

**Mitsubishi Tanabe Pharma Corporation**  
**Medium-Term Management Plan 11-15**

***New Value  
Creation***

**President & Representative Director**

**Michihiro Tsuchiya**



Mitsubishi Tanabe Pharma

# Agenda

## ■ Key Concept

## ■ Review of Medium-Term Management Plan 08-10

## ■ Medium-Term Management Plan 11-15

### ■ Becoming a Company that Can Continue to Create New Value

### ■ Strategic Challenges

- 1 Bolstering Our Ability to Discover New Drugs
- 2 Advancing Domestic Operations, Centered on New Products
- 3 Building a Foundation for the Expansion of Overseas Operations
- 4 Accelerating Operational and Structural Reforms

### ■ Numerical Targets

## ■ Together with Society

# New **Value** Creation

Mitsubishi Tanabe Pharma will move on to a new growth stage under the Medium-Term Management Plan 11-15.

The key concept of that new stage is *New **Value** Creation* .  
Guided by that concept, we will become a company that can continue to create new value.

We will build a management foundation for the discovery and global provision of new drugs that respond to unmet medical needs, and we will strive to contribute to improving the quality of life for large numbers of patients around the world.

**This is our mission: providing a wide-range of value to society.**

\* Unmet medical needs: Medical needs for which there are no effective treatments or drugs

# Working to Realize Our Vision

New **Value** Creation



Mitsubishi Tanabe Pharma

## Our Vision

We strive to be a global research-driven pharmaceutical company that is trusted by communities.

## Our Plan for 2015

We have a product pipeline that responds to unmet medical needs around the world.

We have the capacity to implement stable investment in R&D.

We are moving ahead with the establishment of a foundation for global development.

▶ 2015

Medium-Term  
Management Plan 11-15

New **Value** Creation

▶ 2011

# **Review of Medium-Term Management Plan 08-10**

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## Results of Medium-Term Management Plan 08-10 and Ongoing Challenges: 1

	Results	Challenges
<b>Enhancing the company's domestic sales presence</b> ○	<ul style="list-style-type: none"> <li>Enhanced the value of Remicade</li> <li>Enhanced specialized fields (Remicade, cerebral)</li> <li>In-licensed Kremezin and Lexapro</li> </ul>	<ul style="list-style-type: none"> <li>Steady penetration and nurturing of new products</li> <li>Establishing an efficient and effective information provision system</li> </ul>
<b>Steady progress in key development projects</b> ◎	<ul style="list-style-type: none"> <li>Remicade: Acquired approval for psoriasis, ankylosing spondylitis, and ulcerative colitis and for increased dosage for RA</li> <li>Filed NDAs for Simponi, Telavic, Imusera</li> <li>Moved MP-513 and TA-7284 to subsequent development stages</li> <li>Launched FTY720 in Europe and U.S. (Novartis)</li> </ul>	<ul style="list-style-type: none"> <li>Obtaining approval as rapidly as possible for drugs in late-stage development in Japan and overseas</li> <li>Enhancing pipeline that will support sustained growth</li> <li>Rapid establishment of POC*<sup>1</sup></li> <li>Ongoing LCM*<sup>2</sup> for priority products</li> <li>Strengthening discovery capabilities for responding to unmet medical needs</li> </ul>
<b>Progress in developing overseas pharmaceutical operations</b>	<ul style="list-style-type: none"> <li>Established sales companies in the U.S. and China</li> <li>Expanded countries where argatroban is sold in Europe</li> </ul>	<ul style="list-style-type: none"> <li>Establishing operational foundation in the U.S.</li> <li>Accelerating operational expansion in China</li> </ul>

\*1. Proof of concept: Establishment of efficacy and safety in humans

\*2. Life cycle management: Contributing to more patients through additional indications, etc.



## Results of Medium-Term Management Plan 08-10 and Ongoing Challenges: 2

	Results	Challenges
<b>Progress in generic operations</b>	<ul style="list-style-type: none"> <li>Established operational foundation</li> <li>Established Tanabe Seiyaku Hanbai</li> <li>Took an equity position in Choseido Pharmaceutical</li> <li>Expanded the number of products handled</li> </ul>	<ul style="list-style-type: none"> <li>Bolstering lineup with launch of large-scale products</li> <li>Nurturing products through cooperation within the Group</li> <li>Expanding operations with consideration for strategic cooperation</li> </ul>
<b>Creating an efficient organization and cost structure</b>	<ul style="list-style-type: none"> <li>Generated cost synergies (cumulative total of ¥23.5 billion)</li> <li>Consolidated functional subsidiaries (production services)</li> <li>Consolidated research bases, Osaka head office, training centers</li> </ul>	<ul style="list-style-type: none"> <li>Further functional and worksite reorganization (production, research, head office, branches, etc.)</li> <li>Strategic nurturing of organizational systems and human resources</li> </ul>
<b>Numerical targets</b>	<ul style="list-style-type: none"> <li>Net sales Plan: ¥460.0 billion → Results: ¥409.5 billion</li> <li>Operating income Plan: ¥95.0 billion → Results: ¥76.5 billion</li> <li>Did not achieve numerical targets for net sales or operating income</li> </ul>	<ul style="list-style-type: none"> <li>Implementing additional measures to achieve numerical targets, preparing for alternate scenarios</li> </ul>

**Dynamic Synergy**, the key concept of the Medium-term Management Plan 08-10, generated steady results linked to future growth.

## Medium-Term Management Plan 11-15

### ▮ Becoming a “Company that Can Continue to Create New Value”

### ▮ Strategic Challenges

- 1 Bolstering Our Ability to Discover New Drugs
- 2 Advancing Domestic Operations, Centered on New Products
- 3 Building a Foundation for the Expansion of Overseas Operations
- 4 Accelerating Operational and Structural Reforms

### ▮ Numerical Targets



# Becoming a “Company that Can Continue to Create New Value”

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## View of External Management Environment

### Industrially developed markets (Japan / U.S. / Europe)

- Markets receptive to innovative medicine

Market scale: **large**  
Growth rate: **low**

- Measures to control health care to limit social insurance expenditures (focus on medical cost performance)

### Emerging markets (China, etc.)

- Markets in which the level of medical treatment is rising rapidly in conjunction with economic growth

Market scale: **rapidly expanding**  
Growth rate: **high**

- Possible to implement development in a short period of time for products that have been approved in Europe / U.S.

### Increasing difficulty in drug discovery

- Progress in science and technology; more-complicated, more-advanced disease mechanisms
- Rising development costs, rising approval hurdles



### Ongoing polarization in pharmaceuticals

“Innovative, high-priced drugs” and “commodity, low-priced drugs.”

### Convergence toward global mega pharmaceutical companies, specialty pharmaceutical companies, and mega generic pharmaceutical companies.

New global drugs: Key points are the ability to discover new drugs and massive upfront investment

Specialty drugs: Key point is bolstering competitiveness through area specialization

Generic drugs: Key points are reliability and cost competitiveness

## Overview of Medium-Term Management Plan 11-15

### Key Concept

# New **Value** Creation

### Period

April 2011 to March 2016 (five years)

### Objectives that Will be Realized under the Medium-Term Management Plan 11-15

## Becoming a company that can continue to create new value

### Building a foundation for future growth

- Taking on the challenge of unmet medical needs
- Discovering drugs and building a foundation to provide them around the world
- Investing aggressively in future growth

Steadily nurturing and providing new products and priority products, centered on Remicade

