



TSUMURA & CO.

New Medium-Term Management Plan (Fiscal 2016–Fiscal 2021)

# Creating New Value Through Innovations in Kampo

May 13, 2016

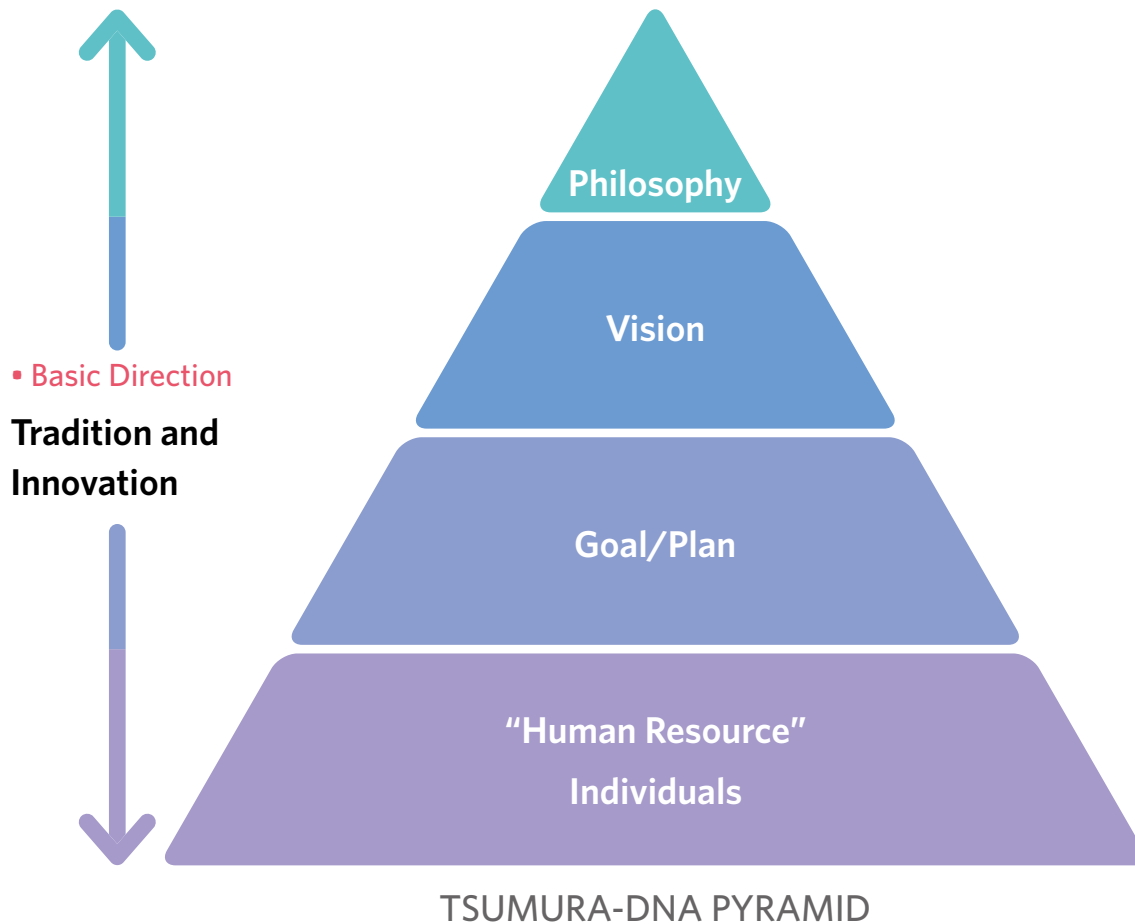
President, Representative Director **Terukazu Kato**



TSUMURA



# Philosophy-Based Management



- Corporate Philosophy: Basic value/beliefs

The Best of Nature and Science

- Corporate Mission: Aim to continue to be a necessary company for Society

To contribute to the unparalleled medical therapeutic power of the combination of Kampo medicine and Western medicine

- Vision for 2021: Long-term business vision

The "Kampo" Company

The "People" Company

The "Global Niche" Company

- New medium-term management plan

Creating new value through innovations in Kampo

- Organizational foundation

Organization comprising people that share Tsumura's beliefs and mission, follow the same direction as the Company's vision, and strive for self-fulfillment

## Long-Term Business Vision “Vision for 2021”

Aim to be a value-creation company that contributes to people’s health through its Kampo business

---

### The “Kampo”

#### Company

---

Contributing to creating a healthcare environment where all patients can receive treatment that includes “Kampo” medicine where appropriate in any healthcare institution or medical specialty in Japan.

### The “People”

#### Company

---


“Kampo” medicine is a pioneering field with no previous examples to build on worldwide. Therefore, we shall evolve into a corporate group comprised of “people” with professional skills that can independently pave the way forward for our Kampo business and is trusted by all.

### The “Global Niche”

#### Company

---

Leveraging the technology and know-how of the Tsumura Group to their full extent, we will take on the challenge of developing and launching TU-100 (Daikenchuto) in the U.S. pharmaceutical market as well as creating new businesses in China.



---

Fiscal 2012–Fiscal 2015

Overview of the Previous Medium-Term  
Management Plan



**TSUMURA**

## Outline and Quantitative Reflection

### 1. Expanding the Kampo Medicine Market

Expand the prescription Kampo product market in Japan

### 2. Enhancing Earning Power

Reform the Company's cost structure through the introduction of new technology and other measures

### 3. Executing Effective Financial and Capital Policies

Increase corporate value by executing effective financial and capital policies

Consolidated: ¥ billion	Fiscal 2015 target	FY 2012 results	FY 2013 results	FY 2014 results	Fiscal 2015 results	Compared to initial plan
Net sales	<b>123.0</b>	105.6	110.0	110.4	<b>112.6</b>	-10.4
Operating profit	<b>29.5</b>	23.1	22.4	19.4	<b>19.8</b>	-9.7
Operating profit margin (%)	<b>24.0</b>	21.9	20.4	17.6	<b>17.6</b>	-6.4
Net income	<b>19.0</b>	15.3	18.0	14.0	<b>12.5</b>	-6.5
EPS (Yen)	<b>269</b>	217	255	199	<b>178</b>	-91
ROE (%)	<b>14.0</b>	14.1	14.5	10.1	<b>8.3</b>	-5.7
Sales of 129 Kampo formulations	<b>118.0</b>	99.4	102.6	105.1	<b>107.5</b>	-10.5
Of which, five "drug fostering program" formulations	<b>38.6</b>	26.2	28.0	28.5	<b>29.1</b>	-9.5

Record-high operating income

Record-high net income

## Reasons for Failing to Reach Planned Targets

1

### **Slowdown in growth of “drug fostering program” formulations**

Insufficient emphasis and concentration on promotion of medical specialists in the “drug fostering program” domain  
Ineffective utilization of new scientific evidence (turning evidence into marketable materials, etc.)

