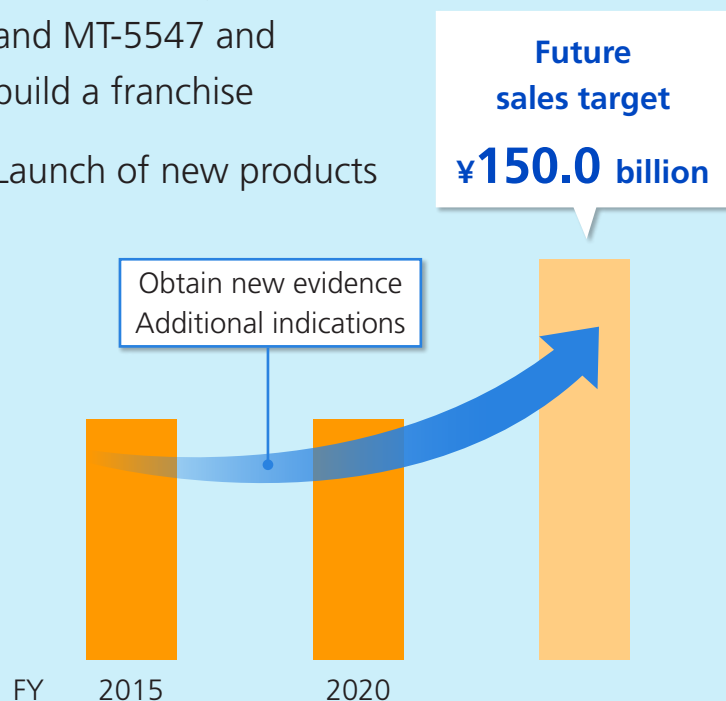


Future Targets in Priority Disease Areas

Autoimmune Diseases

Priority products: Remicade, Simponi, Imusera

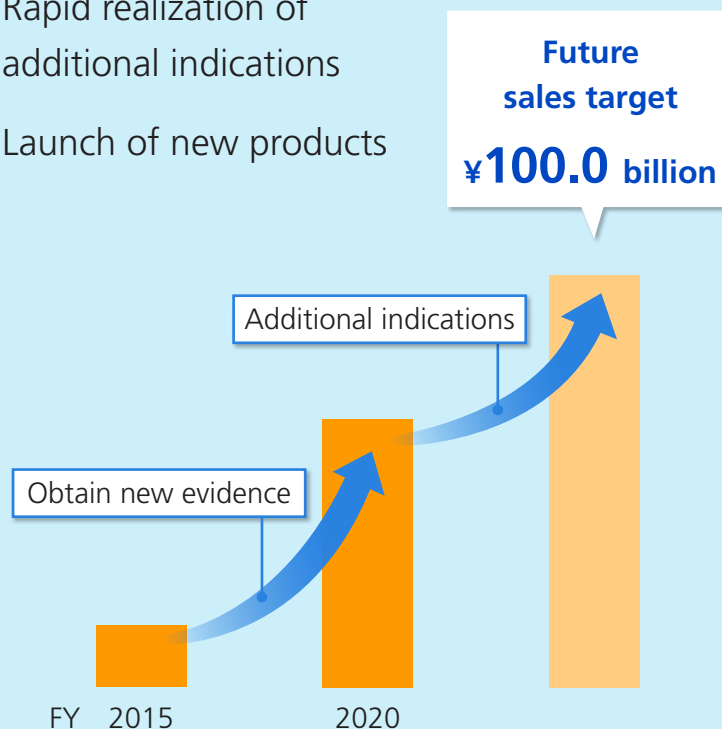
- ▶ Maintain No. 1 share
- ▶ Aim to quickly launch MT-1303 and MT-5547 and build a franchise
- ▶ Launch of new products



Diabetes and Kidney Diseases

Priority products: Tenelia, Canaglu

- ▶ No. 1 presence through new drug growth
- ▶ Rapid realization of additional indications
- ▶ Launch of new products





Initiatives in the Field of Autoimmune Diseases



Remicade



Simponi

No. 1 share in the field

Sustain sales in the field by offsetting the influence of the Remicade NHI drug price revision with higher Remicade sales volume and increased Simponi sales

1

Remicade: Increasing product value through LCM

▶ Future development policy

RA: Wide-ranging education, extending from patients using biologics for the first time to patients for whom other biologics have not been sufficiently effective

Ulcerative colitis: Expand administration of biologics by working to solidify the position of higher treatment objectives

▶ Additional indications

Kawasaki disease, pediatric IBD

▶ Additional dosage

Psoriasis (increased dosage)

2

Simponi: Build into No.1 subcutaneous injection

▶ Future development policy

Work to achieve widespread recognition as biologic that offers both effectiveness and convenience