### Fiscal 2015 Numerical Management Objectives

Net sales: **¥500.0 billion**

Operating income: **¥100.0 billion**

## Creating a Sustained Growth Spiral

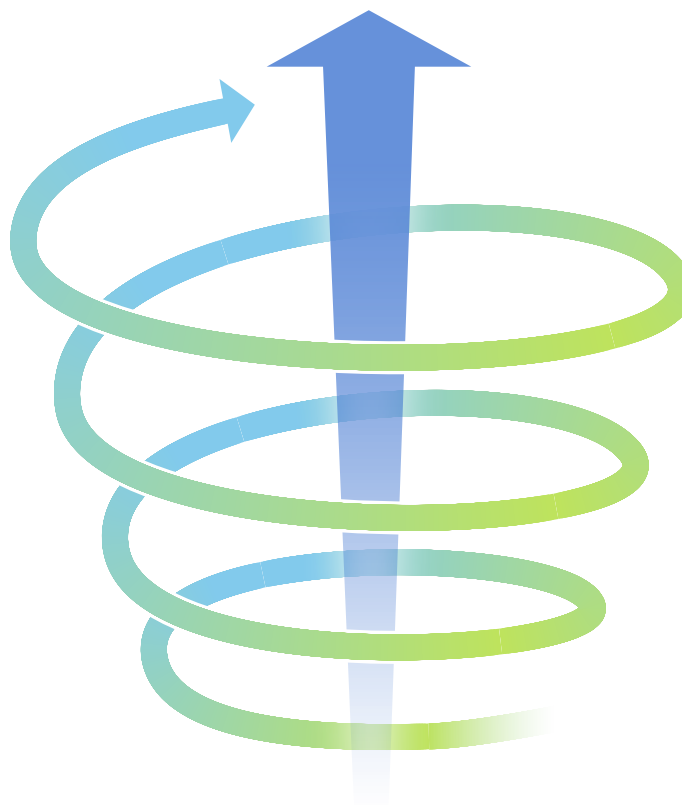
Creating a sustained growth spiral  
by continually reinvesting profits

### Continual reinvestment

**Bolstering our ability  
to discover new drugs**

**Building a foundation  
for the expansion of  
overseas operations**

- Investment to enhance pipeline
- Investment to rapidly nurture new products
- Investment to strengthen foundation for overseas operations



### Increasing our revenue / profit generating capacity

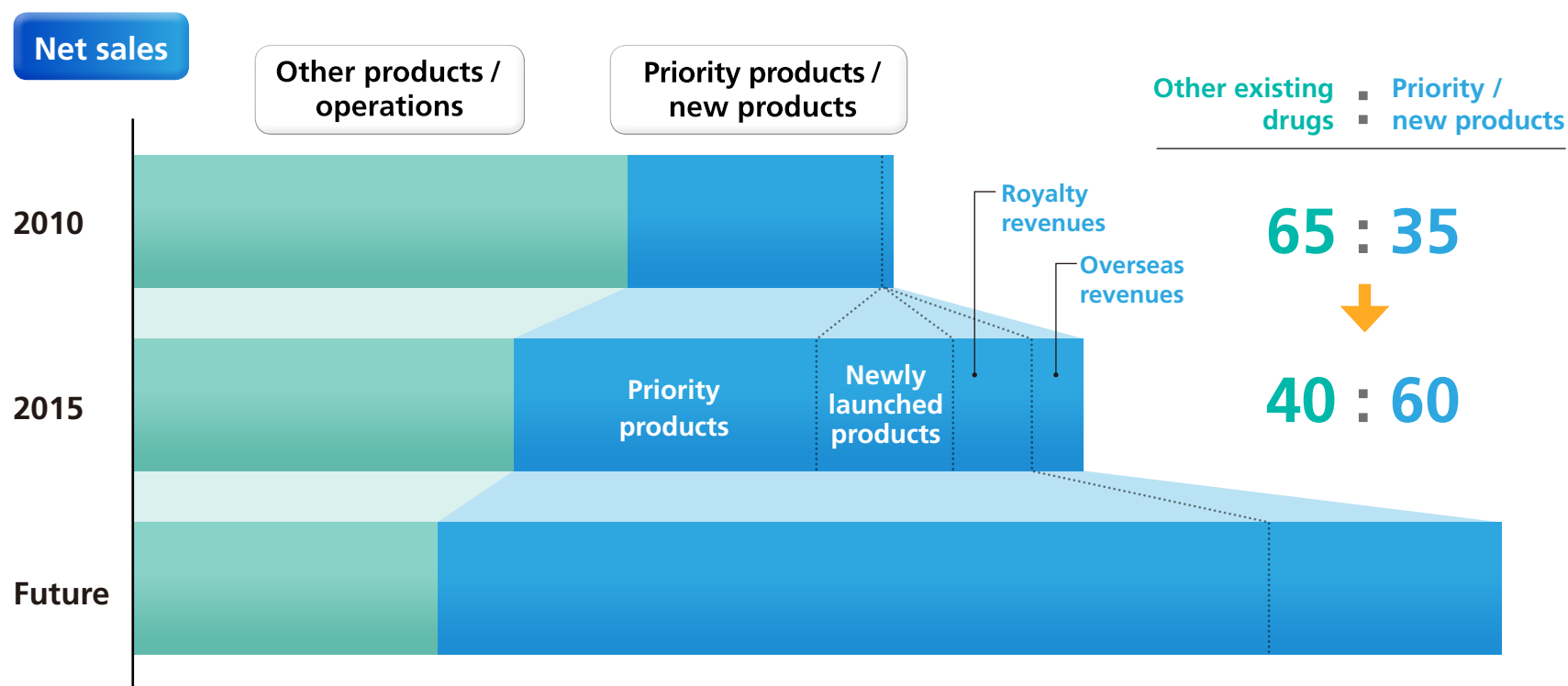
**Advancing domestic  
operations, centered  
on new products**

**Accelerating operational  
and structural reforms**

- Revenues / profits from existing businesses
- Maximizing revenues / profits from new products
- Expanding scale of and revenues / profits from overseas businesses
- Large-scale product royalty revenues
- Low cost operations

## Sustained Growth and Organizational Restructuring

By continually launching new drugs, we will reform our revenue / profit structure so that overall profits are centered on priority products and new products.



## Medium-Term Management Plan 11-15: Strategic Challenges

- 1 Bolstering Our Ability to Discover New Drugs
- 2 Advancing Domestic Operations, Centered on New Products
- 3 Building a Foundation for the Expansion of Overseas Operations
- 4 Accelerating Operational and Structural Reforms



# **1 Bolstering Our Ability to Discover New Drugs**

## ***Value Creation***

Discovering new drugs that respond to unmet medical needs

# Overview of New Drug Launches

Areas	Principal target diseases in research stage to early development stage	Products expected to be launched under Medium-Term Management Plan 11-15*			
		Acquisition of POC	Late-stage development	Launch	LCM
<b>Marketing franchise areas</b> <b>Autoimmune diseases</b>	<ul style="list-style-type: none"> <li>RA, Crohn's disease, psoriasis, etc.</li> </ul>			Simponi	Remicade
<b>Kidney diseases</b>	<ul style="list-style-type: none"> <li>Complications of dialysis</li> </ul>	MP-146	MCI-196		
<b>Diabetes (including complications)</b>	<ul style="list-style-type: none"> <li>Chronic kidney disease</li> <li>Complications of diabetes</li> </ul>	TA-7284	MP-513		
<b>New disease areas</b> <b>Neurological disorders, etc.</b>	<ul style="list-style-type: none"> <li>Multiple Sclerosis</li> <li>Schizophrenia, dementia, pain, etc.</li> </ul>	MP-214		ACREF Imusera	Radicut
<b>Other areas</b>			BK-4SP (vaccine)	Telavic	Talion Maintate

\* Including additional indications

## In-licensed products

Launch in fiscal 2016 or thereafter		
TRK-820 (kidney diseases: refractory pruritus)	New biologics	New vaccines