2

### **Worsening costs due to the reoccurring rise in crude drug prices**

Rise in cost of raw materials for crude drugs from 2013 and on brought about by higher prices for ginseng and other materials starting from 2011 → Worsening costs

3

### **Worsening costs due to foreign exchange of depreciating yen**

Rise in procurement costs for raw material crude drugs in China due to the rapid weakening of the yen from 2013 and on → Worsening costs

## Changes in the Operating Environment

- ✓ Reoccurring rise in price for certain raw material crude drugs
- ✓ Volatile foreign exchange rate and rapid depreciation of the yen

### Impact on cost of sales ratio (disparity from plan)


Fiscal 2015  
Initial plan **34.7%** → Results **40.0%** **+5.3 pts**

Factor	Effect
Crude drug price (rising unit cost)	<b>+3.5 pts</b>
Crude drug price (foreign exchange rate)	<b>+1.6 pts</b>
Other (increasing production efficiency, reducing production volumes, etc.)	<b>+0.2 pts</b>
<b>Total</b>	<b>+5.3 pts</b>

## Quantitative Results and Issues in Three Strategic Challenges

Strategy	Expanding the Kampo Medicine Market	Enhancing Earning Power	Executing Effective Financial and Capital Policies
<p><b>Results</b></p>	<ul style="list-style-type: none"> <li>&gt; Actively implemented Kampo medicine seminars, lectures, and briefings</li> <li>&gt; Promoted clinical research through double-blind, placebo-controlled studies at multiple institutions as well as basic research, produced high-quality scientific evidence</li> <li>&gt; Created scientific quality evaluation method for TU-100 (Daikenchuto)</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Established new manufacturing system that uses less manpower and is more efficient</li> <li>&gt; Expanded Cultivated Land under Own Management area</li> <li>&gt; Controlled sales, general and administrative expenses by increasing business efficiency</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Revised non-operating assets</li> <li>&gt; Carried out a stable dividend</li> <li>&gt; Strategically stockpiled raw material crude drugs</li> </ul>
<p><b>Remaining issues</b></p>	<ul style="list-style-type: none"> <li>▪ Utilization of evidence in the “drug fostering program” formulations, especially TJ-43 (Rikkunshito)</li> <li>▪ Implementation of Phase II clinical tests for TU-100</li> </ul>	<ul style="list-style-type: none"> <li>▪ Marketing efficiency improvements</li> <li>▪ Cultivating crude drugs Technological development and actual production for raw material crude drugs</li> </ul>	<ul style="list-style-type: none"> <li>▪ Yet to achieve ROE of 14%</li> <li>▪ Inventory control for raw material crude drugs</li> </ul>





Fiscal 2016–Fiscal 2021

Outline of New Medium-Term Management Plan



**TSUMURA**

## Issues and Opportunities Tsumura Faces within the New Plan

### Issues

Impact of fluctuating foreign exchange rates and rising crude drug prices on profits, drug price revisions

### Opportunities

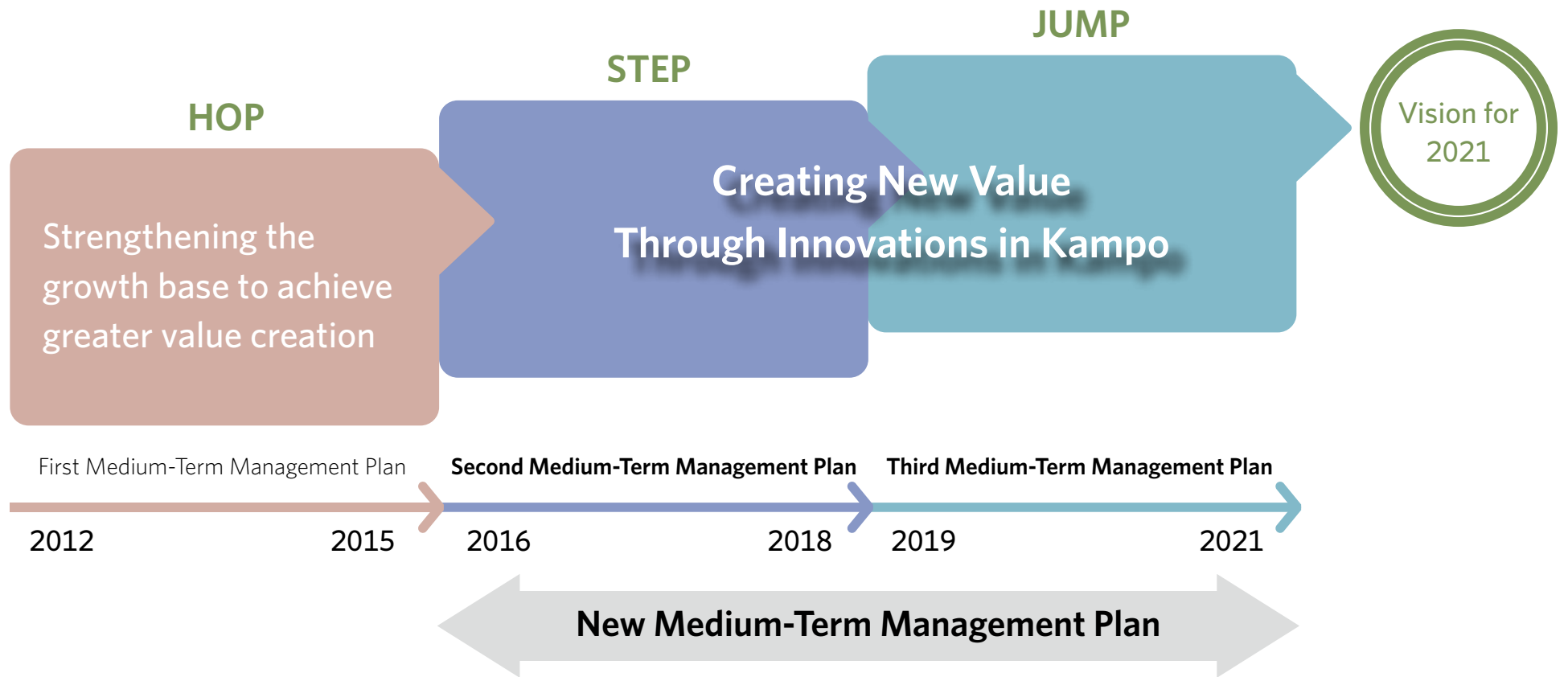
Rapidly aging society, longer healthy life expectancies, countermeasures for dementia, countermeasures for cancer, promotion of the active role of females in the workplace