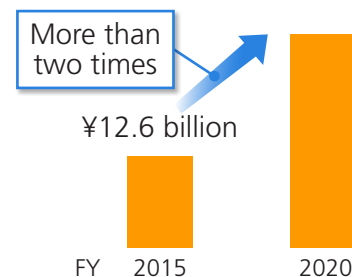
▶ Additional indications

Ulcerative colitis


▶ Additional formulation

100mg syringe

Simponi Sales



Initiatives in Diabetes and Kidney Diseases

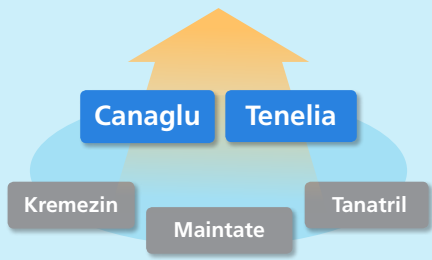


Tenelia

Canaglu

Further strengthen cooperative relationship with Daiichi Sankyo

Demonstrate synergies with existing drugs



Canaglu

Tenelia

Kremezin

Maintate

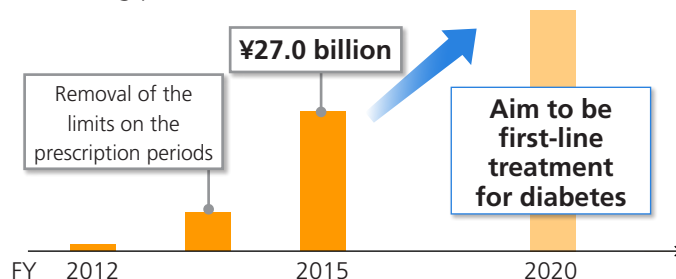
Tanatril

1 Tenelia: Further growth/expansion of share

▶ Future development policy

Differentiate through ease-of-use and effectiveness, such as for senior citizens and patients with impaired kidney function

Combined sales for the Company and Daiichi Sankyo
(NHI drug price basis)



2 Canaglu Build foundation in market

▶ Future development policy

Establish positioning with reference to safety and efficacy

▶ Additional indications

Diabetic nephropathy

▶ Overseas evidence

CANVAS trial (cardiovascular)

CREDENCE trial (kidney diseases)

▶ Launch of combination drug

Expand options through MT-2412

(Combination drug of Canaglu and Tenelia)

2. Strengthening IKUYAKU and Marketing Initiatives in the Areas of Central Nervous System Diseases and Vaccines

Central nervous system diseases

1 Lexapro: Strengthen marketing

▶ Development policy

Leverage opportunity presented by additional indication of social anxiety disorder (SAD) to establish positioning, based on “effectiveness for anxiety.”

2 Continue to launch new drugs in this area

▶ MP-214

Plan to file application in fiscal 2016 as schizophrenia treatment agent

▶ MT-5199

Advance development for tardive dyskinesia and Huntington’s chorea

Vaccines

Open up the future of health from the perspective of new methods of preventing infectious diseases

▶ Strengthen collaboration with BIKEN

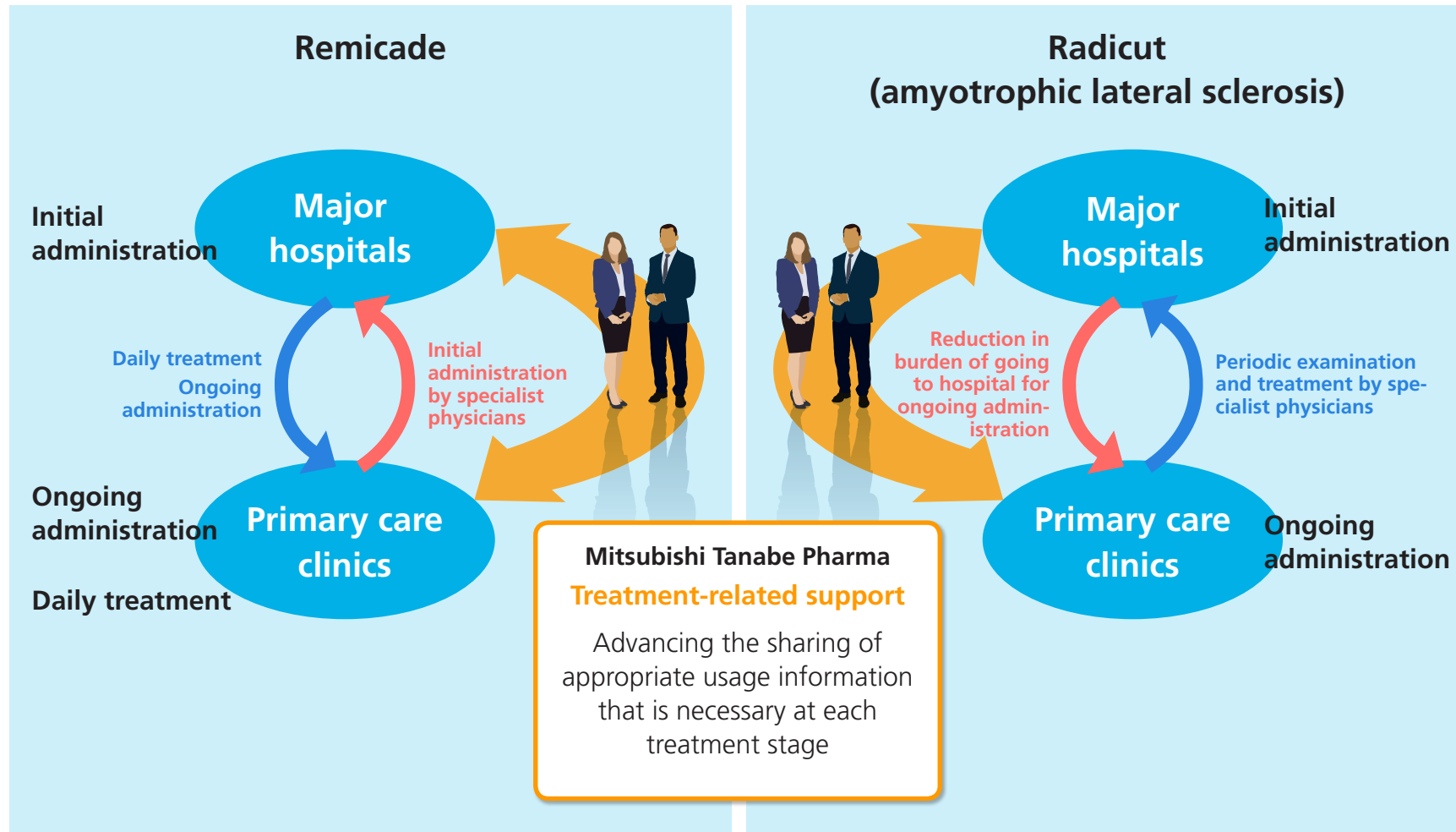
▶ Developing new combined vaccines and in-licensing new devices