Development region

Europe / U.S. Japan



## Enhancing Pipeline for Sustained Growth

### Objectives

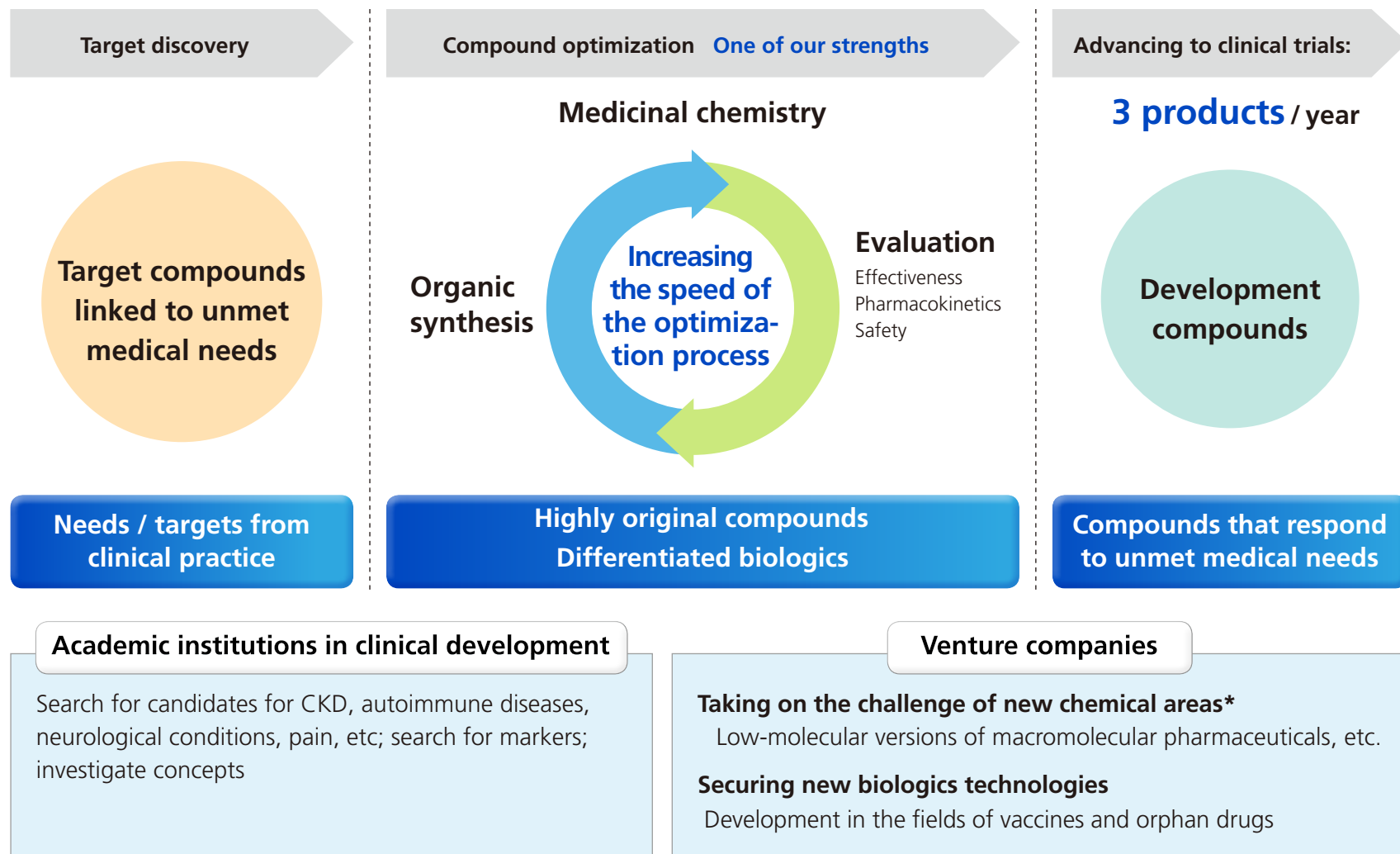
- Launched products: **10 products\*** (fiscal 2011-2015)
- Products advancing to late-stage development: **8 products** (fiscal 2011-2015)
- Products starting clinical trials: **3 products** / year (fiscal 2015 objective)



- Accelerate acquisition of POC by consolidating discovery and early stage clinical trials
- Advancing in-licensing and alliances
- Bolstering global development function  
(strengthen four part system: U.S., Europe, China, Japan)
- Strengthen producing function for clinical trial drugs to respond appropriately to increase in number of drugs in development

\* Japan: Simponi, Telavic, Imusera, ACREF, MP-513, TA-7284, MP-214, BK-4SP  
Overseas: MCI-196, MP-146

## Bolstering the Drug Discovery Function



\* Discovery technologies for target molecules to which there is not a sufficient response with existing low-molecule compounds or antibodies.

### Continued pipeline strengthening in marketing franchise areas\*

#### Autoimmune diseases

- Remicade, Simponi
  - Continued implementation of LCM
- MT-1303 (successor to Imusera)
  - Development for autoimmune diseases
- Early development stage products, research stage products
  - RA, psoriasis, orphan diseases, etc.

#### Diabetes / kidney diseases

- MP-513, TA-7284
  - Rapid launch
  - Advancing measures to promote rapid market penetration to maximize value
- MCI-196, MP-146
  - Development in Europe / U.S. markets
- Early development stage products, research stage products
  - Strengthening initiatives in chronic kidney disease, diabetes complications, etc.

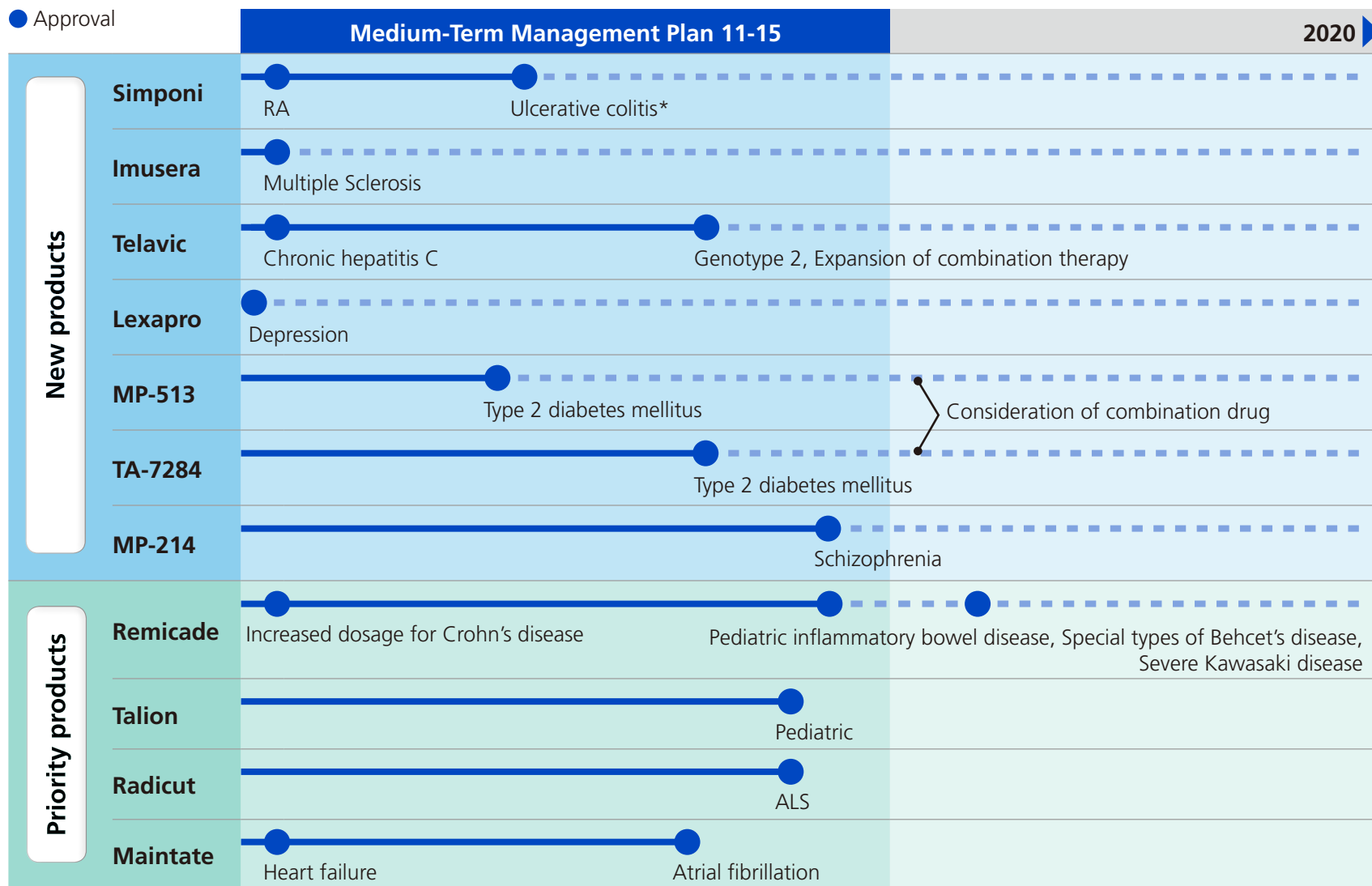
\* Product areas that strengthen our marketing foundation