→ Changes in disease structure (diseases of the elderly, diseases specific to women)

#### Measures by the Ministry of Health, Labour and Welfare

- > *Kenko Nippon 21* (second stage)      Healthy life expectancies, prevention of outbreak and worsening of lifestyle diseases
- > New Orange Plan      Promotion of measures to care for dementia
- > Comprehensive Regional Care System      Promotion of general physicians and home healthcare
- > Comprehensive Strategy to Strengthen the Pharmaceutical Industry
  - ➔ Strategy states that there is a need for the stable provision of high-quality products in regard to the essential and traditional pharmaceuticals that support medical treatment, such as vaccines, intravenous pharmaceuticals, Kampo products, and external-use pharmaceuticals.
- > Plan to Accelerate Countermeasures for Cancer
  - ➔ Strategy states the importance of promoting research related to supportive care that uses nutritional therapy, rehabilitation, and Kampo medicine from the perspective of reducing postoperative complications and prognostic symptoms

# Themes of the New Medium-Term Management Plan and Roadmap to Realizing Long-Term Vision



## Numerical Targets

	FY2018	FY2021
Net sales	<b>¥120 billion</b>	<b>¥135 billion</b>
Operating profit	<b>¥14 billion</b>	<b>¥19 billion</b>
Operating profit margin	<b>11.5%</b>	<b>14%</b>
Net income	<b>¥10 billion</b>	<b>¥13 billion</b>
EPS	<b>¥140</b>	<b>¥185</b>
ROE	<b>6%</b>	<b>8%</b>

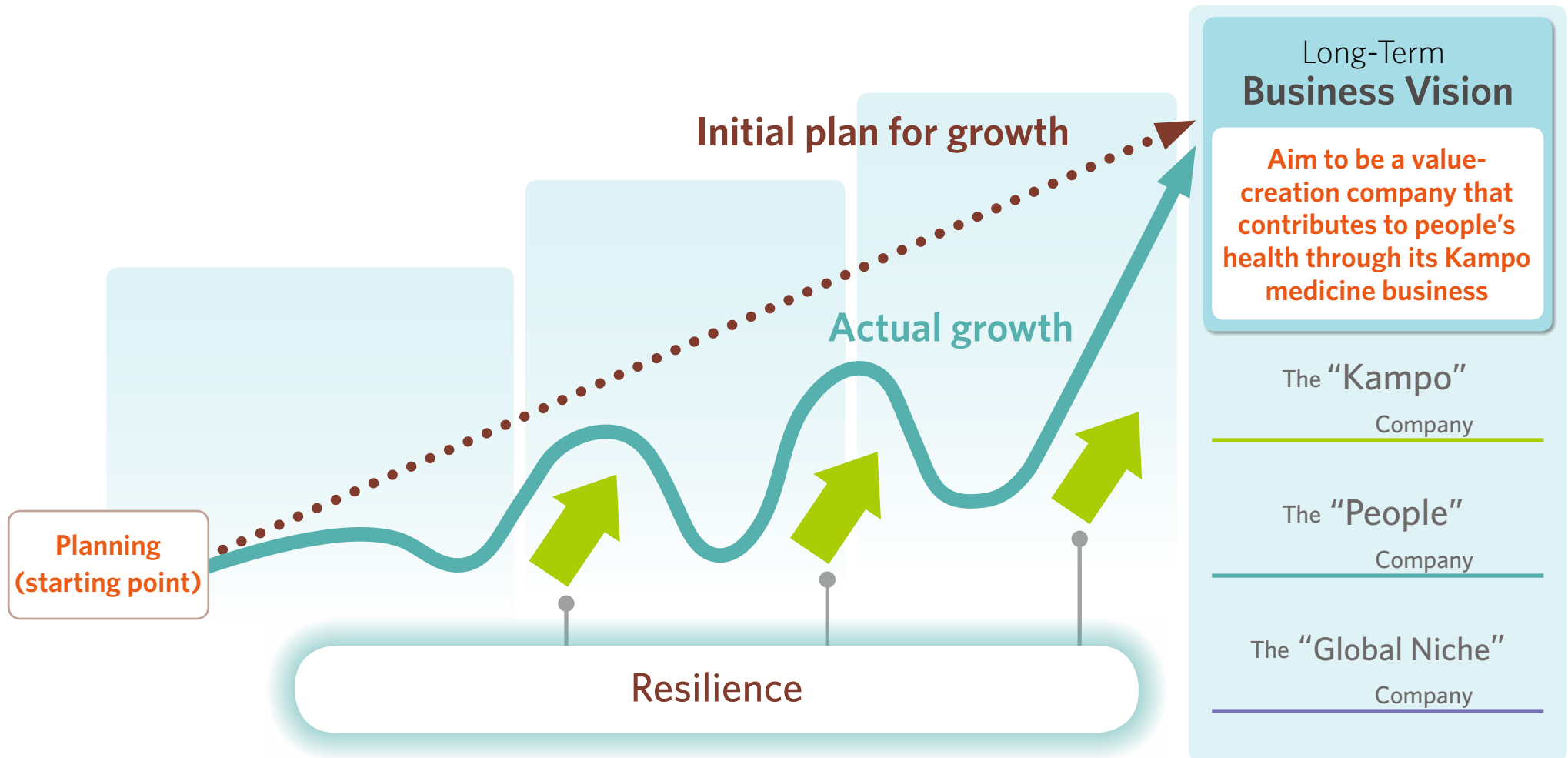
### Preconditions

Drug price revisions:  
Fiscal 2016, 2017, 2018 and 2020

Foreign exchange rates:  
¥115 = 1 US\$

- > Aim for stable growth in the Kampo business despite expectations of the adverse impact of drug price revisions
- > While the influence from soaring raw material crude drug prices will continue, aim for recovery in regard to profits after levels bottom out in fiscal 2018 and growth at a gradual speed thereafter
- > Numerical targets for fiscal 2021 are slated to be announced again at the start of the third stage of the medium-term management plan (fiscal 2019) based on changes in the operating environment

