

Updates to Shionogi Growth Strategy (SGS2020)

October 31, 2016

SHIONOGI

Summary of SGS2020

Vision **Grow as a drug discovery-based pharmaceutical company**

Top-line growth

Clear priorities and focused resourcing
Growth led by FIC and LIC compounds

Sales areas

- Japan
- US

Therapeutic areas

- Infectious disease
- Pain/CNS

Bottom-line growth

Continued improvement of business operations

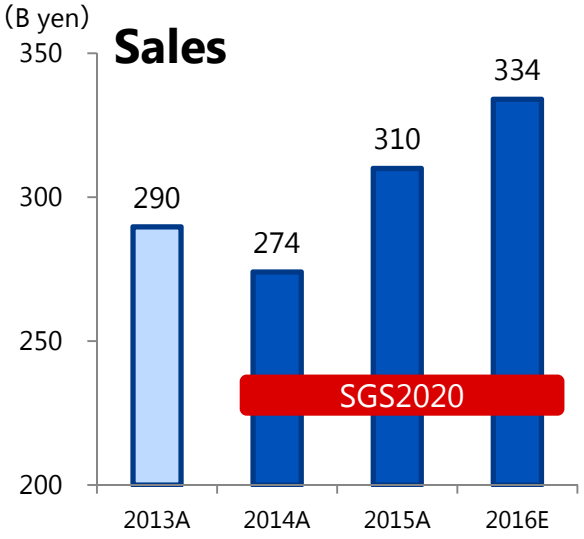
- Growth with current amount of resources
- Stable supply, quality and cost-competitiveness
- Critical role of headquarters in strategic planning and execution
- Develop leaders to accelerate our further growth
- Share the growth

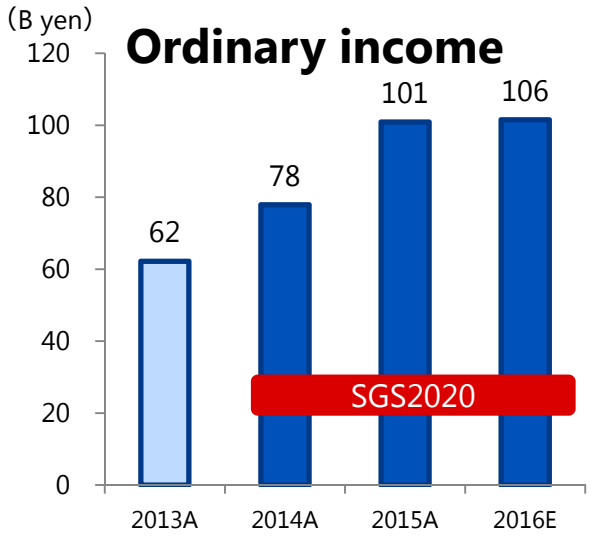
Progress toward Achieving SGS Targets

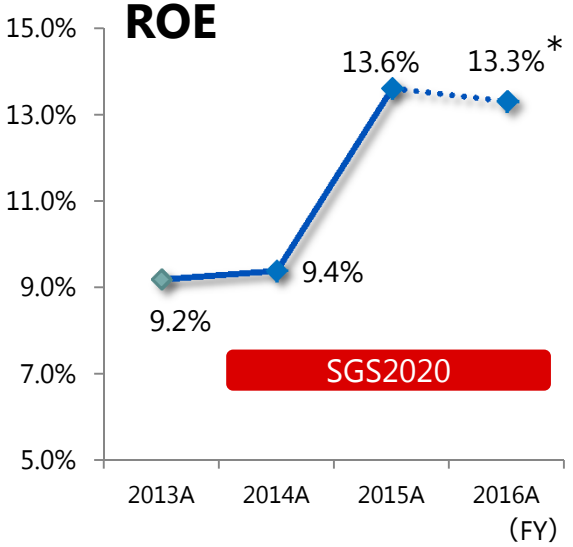
Achieving SGS2020 quantitative targets ahead of schedule

FY2015 Results

- Sales: **310.0 B yen**
- Ordinary income: **Over 100 B yen**, record-high levels for four consecutive years
- ROE: **Over 13%**, drastically improved