## **2 Advancing Domestic Operations, Centered on New Products**

### ***Value Creation***

Continuing to provide products that have value with reliable information

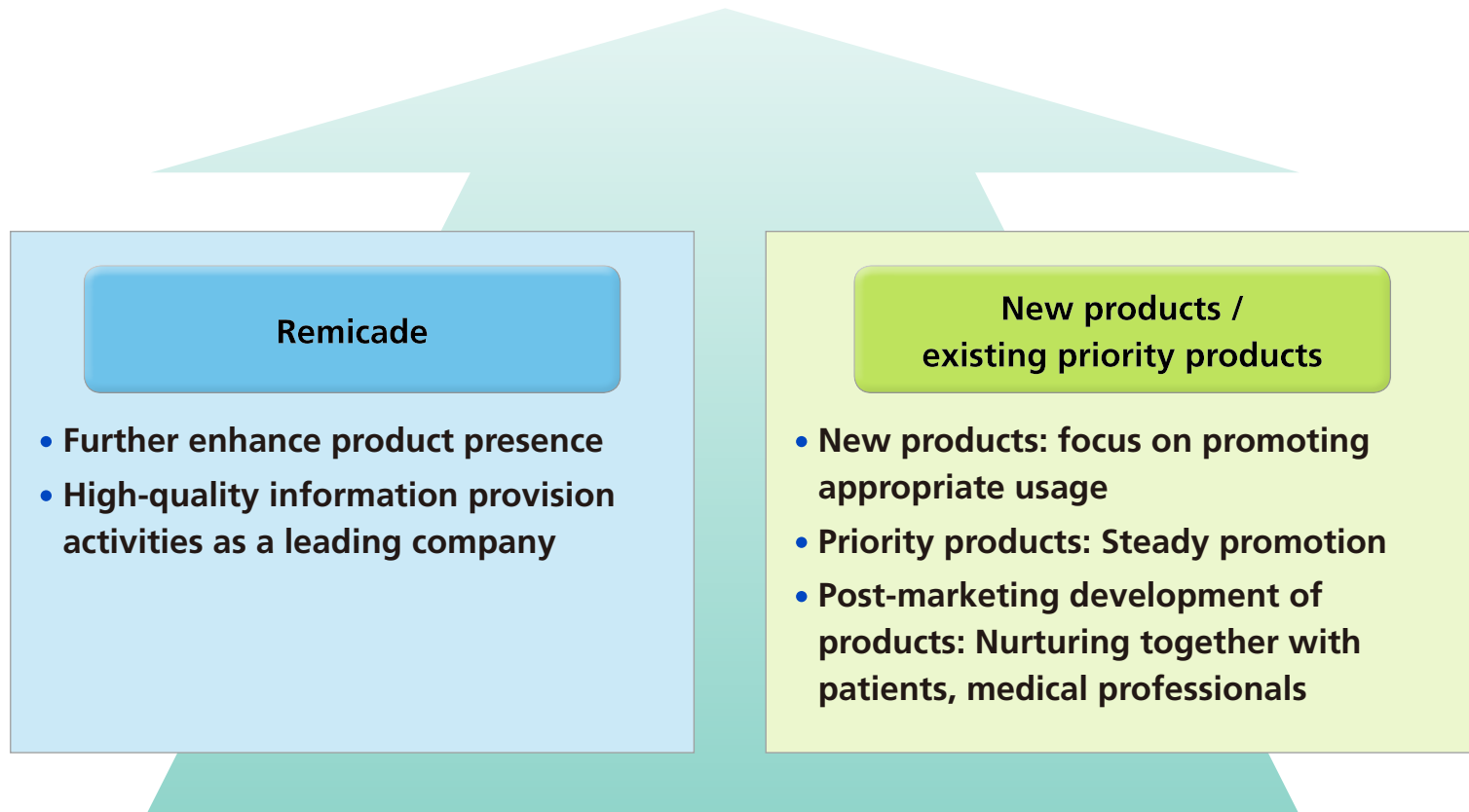
# Growth Drivers in Domestic Operations



\* Under development by Janssen Pharmaceutical

## Sales Policies

Provide lineup of drugs that respond to unmet medical needs, together with **reliable information based on global evidence**, to as many patients as possible.



## Autoimmune Diseases Remicade

### Value for patients

#### Indications:

#### Various inflammatory diseases

Reduces chronic pain and distress suffered by patients and makes it possible for them to enjoy the same lifestyles as healthy people.

Indications	No. of patients
Crohn's disease	30,000
RA	250,000 (patients taking MTX)
Behcet's disease (ocular)	10,000 (uveitis)
Psoriasis	100,000
Ankylosing spondylitis	2,000
Ulcerative colitis	110,000



#### Positioning in treatment

As first-in-class, best-in-class biologics, the first choice for various inflammatory diseases, including orphan diseases

#### Future additional indications

Pediatric ulcerative colitis, special types of Behcet's disease, severe Kawasaki disease

#### Sales system / policies

Strive to enhance quality and quantity of appropriate usage in formation provision through cooperation between MRs specializing in Remicade and general MRs.

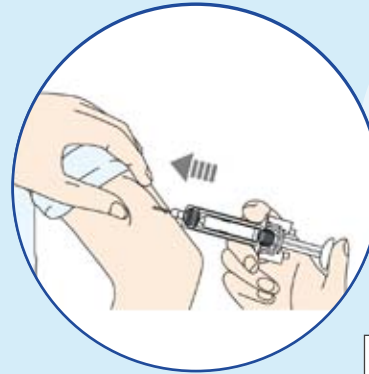
## Autoimmune Diseases **Simponi**

### Value for patients

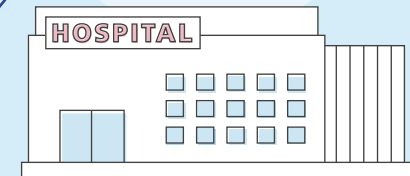
#### Indications: RA

**No. of patients: 500,000**

Treatment can be undertaken with peace of mind, with administration once every four weeks, under the doctor's supervision, in conjunction with patient hospital visits.



Subcutaneous  
injection under  
doctor's care



#### Positioning in treatment

Subcutaneous injection that is the first choice in RA treatment  
High effectiveness and treatment continuity

#### Sales system / policies

Drawing on the marketing base and reputation for reliability established with Remicade, we will work to promote its use on a foundation of appropriate usage and effectiveness (co-marketing with Janssen Pharmaceutical)



## Autoimmune Diseases Imusera

### Value for patients

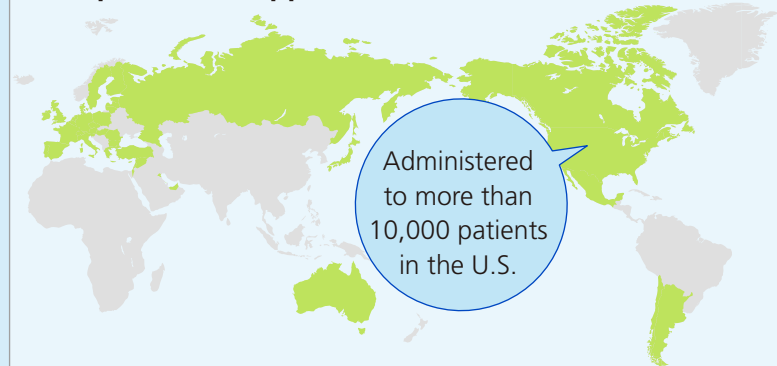
#### Indications: MS

**No. of patients: 14,000**

Offers superior treatment effectiveness due to new mechanism of action discovered by the Company. It is the world's only oral formulation for MS.

It lowers the psychological and physical burden faced by patients being treated with existing self injection methods.

Acquisition of approval in more than 50 countries



No. of patients worldwide: 2.5 million

#### Positioning in treatment

Provides a new choice in drug treatment of MS, where unmet medical needs remain.

#### Sales system / policies

Through the use of global prescription data and the implementation of domestic all-patient survey, we will accumulate evidence and earn the trust of prescribing doctors.