# Strength to Turn Adverse Operating Conditions into Growth



## Strategic Challenges 1-3

- 1** Expansion and stable growth in the Kampo market
- 2** Continued reinforcement of profitability and maximization of cash flow
- 3** Taking on the challenge of new businesses in China



---

Strategic Challenge 1:  
Expansion and Stable Growth  
in the Kampo Market

## Basic Strategy to Expand the Kampo Market

Appropriate provision of information such as scientific evidence, guidelines, and proper use of different formulations based on the Kampo medicine style  
(Basic activities: interviews, briefings, and Kampo seminars)



Medical  
Representatives  
(MRs)



### HP market (university hospitals, designated hospitals for clinical training, etc.)

Promotion activities centered on scientific evidence  
Focus on medical specialists in important domains → Develop demand for new formulations

### GP market (general practitioners, clinics, etc.)

Promotion activities based on the Kampo medicine style  
Enhance the Kampo proficiency level of GPs, primarily with existing clients  
→ Increase quantity of formulations, have GPs prescribe multiple formulations

#### Three Important Domains

1. Geriatric health
2. Cancer domain (supportive care)
3. Women's health



## Expansion of “Drug Fostering Program” Formulations and “Growing” Formulations



Prioritize unmet medical needs

BPSD, frailty, supportive care for cancer (postoperative dysfunction, loss of appetite, stomatitis), menopausal disorders, etc

**Aim to have three formulations, TU-100 (Daikenchuto), TJ-54 (Yokukansan), and TJ-43 (Rikkunshito), with over ¥10.0 billion in sales by fiscal 2021**

\*1 Looking at the recent structure of disease, the Company has selected certain diseases in fields where medical treatment needs are high that are difficult to treat with Western drugs and that Kampo products have demonstrated special efficacy for. The Company will establish a base of scientific evidence related to treating these diseases with Kampo medicine.

\*2 A growth driver that aims to be listed in medical treatment guidelines as a strategic formulation following the five “drug fostering” program formulations through the establishment of scientific evidence (data on safety, efficacy, etc.) in fields where satisfaction toward treatment and the contribution of medicine are low.

## Enhancement of Evidence Collection

Establish evidence of safety and efficacy → Enhance package inserts

Further develop “Drug fostering program” formulations followed by “Growing” formulations → Publish medical treatment guidelines

Collect clinical EBM, action mechanisms, side effect frequency surveys, ADME, and health economic data

	Meta-analysis	RCT	Action mechanisms	Side effect frequency surveys	ADME	Publish guidelines (include recommendations for Kampo medicine)
TJ-100 (Daikenchuto)	Paper submitted	23	◎	◎	◎	Pediatric chronic functional constipation disease, systemic sclerosis
TJ-54 (Yokukansan)	1	12	◎	◎	◎	Dementia disease
TJ-43 (Rikkunshito)	—	16	◎	Ongoing	◎	Functional gastrointestinal disease, the diagnosis and treatment of psychosomatic diseases, GERD
TJ-107 (Goshajinkigan)	—	14	△	—	○	Benign prostatic hyperplasia, overactive bladder syndrome
TJ-14 (Hangeshashinto)	—	5	○	—	—	—

## New Approach for Establishing Evidence

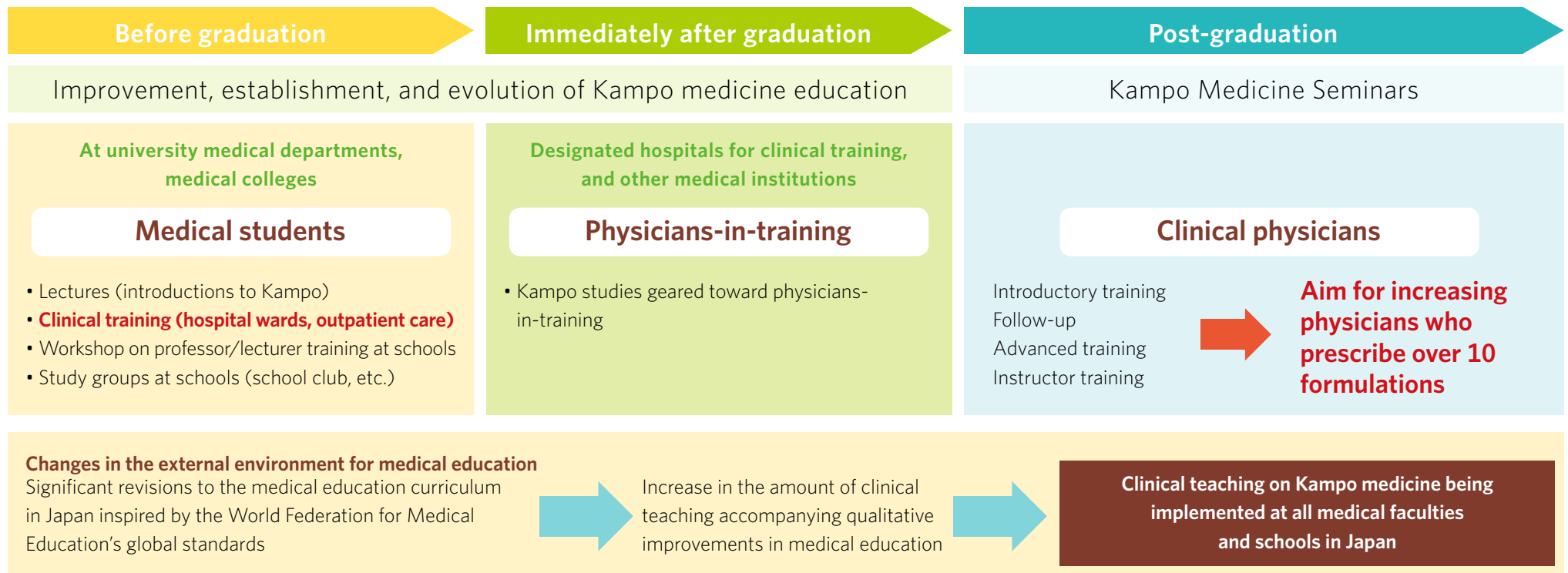
Leverage new technologies (IT, new analysis methods, network analysis, etc.) to accelerate research on Kampo medicine and Kampo formulations