*FY2016 original forecast

Achievements in SGS2020

Clear priorities and focused resourcing Growth led by FIC and LIC compounds

- **Sales of Crestor® exceeded 100B yen by Shionogi/AZN in Japan**
- **Accelerating development and NDA filings**
  - NDA: naldemedine (JP/US), guanfacine hydrochloride (JP)
  - Launched: Actair® (JP), Mulpleta® (JP), Senshio® (EU)
- **Innovative alliances**
  - Modification of the Cymbalta® contract (JP)
  - Alliance with Roche regarding S-033188 (global)

Continued improvement of business operations

- **Achieved positive operating income without royalty**
- **Continued expense reductions**
  - COGS: 26.9% → 24.1%
  - Inventory turnover: 7.4 months → 6.8 months
- **Structural reforms**
  - Divested Ezose Sciences, a US subsidiary providing glycan analytical services (Aug. 2014)
  - Established Shionogi Healthcare, consumer healthcare business (Jan. 2016)
  - Restructured diagnostic business (Apr. 2016)
  - Divested twenty-four long-listed drugs (May/Aug. 2016)

Remaining Key Actions for Achieving SGS2020

Global business

- In the most important market, the US, our business hasn't yet achieved profitability
- Osphena® is growing, but slowly

Japanese business

- The sales of new products, including Cymbalta®, Mulpleta® and Actair® are lower than expectations

Productivity

- Without royalty, operating profit per employee is on a plateau

Prompt maximization of new products' value

External Environment of Pharmaceutical Industry

Patients' active participation in healthcare

- Increase in overall medical needs, but also increased segmentation
- Increased expectations for efficacy, safety and efficiency of new drugs
- Growing expectation for longer healthy life expectancy
- Increasing trends toward self-medication

Changes in R&D environment

- Applying innovative technologies such as iPS cells to enable regenerative medicine and new drug discovery
- Addressing unmet medical needs with drug discovery
- Committing on stemming the rising tide of drug-resistant bacteria and viruses

Trends in global pharmaceutical market

- Developed countries: Financial pressure on health insurance, controversy around high drug prices, pursuit of ROI improvement by public and private healthcare systems
- Emerging countries: rapidly increasing healthcare needs and greater voice commensurate with economic growth

Transformation of healthcare business

- Increasing analyzable healthcare data with IoT, and implementing structure supporting broader utilization and sharing of data
- Borderless healthcare business, networked with new entrants from outside healthcare industry

Growth Strategy for 2020

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

Region to grow	Keys to growth
Japan/US Development in EU/Asia	**Addressing society's needs**
Infectious disease **Pain/CNS**	**Balance of innovation and health economic efficiency**

Social Challenges that Shionogi Strives to Address

Creating a more vigorous society

- Help people who are isolated due to pain/suffering to re-enter society
- Provide relief from psychological uncertainty allowing fulfillment of one's innate ability
- Maintain the dignity of the individual through all the stages of life





- Develop new drugs against infectious diseases that lack effective medical treatments
- Reduce outbreaks of bacterial and viral resistance by promoting proper use of anti-infective drugs

Protecting people from the threat of infectious diseases

Creating a More Vigorous Society

Pain

- Helping those with chronic pain to live more active lives
  - ⇒ **Cymbalta®**
  - ⇒ **OxyContin®**
- Help patients and society to manage the negative aspects of opioids
  - ⇒ **OxyContin® tamper resistant formulation**
  - ⇒ **Naldemedine**



CNS

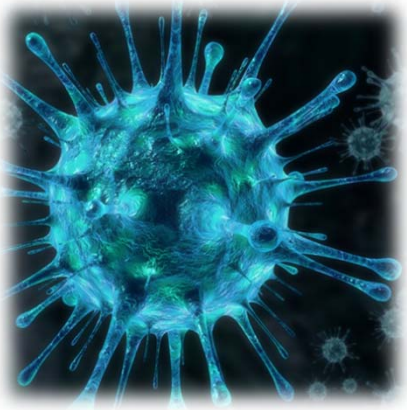
- Relieve patients, their families and friends from the impact of psychiatric/nervous system disorders and restore fuller participation in society
  - ⇒ **Guanfacine hydrochloride**
  - ⇒ **Lisdexamfetamine**
  - ⇒ **Cymbalta®**
  - ⇒ **Janssen/Shionogi project compound**