## Hepatic Diseases Telaviv

### Value for patients

#### Indications: Chronic hepatitis C

**No. of patients: 400,000 to 500,000 / year**

**No. of 2-drug combination therapy patients: 20,000 to 25,000 / year**

**Expected to be highly effective, even for patients for whom existing treatments have not been effective.**

**Treatment period reduced by half, lessening the treatment burden borne by patients.**

#### Status of overseas approvals

**U.S.** (May 2011)

**Canada** (August 2011)

Vertex

**Europe** (September 2011)

Johnson & Johnson

#### Positioning in treatment

**Basic treatment agent of chronic hepatitis C.**

**Working to expand indications to genotype 2 and to increase combination therapy.**

#### Sales system / policies

**In safety management operations, we will work in cooperation with hepatologists and dermatologists at medical institutions implementing an all-patient survey, and we will promote 3-drug combination therapy.**

## Psychiatric and Neurological Conditions: **Lexapro**

### Value for patients

**Indications: Depression / depressive symptoms**

**No. of patients: 1 million**

Supports the return to society, the most important factor for patient QOL, with high treatment continuity

Has been administered to more than 230 million people worldwide, top share among SSRIs



#### Positioning in treatment

Good balance between effectiveness and tolerability. Simple administration. Therefore, first line drug for depression, with high treatment continuity.

#### Sales system / policies

Comarketing with Mochida Pharmaceutical, which is the license holder in Japan. Will aim to achieve top share among SSRIs\* through co-promotion with Yoshitomiyakuhin, which has a top class presence in the psychiatric area in Japan.

\* SSRI: selective serotonin reuptake inhibitor

## Diabetes Mellitus: MP-513, TA-7284

### Value for patients

#### Indications: Type 2 diabetes mellitus

**No. of patients with diabetes: 8.9 million**

MP-513 and TA-7284 are oral drugs with new mechanism that can be administered in combination and are available for a wide range of patients. They can control blood sugar with a high degree of safety.

#### Status of overseas development

##### TA-7284

Planning to file NDA in 2012

Johnson & Johnson



#### Positioning in treatment

**MP-513:** Among DPP4 inhibitors, which are growing rapidly, optimal drug for initial treatment, with both effective blood sugar control and ease-of-use.

**TA-7284:** Makes possible new treatment strategy for diabetes (SGLT2 inhibitor)

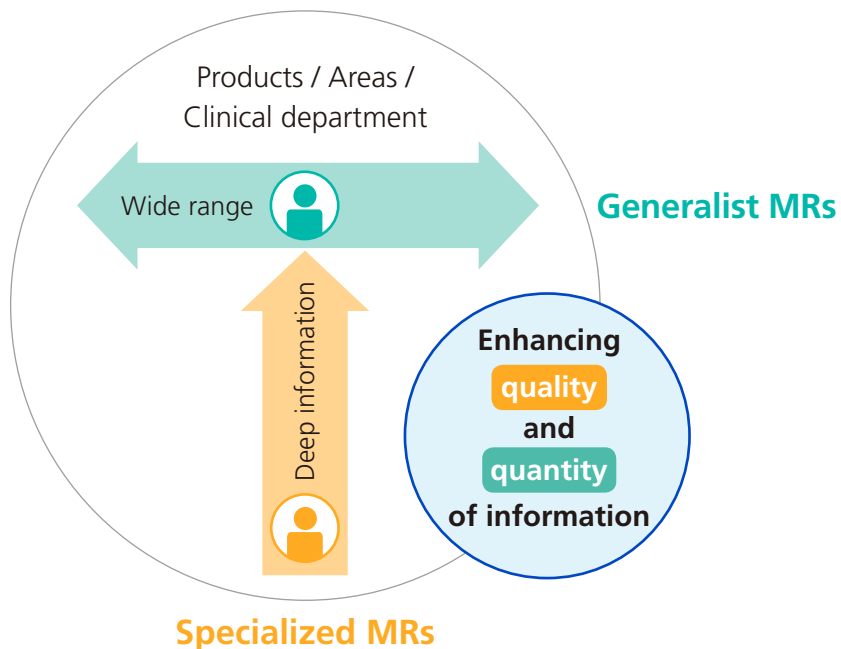
#### Sales system / policies

Will implement marketing strategy to nurture these two drugs as standards in diabetes treatment. (Will consider combination drug.)

# Information Provision System that Meets Diverse Customer Needs

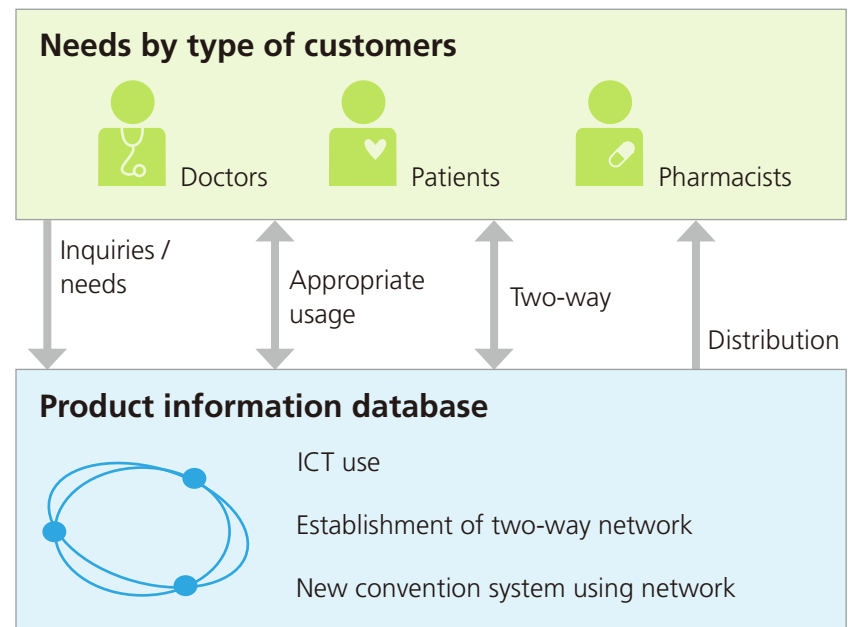
## “T-Shaped” Marketing System

**Bolster cooperative work between MRs and specialized MRs**



## On-demand information provision system

- **Deeper information provided**  
Evidence, appropriate usage information for new drugs
- **Information provision using ICT\***
- **Cross media utilization**



\* ICT: information and communication technology

## **3 Building a Foundation for the Expansion of Overseas Operations**

### ***Value Creation***

Providing drugs that have value to many patients around the world

## Area Strategy

### Industrially developed markets

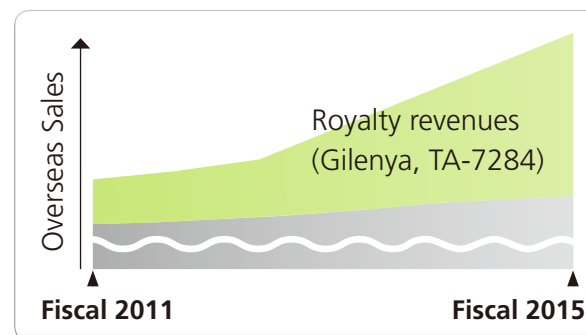
Innovative treatment methods with medical cost performance

- Promotion of products suitable for late-stage development and sales in-house

(kidney diseases, critical / orphan diseases, etc.)

- Following approval in U.S. / Europe, expand to emerging markets

- For drugs other than those above (circulatory and metabolism diseases, etc.), after POC is acquired we will work to rapidly maximize product value, using alliances, etc.