▶ Future initiatives

Utilizing Medicago’s VLP technologies

Advancing Area Marketing

Support medical collaboration through the Company's product lineup



2. Strengthening IKUYAKU and Marketing Overcoming Changes in the Domestic Business Environment

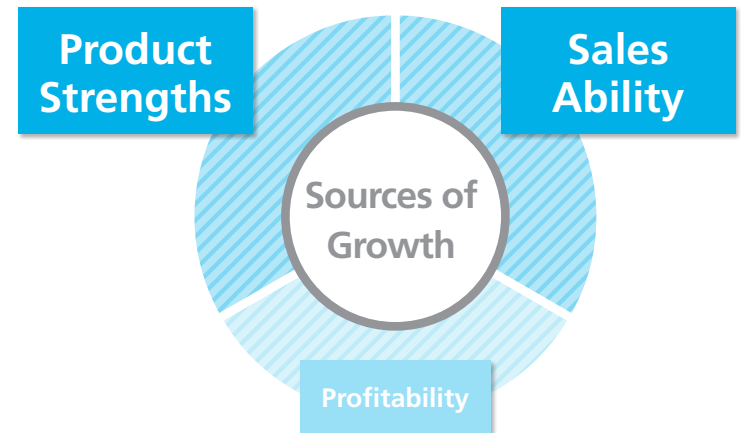
With the domestic market environment becoming increasingly challenging, we will work to achieve sales targets for new drugs and priority products by strengthening IKUYAKU and marketing, leading to strong growth in 2020 and thereafter.