Protecting People from Threat of Infectious Diseases

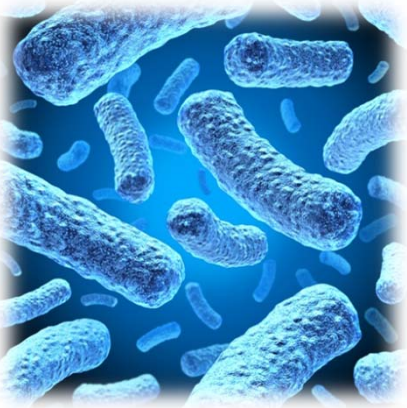
Anti-viral drugs

- Continuing progressive R&D for anti-HIV drugs
  ⇒ **HIV franchise**
- Reduce flu symptoms with a single oral dose
  ⇒ **S-033188**



Drugs for severe infection

- Actively promote antimicrobial stewardship*
- Save lives at risk from multi-drug resistant bacterial infections
  ⇒ **cefiderocol (S-649266)**
- Create novel antibiotics against invasive fungal infections with high mortality rates



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* Timothy H.D. Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship *Clin Infect Dis.* (2007). *44 (2): 159-177*

Pursuing More Efficient R&D with Small Molecule Drug Discovery

Contribute throughout the healthcare value chain by leveraging our capabilities in small molecule drug discovery, creating novel drugs whose innovation brings both health and economic benefits

Open innovation

- Identify novel research concepts

Drug discovery engine

- New SAR* platforms
- Expand platform to include peptides

Development design

- Effective and efficient drug pre-registration and post-marketing product development

Biomarker R&D

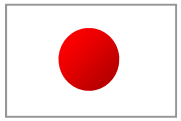
pursuing synergies with our pipeline

Utilization of big data

* Structure-Activity Relationship

Sales & Marketing Strategy in Japan and US

Japan



Further growth based on Pain/CNS

- Maximize Cymbalta®, both depression and pain
- Establish pain franchise with OxyContin® family and naldemedine
- Entry in ADHD with guanfacine hydrochloride and lisdexamfetamine
- Continue to enhance flu field with Rapiacta® and S-033188

US



New growth from Shionogi pipeline drugs

- Entry into pain field with naldemedine
- Entry in anti-infective field with cefiderocol (S-649266) and S-033188 (co-promotion with Roche)
- Maximize the value of Osphena® brand

Continued Improvement of Business Operations

Highest quality/Stable supply/Cost-competitiveness

Manufacturing
Flexible manufacturing framework from clinical supplies through to marketed products