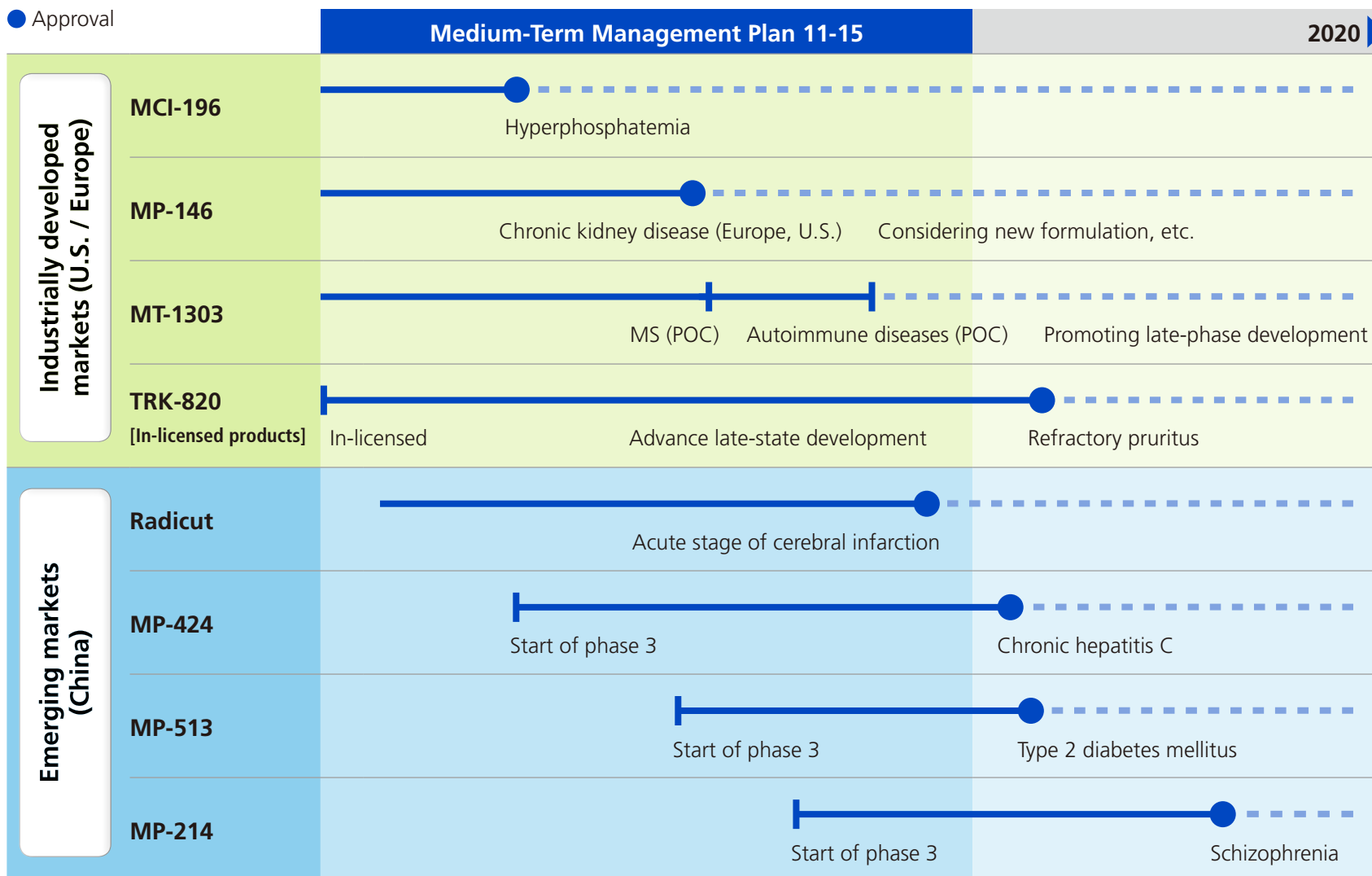
### Emerging markets

Development in Asia, centered on China

- Following approval in Japan, expand to emerging markets (circulatory and metabolism diseases, etc.)

- Promotion of products meeting distinctive medical needs in China / Asia (chronic hepatitis, infectious diseases)

## New Products, Development Products for Expansion of Overseas Operations





## Industrially Developed Markets (U.S. / Europe)

### Basic Strategies

- Renal disease drugs (MCI-196, MP-146): In-house development focused on specialist doctors.
- Establish new focus areas in addition to renal diseases (autoimmune diseases, etc.: MT-1303, etc.), bolster development system
- Aggressively secure management resources (functions, systems, products, technologies) to bolster and expand operating base (TRK-820, etc.)

#### U.S.

- Strengthen product pipeline, with renal disease area positioned as beachhead for business development in the U.S.

#### Europe

- Establish sales bases in 5 European countries (In addition to the U.K. and Germany, newly establish in-house sales bases in France, Italy, Spain)
- Expand sales by acquiring approval in new regions and launching argatroban.

## Emerging Markets (China, Asia)

### Basic Strategies

- Rapidly launch products that have been approved in industrially developed market
- Aggressively in-license products that match characteristics / needs of each market

#### China

- Build in existing foundation with flexible yet optimal production, development, and sales systems that match the Chinese market. Enhance market presence.
- Work to accelerate development and achieve rapid launch
  - Accelerate development of MP-424, aiming for rapid launch
  - Start rapid development of MP-513, MP-214, etc., launch Radicut
  - Accelerate initiatives such as the introduction of products in the area of hepatitis treatment

#### Asia\*

- Build an independent growth organization that maximizes business value

\* South Korea, Taiwan, Southeast Asia

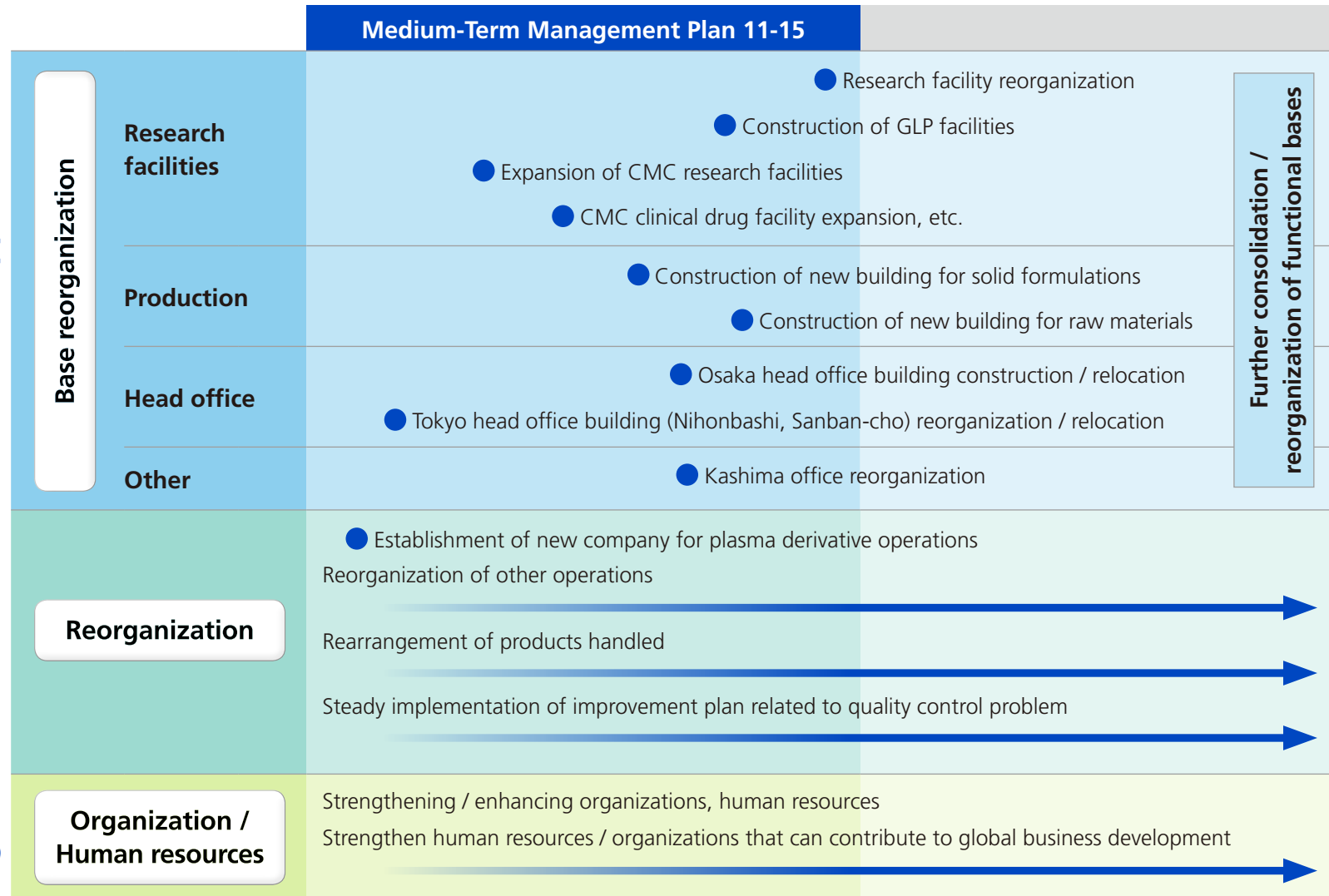
## **4 Accelerating Operational and Structural Reforms**