3

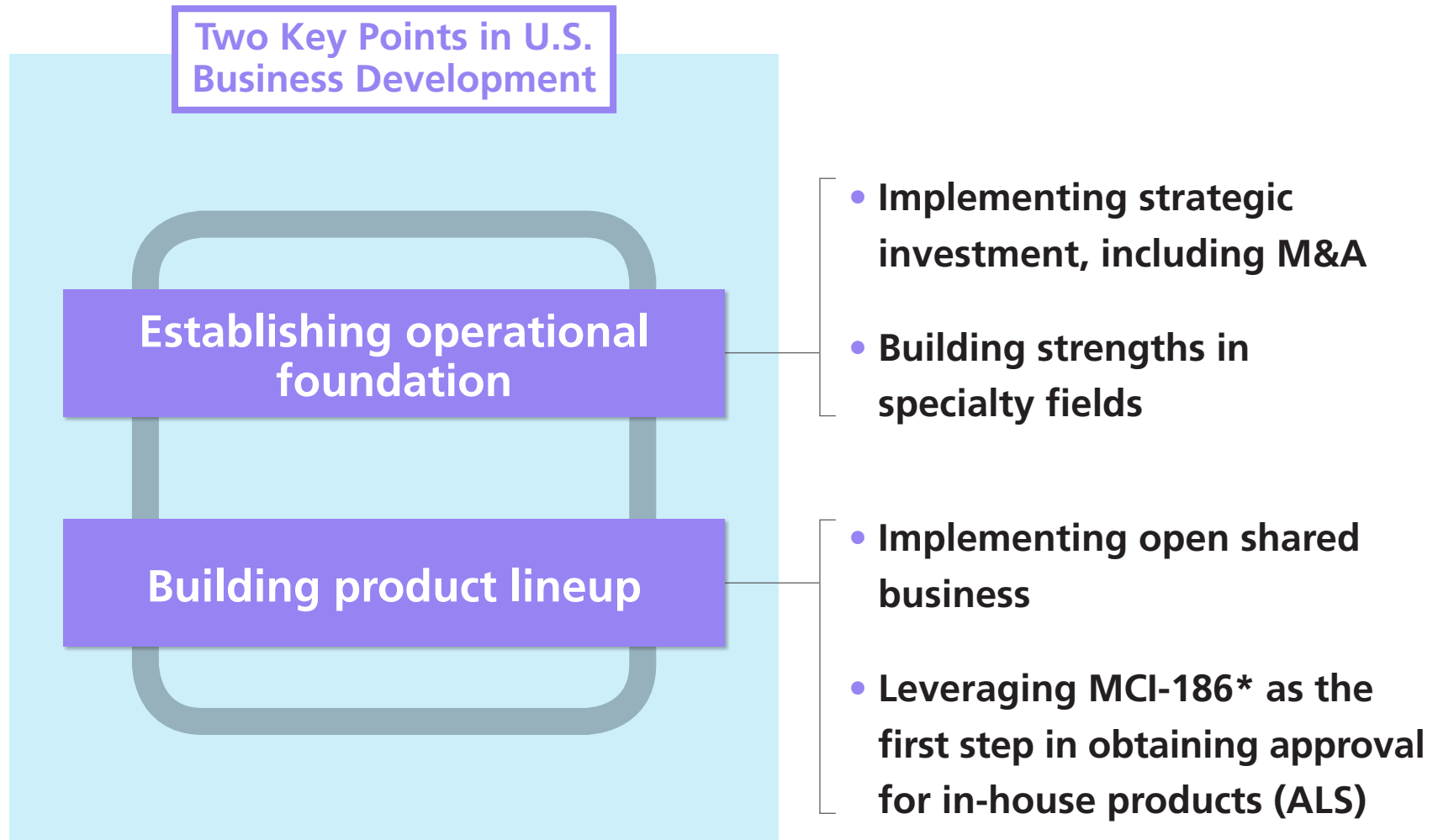
Accelerating U.S.
Business Development

Open Up the Future for Patients



Build foundation for sustained growth

Basic Policies



*Domestic product name: Radicut

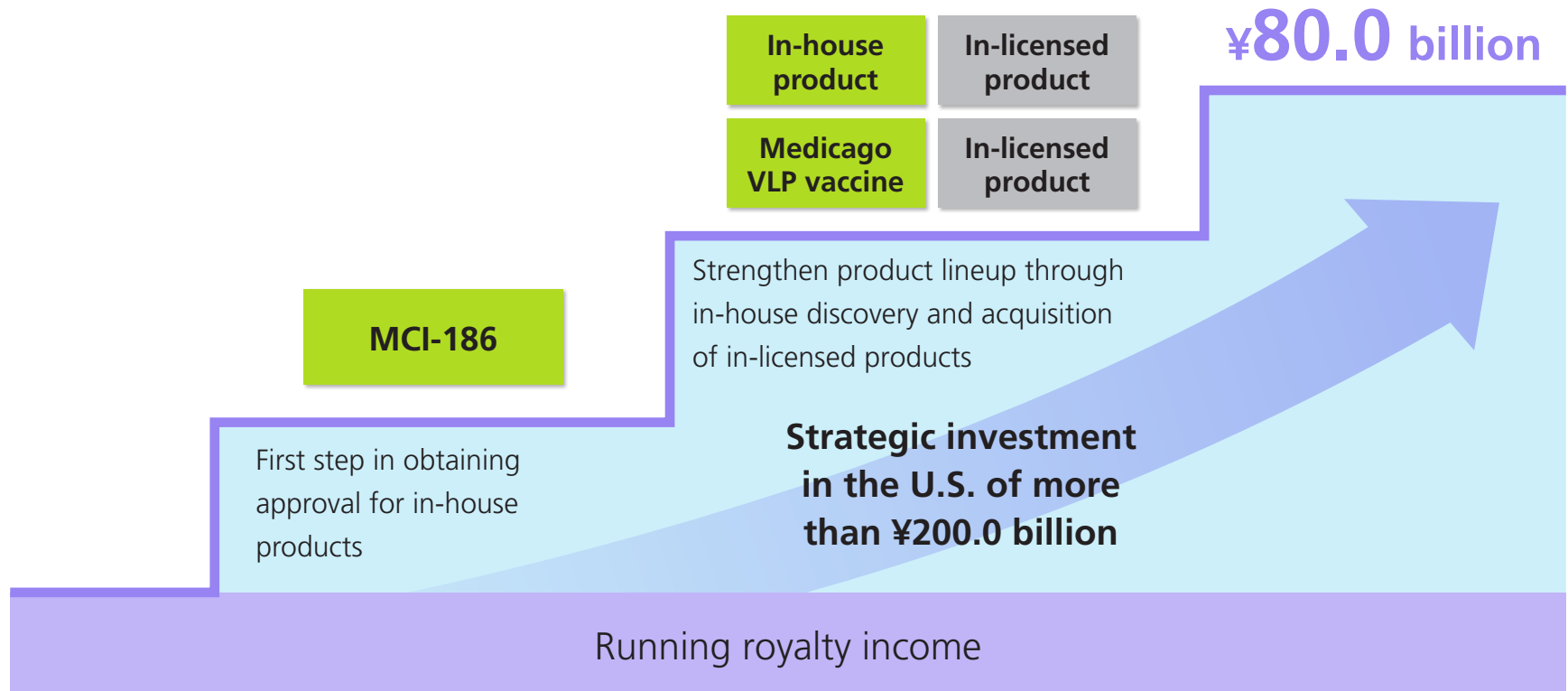
Building a Foundation for U.S. Business

Building a business foundation in specialty fields in the U.S.

- ▶ Build a product lineup, with MCI-186* (indication: ALS) as the first step

*Domestic product name: Radicut

- ▶ Establish a marketing organization that meets the needs of specialists in such fields as neurology



Initiatives with MCI-186 in the U.S.