Logistics
Enhance sales & operations planning globally

Inventory
Establish stocking and inventory management based on BCP

Reliable, well-trusted drugs

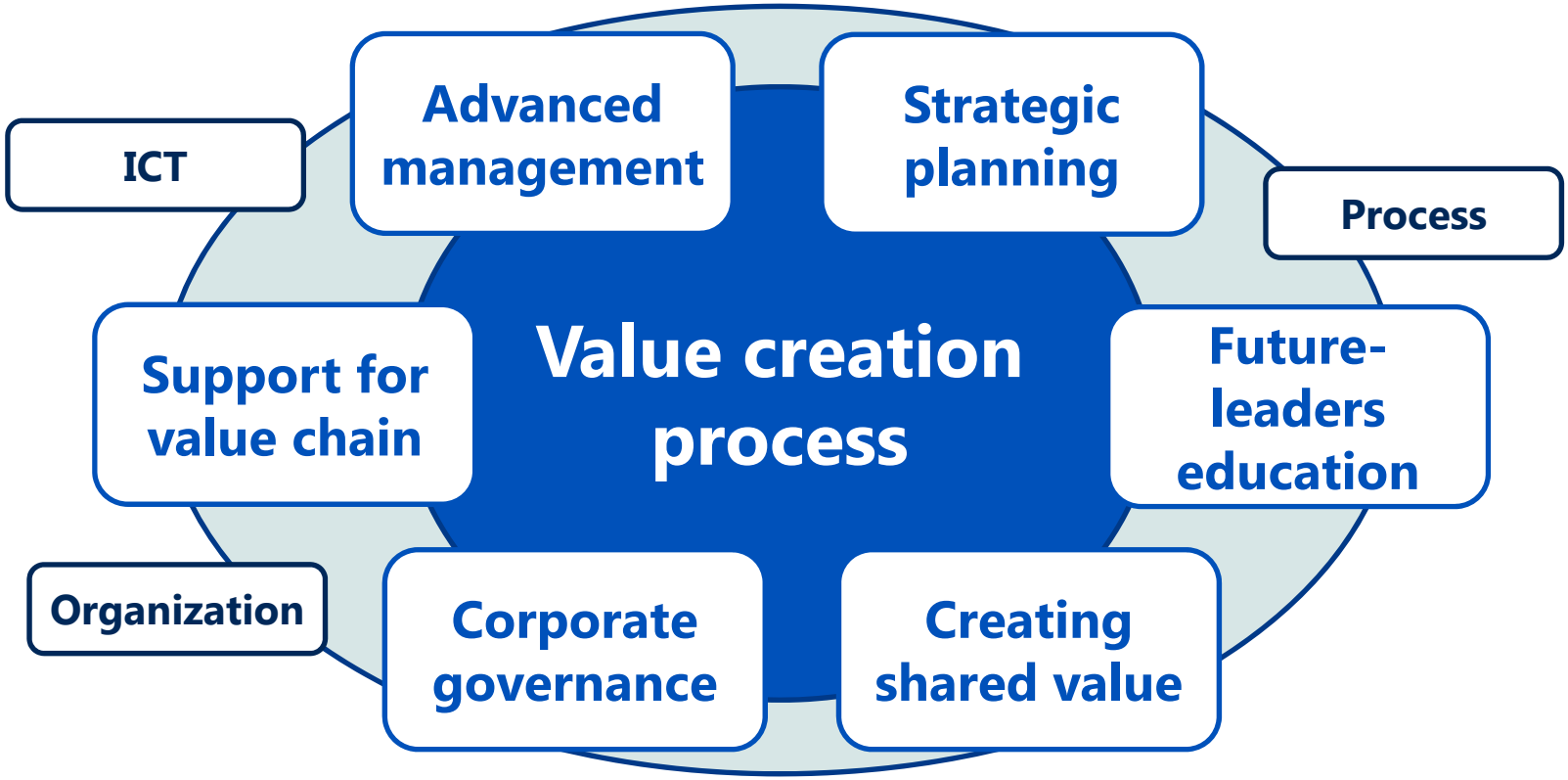
Quality
Proactive action based on forward-looking analysis to address risks before they arise

Pharmaceutical affairs
Close adherence to regulations, high-quality filings, and attention to compliance for marketed drugs

Safety
Provide readily comprehensible, accessible, and comprehensive safety information to meet medical needs

Competitive Headquarters

A headquarters focused on value creation, strategic guidance, and leadership development



New Targets

- Aggressive yet achievable targets
- Focused on independent growth
- Anticipating environmental changes where possible, but flexible enough to accommodate the unexpected

Three focus areas

Growth

Efficiency

Shareholder return

KPIs for Growth

The Company Policy of Shionogi

"strive constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve"
.....(snip)
"For this purpose, Shionogi will need to pursue the search for even better medicines"

Innovative novel products

Bring substantial value to society by creating and fostering new products

KPI as a result

Focused resourcing for the development of new products

Sales of new products: 200 B yen
Ordinary income: 150 B yen

- The most important targets for our growth
- Focused resourcing on what we can control even in the event of changes in the environment

Definition of New Products

Pain/ CNS

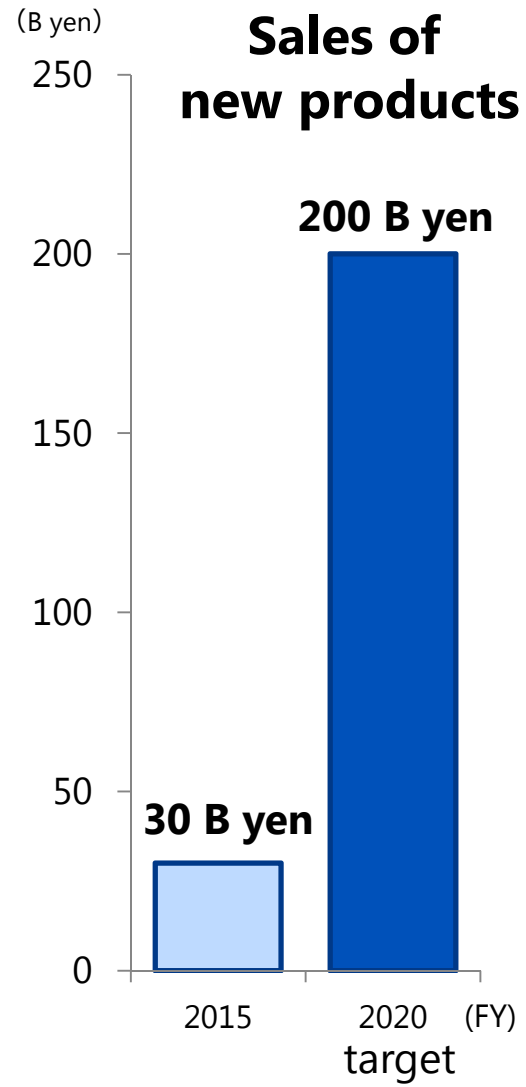
- Cymbalta®
- OxyContin® tamper resistant formulation, OxiNorm®, OxiFast®
- Naldemedine
- Guanfacine hydrochloride, lisdexamfetamine