### ***Value Creation***

Becoming a Company that Can Continue to Create New Value

# Accelerating Worksite, Structural, and Organizational Reforms

Building streamlined systems and bolstering organizations / human resources that support them



## Vaccine Business

From the perspective of disease prevention, contribute to society by supplying vaccines

**Mitsubishi Tanabe Pharma has the highest vaccine sales in Japan**

**Bolster domestic foundation, centered on relationship with BIKEN\***

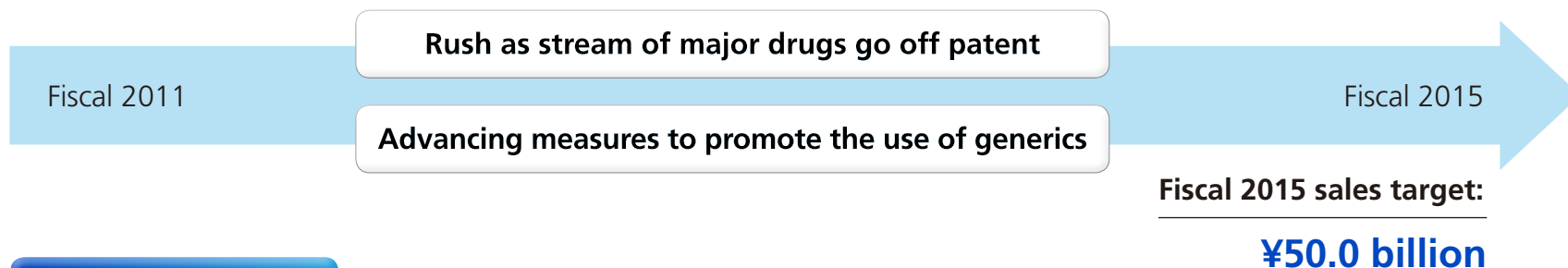
- Based on the sales foundation established to date, strive to maximize value as the top domestic brand, such as through joint development of a combination vaccine for four diseases
- Independently in-license competitive products / technologies, link to new product development, etc. based on cooperation with BIKEN



\* The Research Foundation for Microbial Diseases of Osaka University

## Generic Drug Business Strategy

Provide “Reliable Generics” that leverage the strengths of the Group’s organizational foundation (new drugs, specialized areas)



### Business strategies

1. Maximize sales of large-scale new products through cooperation within the Group (Specialized areas of Tanabe Seiyaku Hanbai, Mitsubishi Tanabe Pharma, Yoshitomi Yakuhin, etc.)

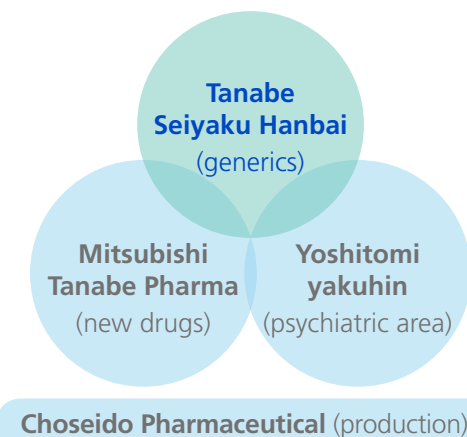
- ① Bolster cooperation with wholesalers and sales companies
- ② Establish marketing foundation with dispensing pharmacies
- ③ Strengthen activities in Group priority areas

2. Build framework for production optimization

Cooperation with Choseido Pharmaceutical, which will handle production

3. Work to enhance presence, with consideration for strategic cooperation

### Cooperation within the Group



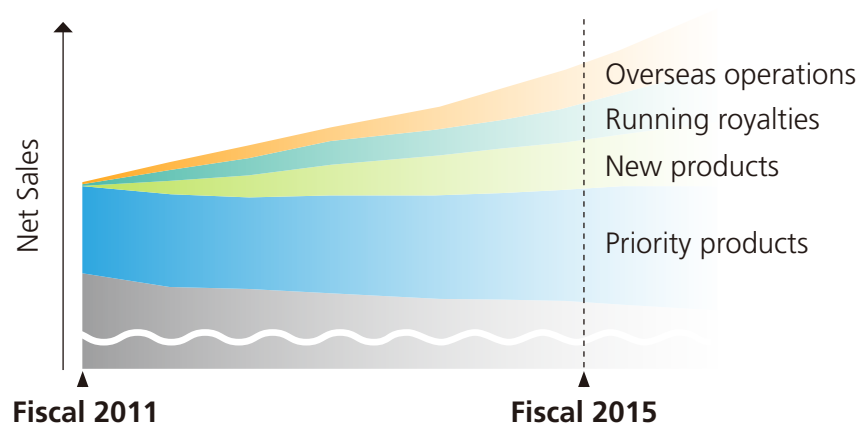
# Numerical Targets

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# Fiscal 2015 Numerical Targets

	Fiscal 2011 forecasts	Fiscal 2015 objectives
Net sales	¥405.0 billion	¥500.0 billion
Operating income	¥68.0 billion	¥100.0 billion
R&D expenses	¥69.0 billion	¥80.0 billion
Overseas sales ratio	6%	15%+

\* On an operating income basis, we are aiming for an overseas sales ratio of 40% in fiscal 2015.





## Aggressive up-front investment to bolster foundation for sustained growth and expand operations

### Total investment

More than ¥100.0 billion over a five-year period  
(capital investment, in-licensing expenses)

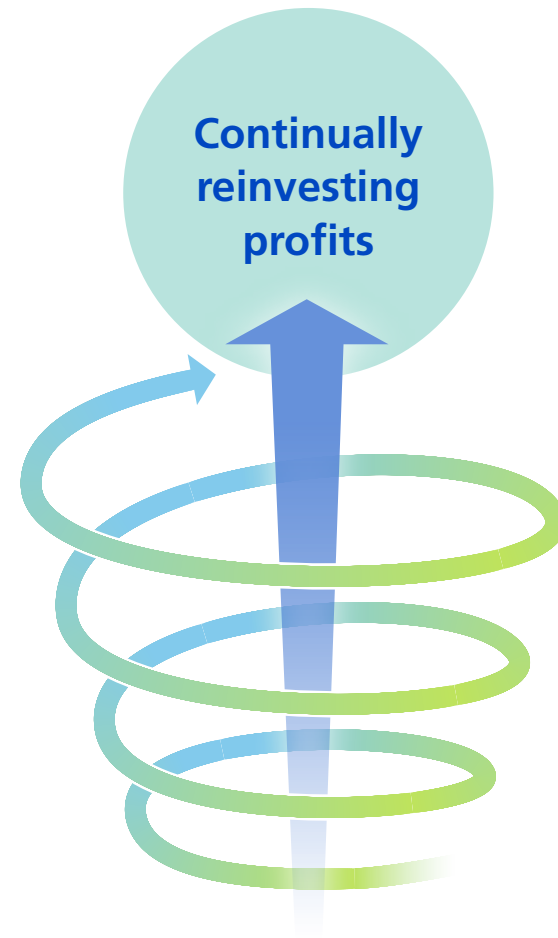
#### Details of major capital investment

- Consolidate / bolster production function
- Consolidate / bolster research function
- Build Osaka head office
- Restructure IT platform

### R&D expenses

¥75.0 billion to ¥80.0 billion / year  
(including above in-licensing expenses)