Amyotrophic lateral sclerosis (ALS)

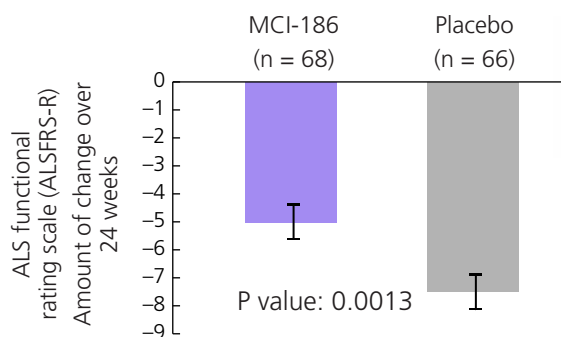
- ▶ **Neurological disease** where **motor neurons degenerate and die**, leading to **muscular atrophy and weakness**.
- ▶ **Progressive disease**, and many patients **die** within 2 to 5 years*¹ after onset of symptoms **due to respiratory failure**.
- ▶ About **6,400 people***² in the U.S. are diagnosed with ALS **each year**.

*1. Source: Web site of Japan Intractable Diseases Information Center

*2. Source: ALS Association web site

MCI-186 World's first demonstration of control of the progress of functional damage due to ALS

Additional indication approved in Japan in June 2015.



P value: 0.0013

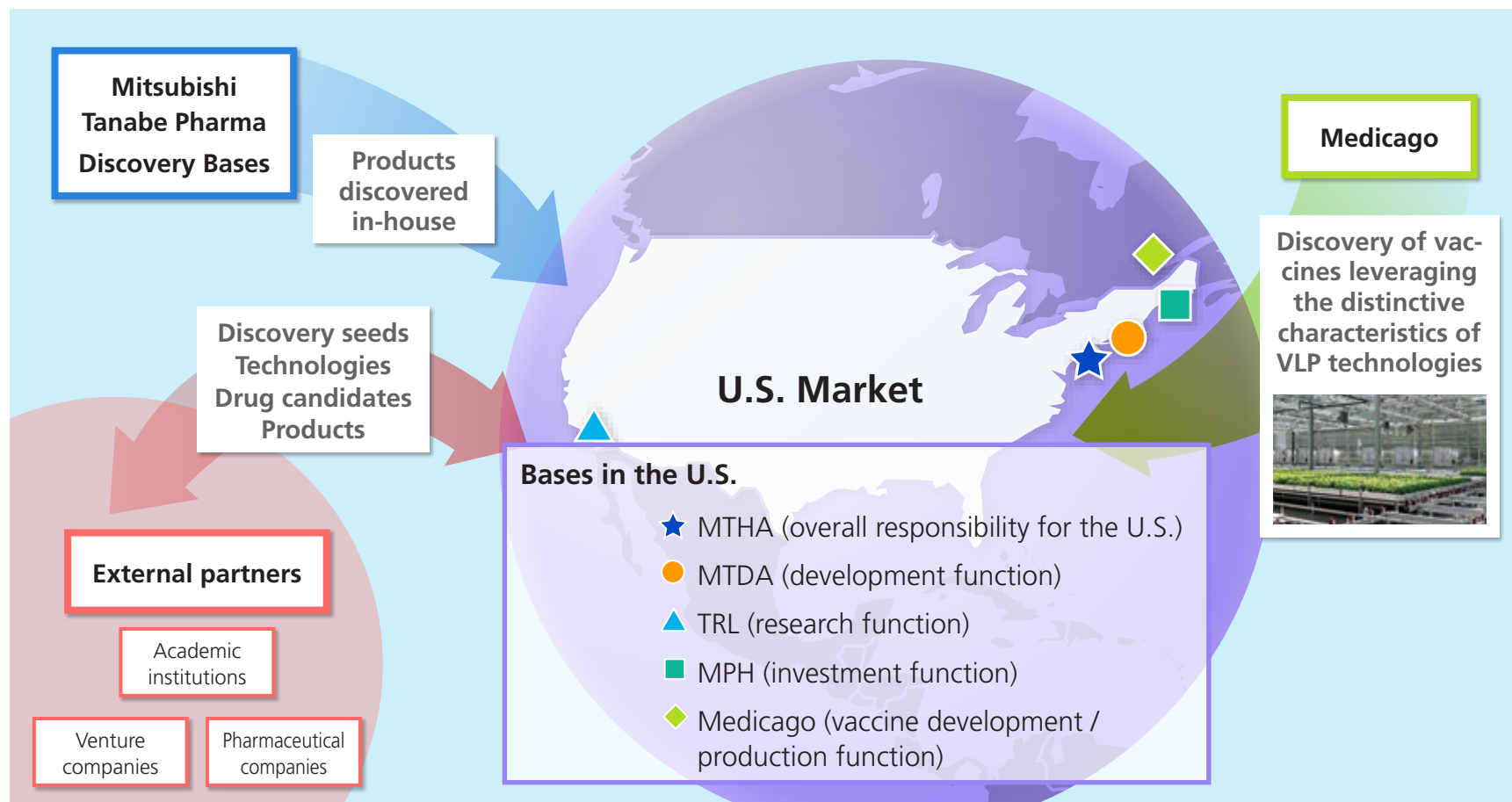
Source: Test results extracted from
RADICUT inj. package insert