Infectious diseases

- S-033188
- Cefiderocol (S-649266)
- Rapiacta®, flu diagnosis kit

Others

- Pirespa®
- Mulpleta® (S-888711)
- Actair®
- Glashvista®
- Osphena® (Senshio®)



KPIs for Efficacy

The Company Policy of Shionogi

"Supply the best possible medicine to protect the health and wellbeing of the patients we serve"
.....(snip)
"For this purpose, Shionogi will need to research, produce and promote in an even more economical manner"

Enhancing our strength

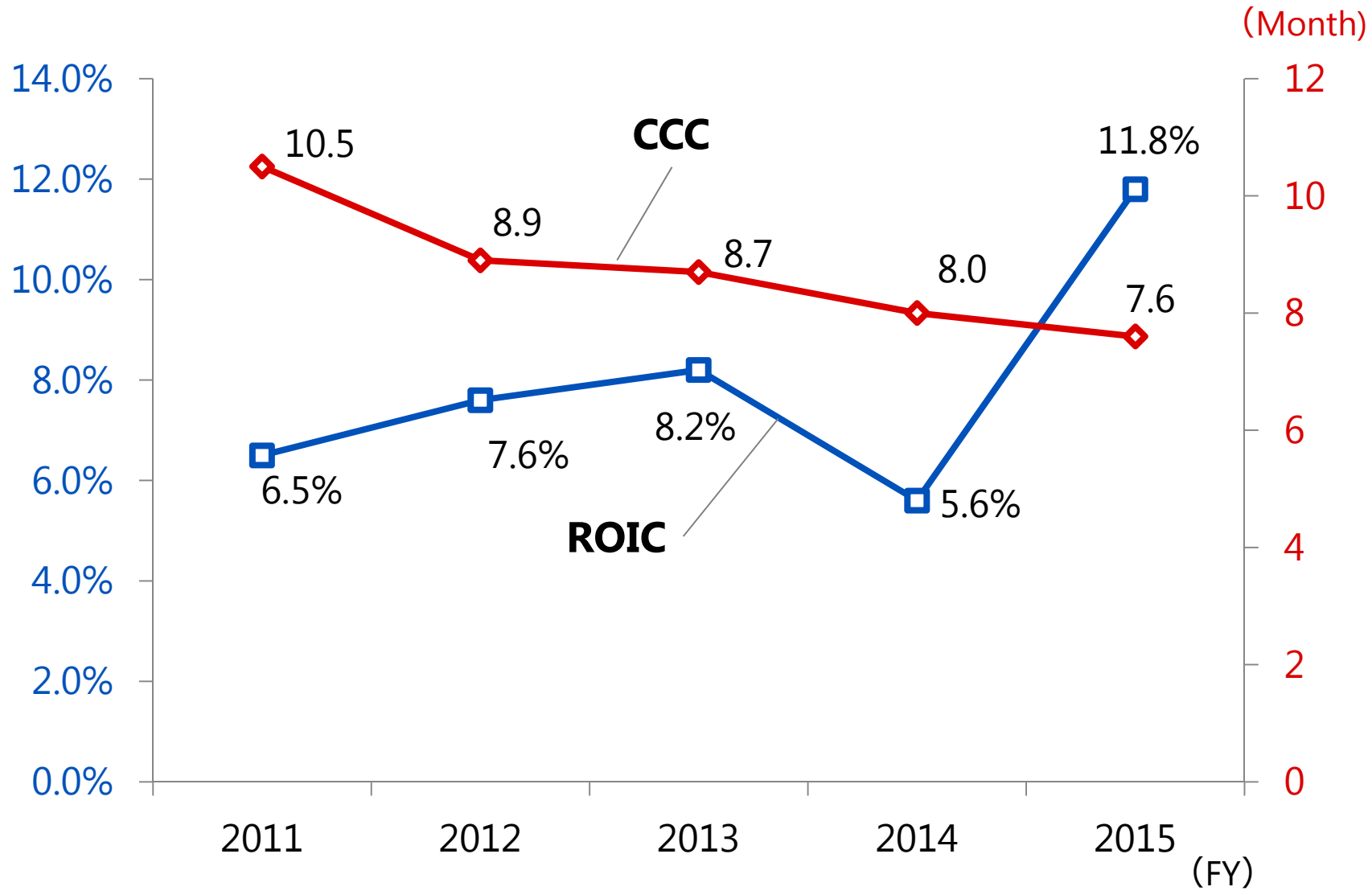
Increase efficiency in operations	Increase efficiency in R&D
• Improved accounting systems to support value-focused decision-making • Increased ability to generate cash flow	• Pursuing effective and efficient development of original drugs