- System biology : University of Oxford's Innovative Systems Biology  
The Systems Biology Institute (SBI)
- Metabolomics : Kobe University's Division of Metabolomics Research
- Intestinal bacteria : University of Chicago's Digestive Diseases Center
- Big data : University of Tokyo's Health Services Research Course

## Supporting Education Related to Kampo Medicine for Doctors and Providing Information to Consumers

### Supporting Kampo medicine education before, immediately after, and post-graduation



### Transmission of information to consumers

Activities geared toward the elderly

Activities targeting cancer patients

Activities geared toward females

## Development of TU-100 (Daikenchuto) in the U.S.

		Previous medium-term management plan				New medium-term management plan		
		FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018 and after
Quality control		Through meetings with FDA, agree on quality evaluation methods using biological assessments and HPLC-FP				<ul style="list-style-type: none"> <li>Agree on quality control systems</li> <li>Establish database for crude drug quality</li> </ul>		
Efficacy and safety	IBS	Endpoint search clinical trials (IBS patients) <b>Scheduled to be completed in fiscal 2016</b>				PII (early stage)		
	POI	Endpoint search clinical trials (patients with laparoscopic colectomy) <b>Scheduled to be completed in fiscal 2017</b>				PII (early stage)		
	Crohn's disease	Responder trials (patients with Crohn's disease) Fiscal 2011-fiscal 2014 PII (early stage)						
	Safety, etc.	Side effects <sup>*1</sup>	ADME <sup>*2</sup>					

Plan to decide on direction and schedule for the late stage of PII and on in fiscal 2018 after finishing and analyzing all of the early stage of PII for IBS/POI and Crohn's disease

\*1 Submit results of surveys on the frequency of side effect manifestation to the FDA

\*2 Submit clinical pharmacokinetic results on healthy U.S. citizens to the FDA

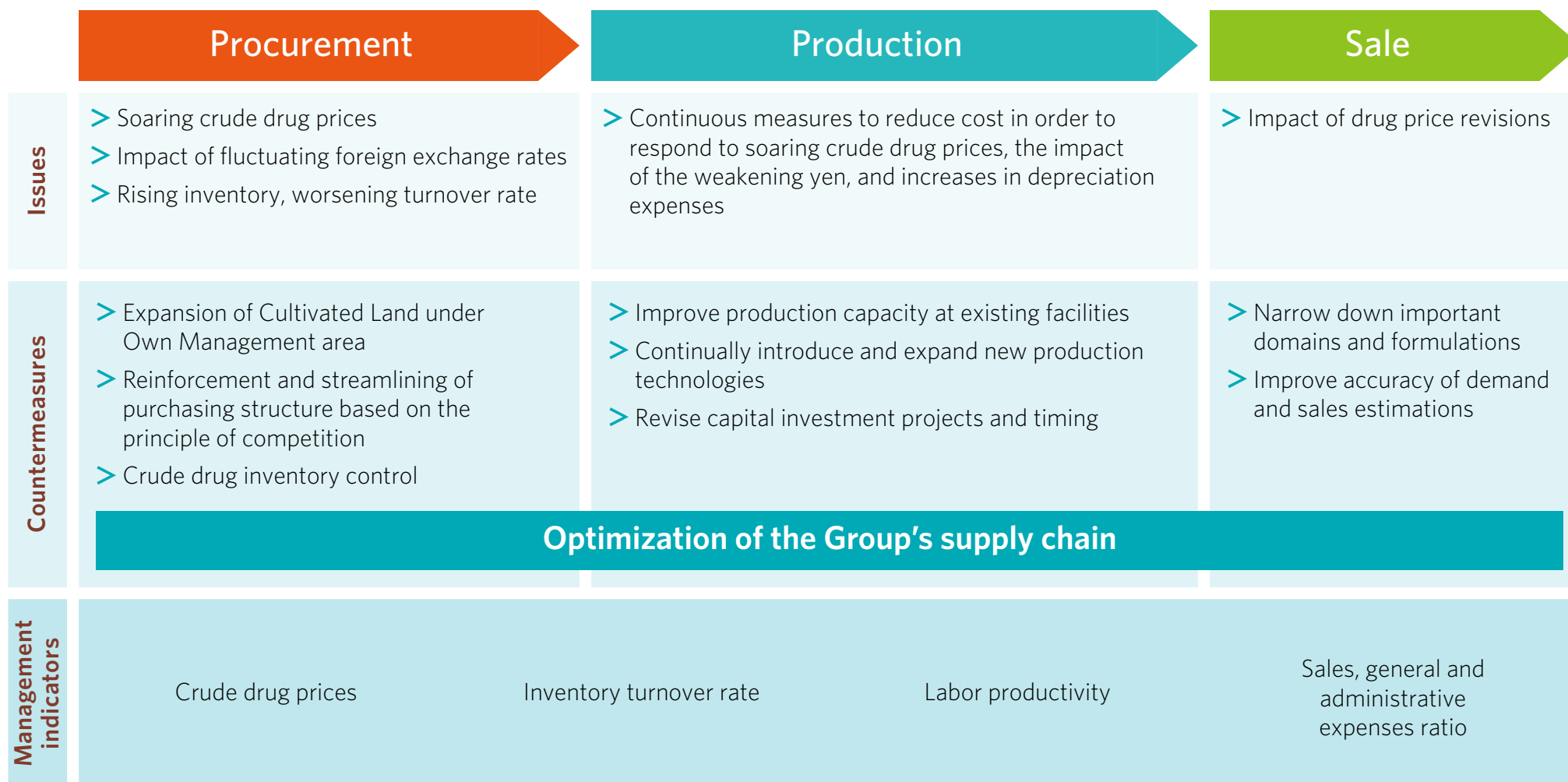
IBS: Irritable bowel syndrome, POI: Postoperative Ileus