Designated as orphan drug
(FDA/EMA)

**Aiming for approval
and launch in the
U.S. in fiscal 2016**

Building Product Lineup through Open Shared Business

Build U.S. product lineup by leveraging products discovered in-house and taking steps to strengthen pipeline through diverse cooperative initiatives



4

Reforming Operational Productivity

Open Up a Certain Future



**Realizing a corporate culture with
a sense of speed and profit structure**

Basic Policies

Two Key Points in Reforming Operational Productivity

Cost reductions

Workforce utilization

- Cost of sales reductions
- SG&A expense reductions
- Allocation and development of workforce to realize strategies
- Working-style reforms
- Advancing the utilization of diverse human resources (diversity and inclusion)

4. Reforming Operational Productivity

Cost Reductions of ¥20.0 Billion (Compared with FY 2015)

Cost of sales: ¥8.0 billion reduction

- ▶ **Pursuing Low Costs** Through Manufacturing & SCM Reforms

SG&A expenses: ¥12.0 billion reduction

- ▶ **Cost cuts**

Pass on the spirit of structural reforms implemented under the Medium-Term Management Plan 11-15, further reevaluate fixed expenses on a Company-wide basis, **maximize cost cuts** in FY 2020

- ▶ **Organizational/workforce optimization**

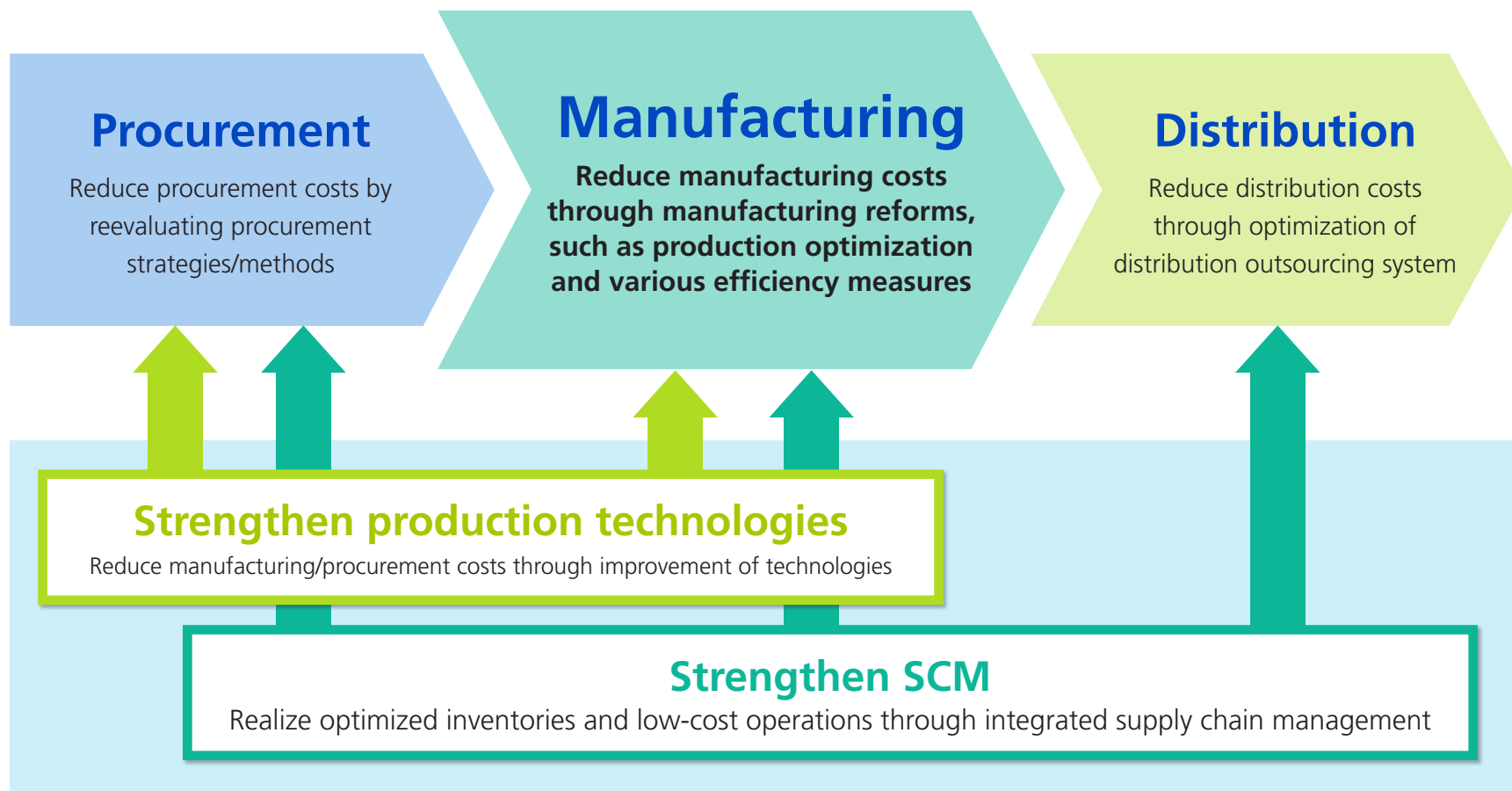
Aim for **domestic consolidated workforce of 5,000 employees*** in FY 2020 in order to address changes in the business environment