### Advance strategic cooperation

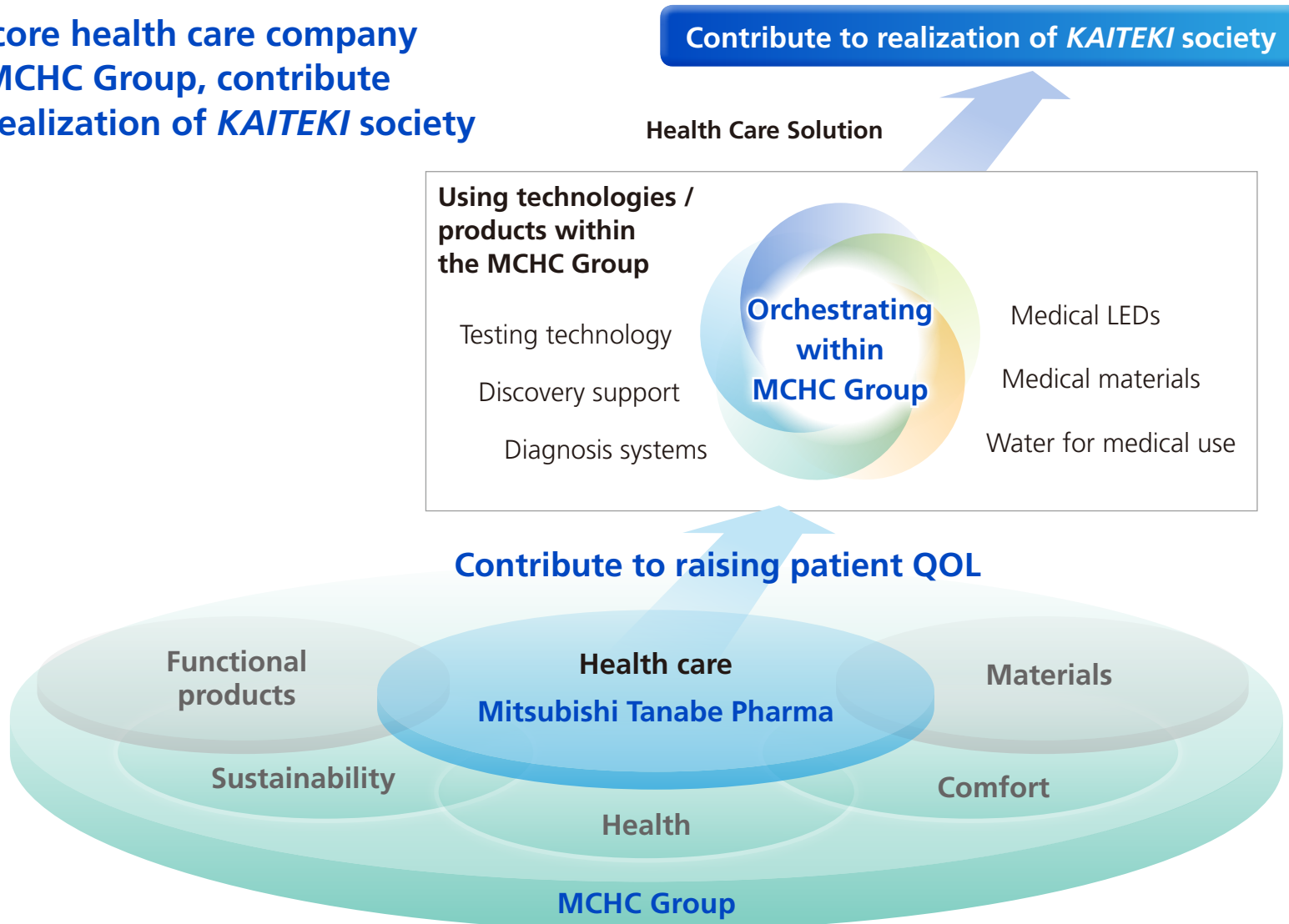


- The Company's basic policy calls for providing a stable, return to shareholders while striving to maximize enterprise value by aggressively investing in future growth.**
- Under this medium-term management plan, in addition to profit growth, we will strive to raise the consolidated dividend payout ratio (prior to amortization of goodwill) to 40% and expand shareholder return.**

## Together with Society



As core health care company  
in MCHC Group, contribute  
to realization of *KAITEKI* society



## Striving to be a Company That is Trusted by Communities



- By steadily implementing the business improvement plans related to the Medway problem and the quality control problem, we will strive to strengthen the overall management foundation and on-site capabilities of the Mitsubishi Tanabe Pharma Group, reform our organizational culture, prevent a recurrence, and regain trust.
- We will raise the effectiveness of our improvement plans through the inspection and advice of outside committees. Further, we will ensure transparency by providing status reports to the public.

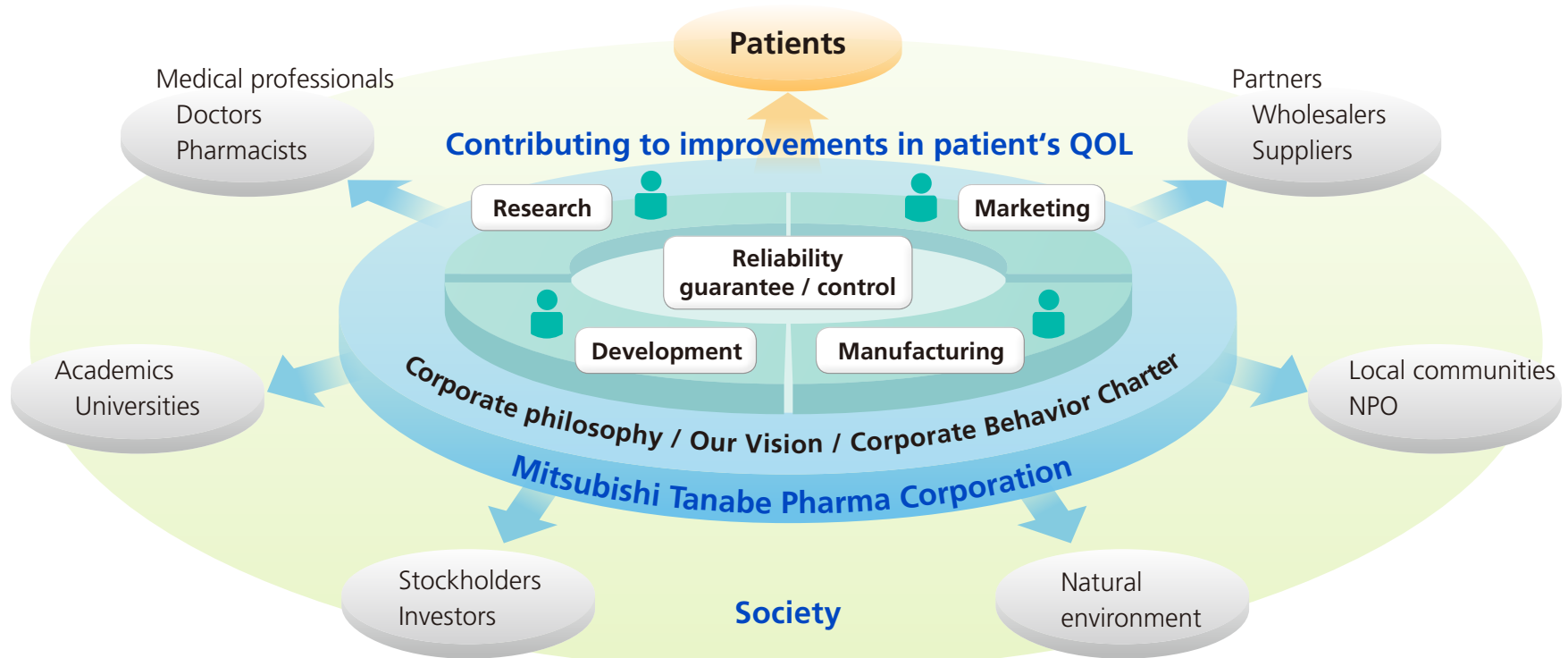


On a foundation of “regaining the trust of society” and “securing quality and safety,” we will be a company that fulfills its social mission—contributing to improvements in patients’ QOL by “manufacturing and providing pharmaceuticals.”

## Contributing to the Sustainability of Society

- Fulfilling our social mission—Contributing to improvements in patients' QOL
- Continuing to be a good corporate citizen
- Contributing to society through growth as a company

### Fostering "social" sustainability



# *New **Value** Creation*

**Becoming a “Company that Can Continue to Create New 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. Actual financial results may differ materially from these forecasts depending on a number of important factors.**