Strategic Challenge 2:

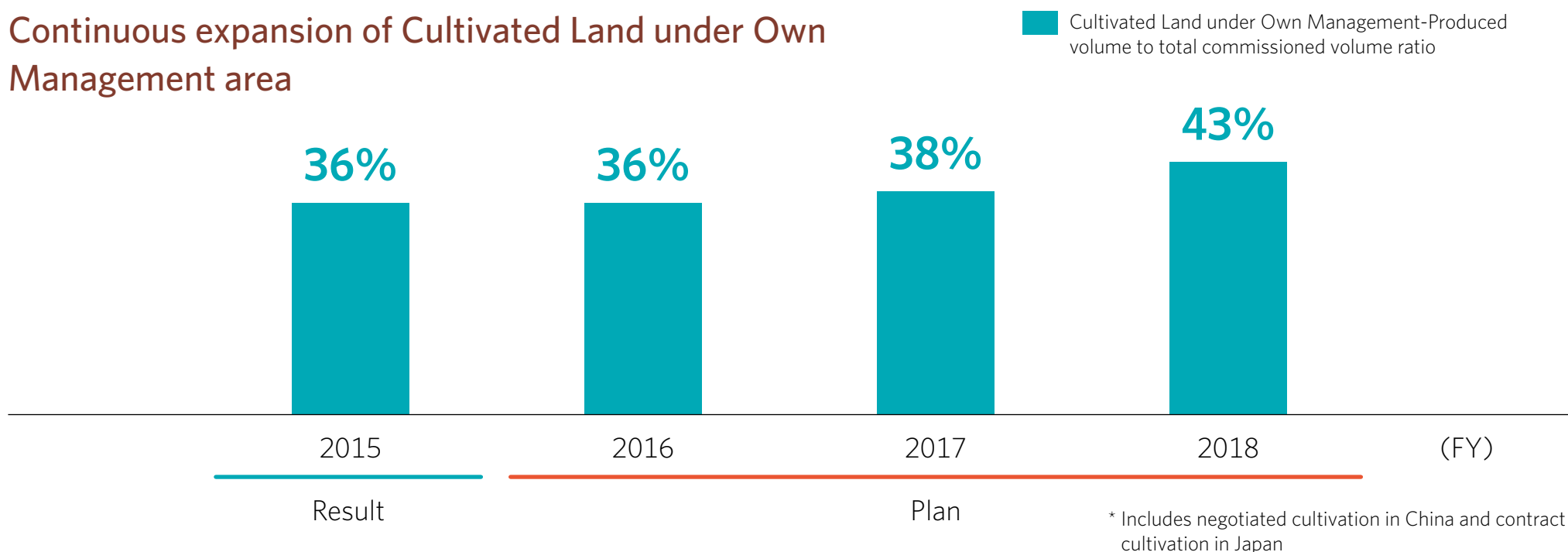
Continued Reinforcement of Profitability  
and Maximization of Cash Flow

## Improvement of Profits Seen in Supply Chain / Overview of Cash Flow Maximization



## Innovations in Crude Drug Procurement that Realize Stable Prices and Enhanced Quality Assurance

### Continuous expansion of Cultivated Land under Own Management area



**Aim for a Cultivated Land under Own Management-Produced volume ratio of 50% in fiscal 2021**

Reinforce and streamline purchasing structure based on the principle of competition

Pursue crude drug quality and further enhancement of systems to ensure safety



## Innovations in Manufacturing Systems that Realize Improved Production Capacity

Establishment of foundation where the effects of cost reductions can be anticipated through the introduction of automated equipment that uses less manpower in the previous medium-term management plan

Expanded introduction of new production technologies

> Improvement of basic production capabilities at existing facilities

Optimization of operating systems for production (revise number of operating days, non-operating times, etc.)

Reduction of difficulties and waste

> Continuous introduction and expansion of new production technologies

Development of new granulation systems and high-speed filling machines → Gradual introduction to new manufacturing buildings

▪ Support for PIC/S GMP ▪ Further improvement of granule and product quality ▪ Promotion of automatization and reduced manpower