*As of the end of September 2015: 6,176 employees

4. Reforming Operational Productivity

Pursuing Low Costs Through Manufacturing & SCM Reforms

Achieve reduction of ¥8.0 billion on cost of sales through strengthening of manufacturing technologies and SCM



Increasing Business Productivity and Utilizing Human Resources

Further increase productivity with the reduction of the consolidated domestic workforce to 5,000 employees and the implementation of business reforms and resource allocation for overseas business development

- 1 Strengthening on-site capabilities in R&D
- 2 Increasing operational productivity of MRs and MSLs*
- 3 Enhancing the capabilities of employees in indirect departments
- 4 Advancing diversity & inclusion



*MSL: medical science liaison

Financial Guidance



Financial Guidance

	IFRS* ¹		[Reference: Japan GAAP]
	FY 2015 forecasts* ³	FY 2020 objectives	FY 2015 forecasts
Net sales	¥411.0 billion	¥500.0 billion	¥418.0 billion
Core earnings*²	¥88.0 billion	¥100.0 billion	¥82.0 billion
Net income attributable to shareholders of the Company	¥47.0 billion	¥70.0 billion	¥46.0 billion
R&D expenses	¥70.0 billion	¥80.0 billion	¥76.0 billion
Overseas sales ratio	25%	40%	28%

*1. Planning to adopt IFRS from FY 2016 (announced June 30, 2014).

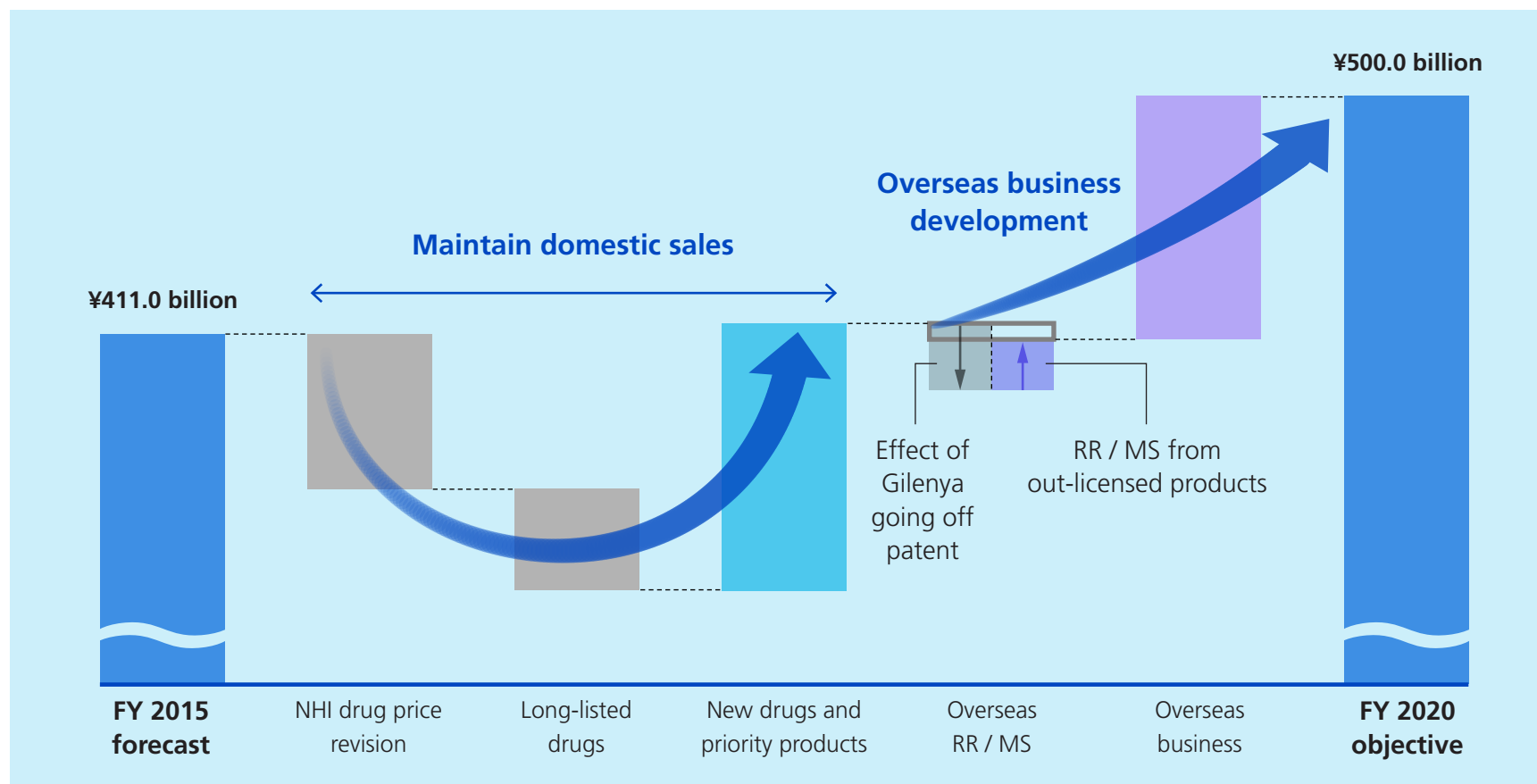
*2. Under IFRS, profit calculated by subtracting extraordinary items (restructuring expenses, etc.) from operating income