**Effect of improved labor productivity (throughout all processes)**

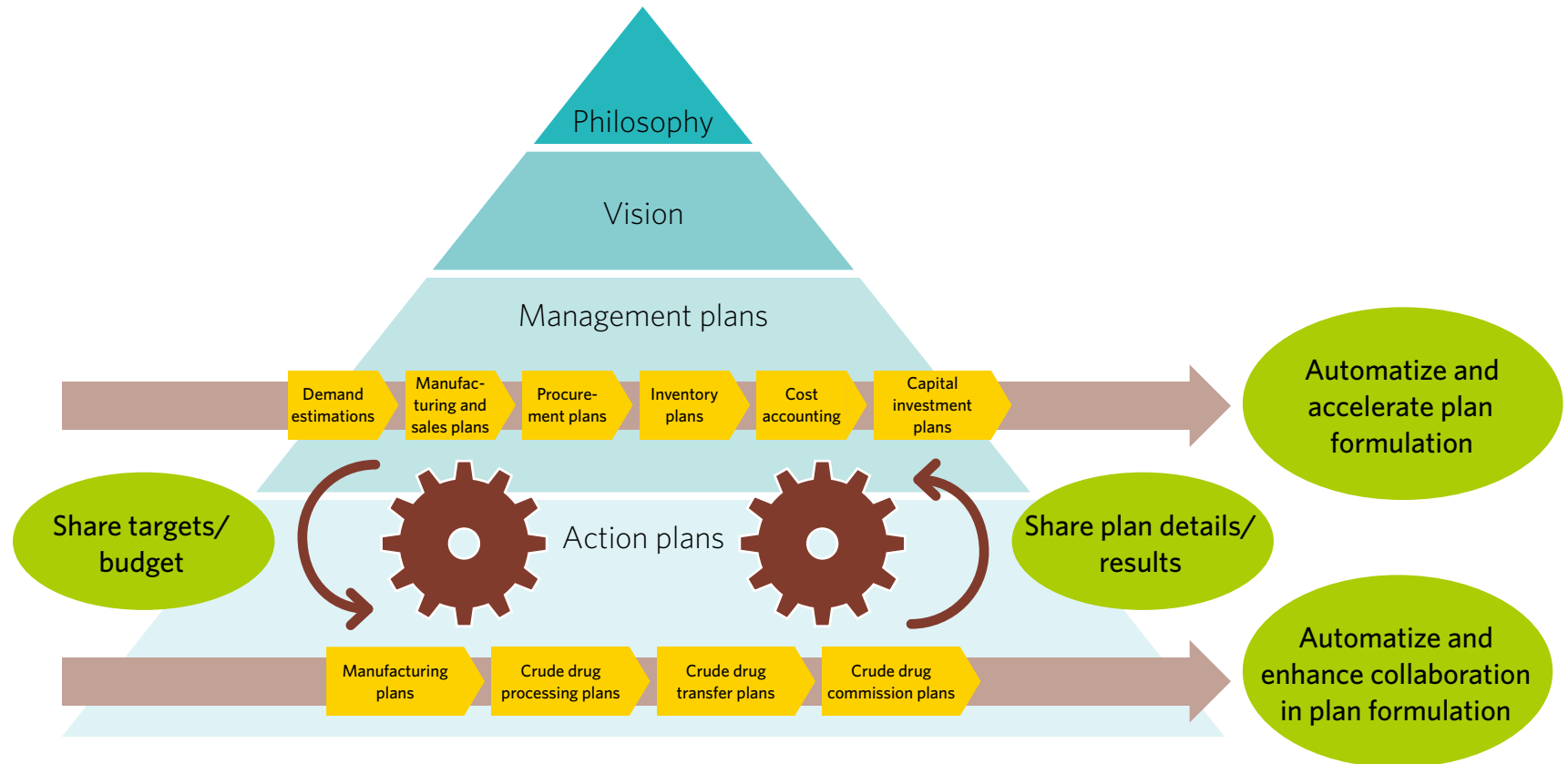
**Aim for 30% increase in fiscal 2021 compared to fiscal 2015**

> Capital investment

**Scheduled average amount for fiscal 2016–fiscal 2018: ¥10 billion a year**

**Scheduled average amount for fiscal 2019–fiscal 2021: ¥8 billion a year**

## Innovations in SCM that Realize Optimization of Groupwide Supply Chain



- > Accelerate plan formation, work to shorten rolling periods, promptly anticipate future risks
- > Optimize the entire supply chain by bolstering cooperation between both “management and factory floor” and “divisions and bases”

## Effective Allocation of Resources

Allocate resources in a way that reflects the intention of management from a medium- to long-term perspective

### **Research and development expenses**

Total amount for fiscal 2016–fiscal 2021 (six-year period): ¥45.0 billion

Basic/clinical research in Japan, development in the U.S., research on crude drug cultivation, etc.

Concentrated investment in the necessary projects for future growth

### **Enhanced cost efficiency**

Continued promotion of optimizing primarily fixed costs, which occurred in the first medium-term management plan

**Aim for a sales, general and administrative expense ratio  
of less than 40% in fiscal 2021**



Strategic Challenge 3:

Taking on the Challenge of New Businesses in China



**TSUMURA**

## Taking on the Challenge of New Businesses in China

### 1. Entering the business for traditional Chinese medicine compound granules (single crude drug extract granules)

- > Establish a joint venture with Shanghai Traditional Chinese Medicine Co., Ltd., a subsidiary of Shanghai Pharmaceuticals Holding Co., Ltd.
- > Build a procurement structure for raw material crude drugs centered on SHENZEN TSUMURA MEDICINE CO., LTD. and China Medico Corporation

### 2. Entering a business collaboration agreement with China Medico Co., Ltd.

- > Strengthen the Company's supply and procurement relationship for raw material crude drugs used in Kampo preparation
- > Strengthen the Company's technical support to China Medico Corporation
- > Conduct joint research on ginseng and other key crude drugs, manage production sites for such crude drugs, and establish a stable, long-term supply structure
- > Engage in joint development of a Chinese crude drug pieces business (Jointly implementing businesses with SHENZEN TSUMURA MEDICINE, a 100% subsidiary of the Company)
- > Continually explore strategy for new joint businesses
- > Bolster relationship with China Medico Corporation by dispatching directors from Tsumura to the China Medico Group (scheduled to begin during fiscal 2016)

### 3. Entering into the crude drug pieces business

- > Engage in sale of crude drug pieces to external customers in China through SHENZEN TSUMURA MEDICINE, a 100% subsidiary of the Company
- > Cooperate with China Medico Corporation in the mutual supply and processing of raw material crude drugs

### 4. Planning the establishment of a holding company in China

- > Control and management of supply chain, human resources, and capital in China spanning from existing businesses to new businesses, such as production of traditional Chinese medicine compound granules and export of crude drugs and extracts to Japan

> Contributing to China, where the Company procures crude drugs, and the health of Chinese people

> Taking on the challenge of entering the Chinese market

## The Tsumura Group’s Point of View on ESG

### Tsumura Group’s Distinctive Initiatives Related to ESG

Tsumura Group contributes to building sustainable society through its mainstay “Kampo and crude drug” business

<p><b>Environment</b></p>	<ul style="list-style-type: none"> <li>▪ Initiatives for protecting crude drug raw materials and the natural environment Continuous research on the cultivation of wild-grown crude drugs</li> <li>▪ Initiatives toward the environment in order to realize a recycling-oriented society Maintain zero emissions (100% recycling rate of industrial waste)</li> <li>▪ Establish and implement environmental targets that are based on the Tsumura Environmental Policy and Tsumura Environmental Principle</li> </ul>
<p><b>Society</b></p>	<ul style="list-style-type: none"> <li>▪ Contribute to the revitalization of the primary industry through crude drug cultivation (utilization of unused agricultural land and expansion of Cultivated Land under Own Management area, etc.)</li> <li>▪ Contribute to medical care in such social issue domains as geriatric health, cancer treatment (supportive care, palliative care), and women’s health</li> <li>▪ Promote diversity among Group directors and employees and create opportunities for the employment of persons with disabilities</li> </ul>
<p><b>Governance</b></p>	<ul style="list-style-type: none"> <li>▪ Establish and operate a highly effective corporate governance system</li> <li>▪ Give consideration to the establishment of a nomination/compensation advisory committee</li> <li>▪ Director remuneration Performance-linked stock compensation</li> <li>▪ Dialogue with shareholders and other investors Promote a policy to continuously and proactively engage in dialogue with shareholders and other investors (including dialogue with outside directors) through the Company’s IR activities in order to establish long-term, trust-based relationships with them</li> </ul>

## Capital and Financial Measures

Guided by the stable business strategy of the Tsumura Group, the Company secures a solid financial structure while actively conducting business investments that contribute to the improvement of corporate value over the medium to long term

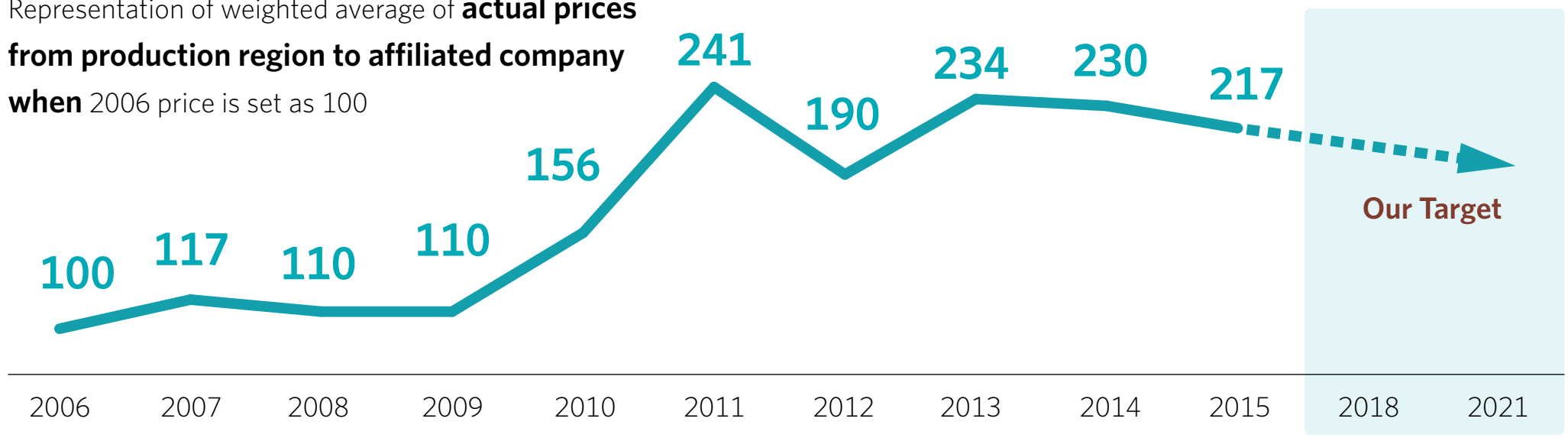
<b>Cash flows</b>	<p>Fiscal 2016–fiscal 2021 (six-year period)</p> <ul style="list-style-type: none"> <li>▪ Capital investments: ¥55.0 billion</li> <li>▪ Investments and loans (new company related to China): ¥6.0 billion</li> <li>▪ Shareholder returns (dividends): ¥27.0 billion</li> </ul> <p style="text-align: right;">In total, expecting roughly ¥88.0 billion in cash outflows</p> <ul style="list-style-type: none"> <li>▪ Expecting ¥96.0 billion in cash flows from operating activities</li> </ul>
<b>Major capital investments</b>	<p>Fiscal 2016–fiscal 2021 (six-year period)</p> <ul style="list-style-type: none"> <li>▪ Ibaraki Plant Standard-based facility (first term, second term): Approx. ¥17.0 billion</li> <li>▪ Shizuoka Plant New granulation and packaging facilities, etc.: Approx. ¥4.2 billion</li> <li>▪ Facilities related to cultivation: Approx. ¥4.0 billion</li> </ul>
<b>Shareholder returns</b>	<ul style="list-style-type: none"> <li>▪ Promote a policy to improve corporate value through capital investments in order to realize the continuous development and growth of “Kampo”</li> <li>▪ Promote a policy to consider medium- to long-term profit levels and cash flows as well as carry out a stable dividend</li> <li>▪ Promote a policy to acquire treasury stock in a flexible manner after making efforts in shareholder returns based on examinations and revisions for an optimal capital structure as well as giving comprehensive consideration to market trends, etc.</li> </ul>
<b>Efficiency</b>	<ul style="list-style-type: none"> <li>▪ The Tsumura Group evaluates each individual investment giving consideration to risks and profitability that accompany the investment. At the same time, the Group works to maintain and improve investment efficiency</li> <li>▪ Aim for ROE of 8% by fiscal 2021</li> </ul>

Reference

# Crude Drug Prices

## Overall procurement price of crude drugs produced in China

Representation of weighted average of **actual prices from production region to affiliated company** when 2006 price is set as 100



2011  
(1) Local demand in China increased;  
(2) Unfavorable weather;  
(3) Speculative investment cornering market

2013  
Price increase of ginseng, etc

2015  
Drop in ginseng prices that exceeded expectations  
1. Declining trend of purchases for speculative gains  
2. Increase in supply to market



TSUMURA & CO.  
Investor Relations Group  
Corporation Communications Dept.

**Cautionary items regarding forecasts**

- The materials and information provided in this presentation contain so-called forward-looking statements. Readers should be aware that realization of these statements can be affected by a variety of risks and uncertainties and that actual results could differ significantly.
- Changes in the healthcare insurance systems or regulations set by medical treatment authorities on drug prices or other aspects of healthcare or in interest and foreign exchange rates could impact negatively on the Company's performance or financial position.
- In the unlikely event that sales of the Company's core products were halted or declined substantially due to a defect, unforeseen side effect or some other factor, it would have a major impact on the Company's performance or financial position.