*3. 2015 full-year results forecasts (announced September 2015) restated in accordance with IFRS

Maintaining Domestic Sales and Enhancing Overseas Business

- Maximizing pipeline value
- Strengthening IKUYAKU and marketing
- Accelerating U.S. Business Development

Toward consolidated sales of ¥500.0 billion



Strategic Investments

Work to increase corporate value by aggressively investing in growth

Strategic investments targeting sustained growth

- ▶ **R&D investments: ¥400.0 billion**
- ▶ **U.S. strategic investments: More than ¥200.0 billion**
 - Building business foundation
 - Building product lineup
- ▶ **Other investments: ¥100.0 billion**
 - Capital investment
 - In-licensing expenses

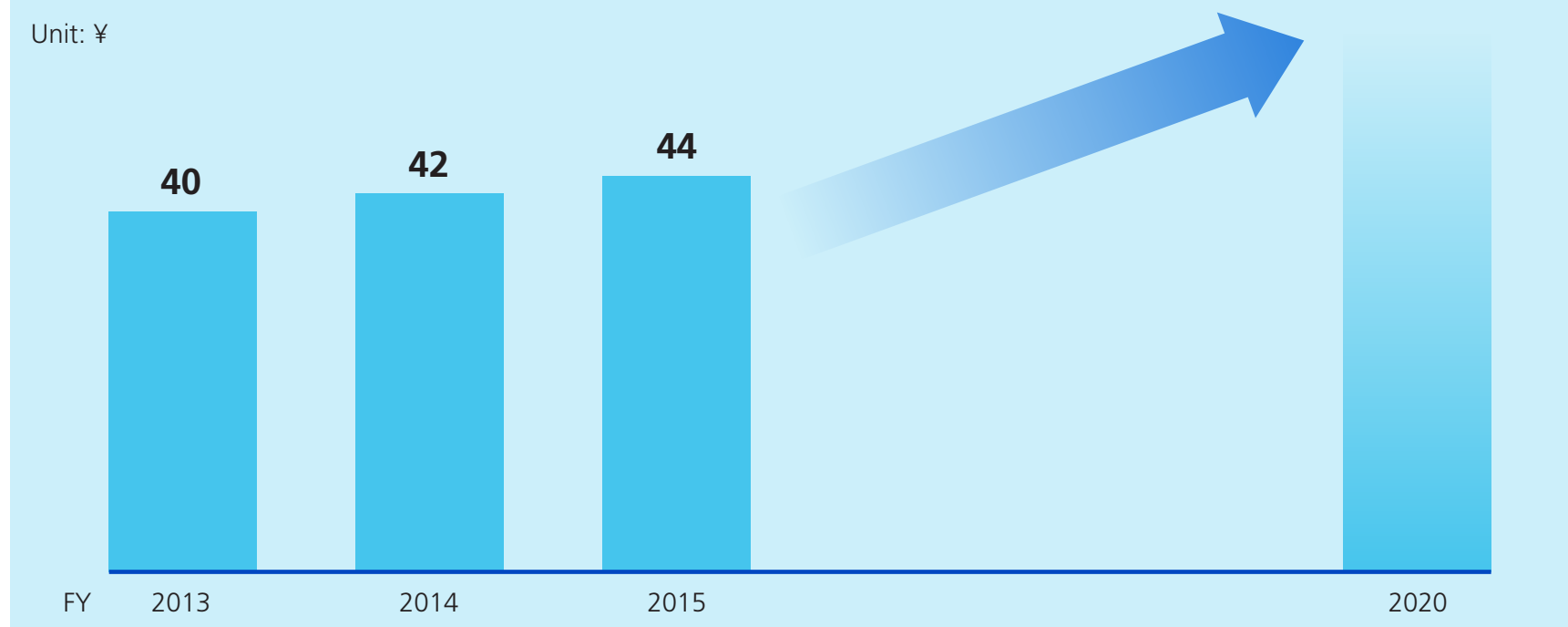
Shareholder Return

- Implement stable, ongoing shareholder return
- Increase target for consolidated dividend payout ratio to 50% (IFRS)
- An increase of 10%* in real terms in comparison with current dividend policy

* Equivalent to an increase of 10% in real terms because under the current dividend policy the consolidated dividend payout ratio of 50% is equivalent to 40% prior to amortization of goodwill.

Dividends per share

Unit: ¥



Mitsubishi Tanabe Pharma's Growth and Four Strategic Priorities to Open Up the Future

Net sales: ¥500.0 billion
Core earnings: ¥100.0 billion
R&D expenses: ¥80.0 billion

Fiscal 2020
Objectives

Four Strategic Priorities

1. Maximizing Pipeline Value

2. Strengthening IKUYAKU and Marketing

3. Accelerating U.S. Business Development

4. Reforming Operational Productivity

Sources of
Growth

Product
Strengths

Sales
Ability

Profitability

Open Up the Future

Open Up the Future

Becoming a company that works with a sense
of speed and is the first to deliver differentiated value



Mitsubishi Tanabe Pharma

Cautionary Statement

The statements contained in this presentation is based on a number of assumptions and belief in light of the information currently available to management of the company and is subject to significant risks and uncertainties.