KPI as a result

ROIC*: Over 13.5%　CCC: 5.5 months**
Our pipeline* ratio: Over 50%**

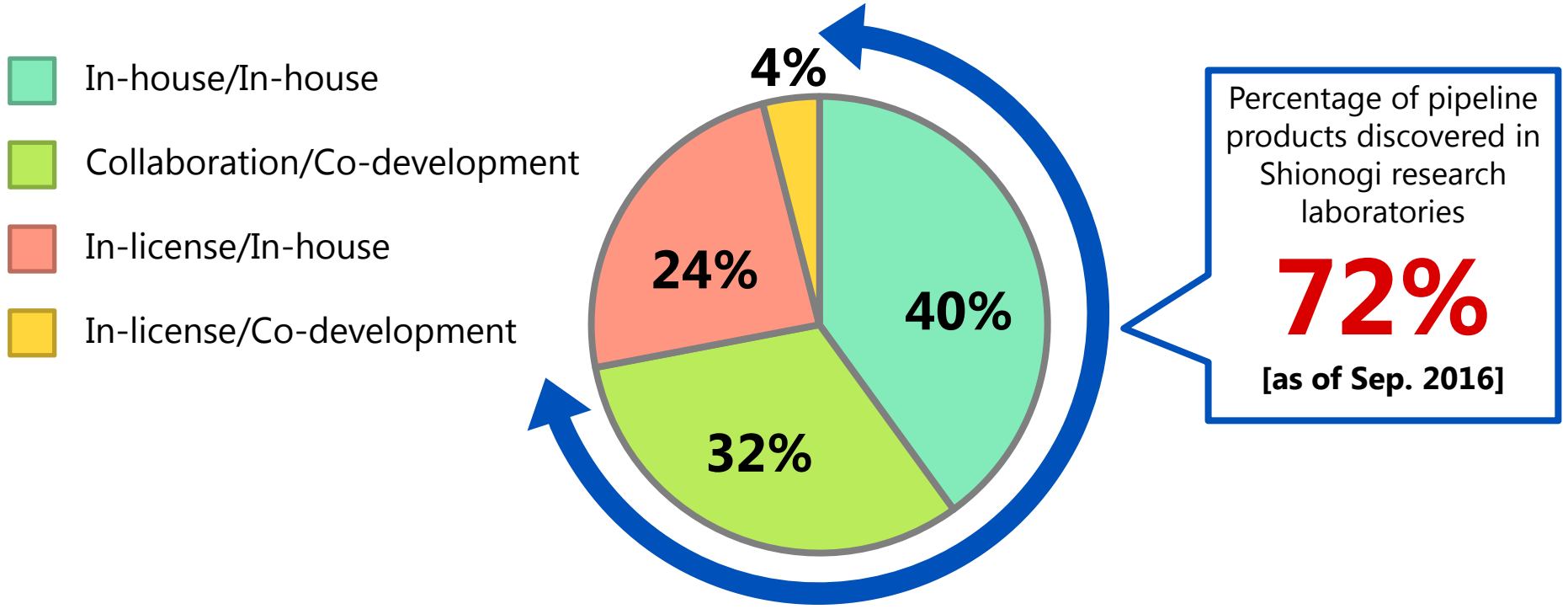
* Return on invested capital　** Cash conversion cycle
*** including collaboration products and internally selected drug candidates

Five-year Trend in ROIC and CCC



Our Pipeline Ratio

More than half of our pipeline* was discovered within Shionogi

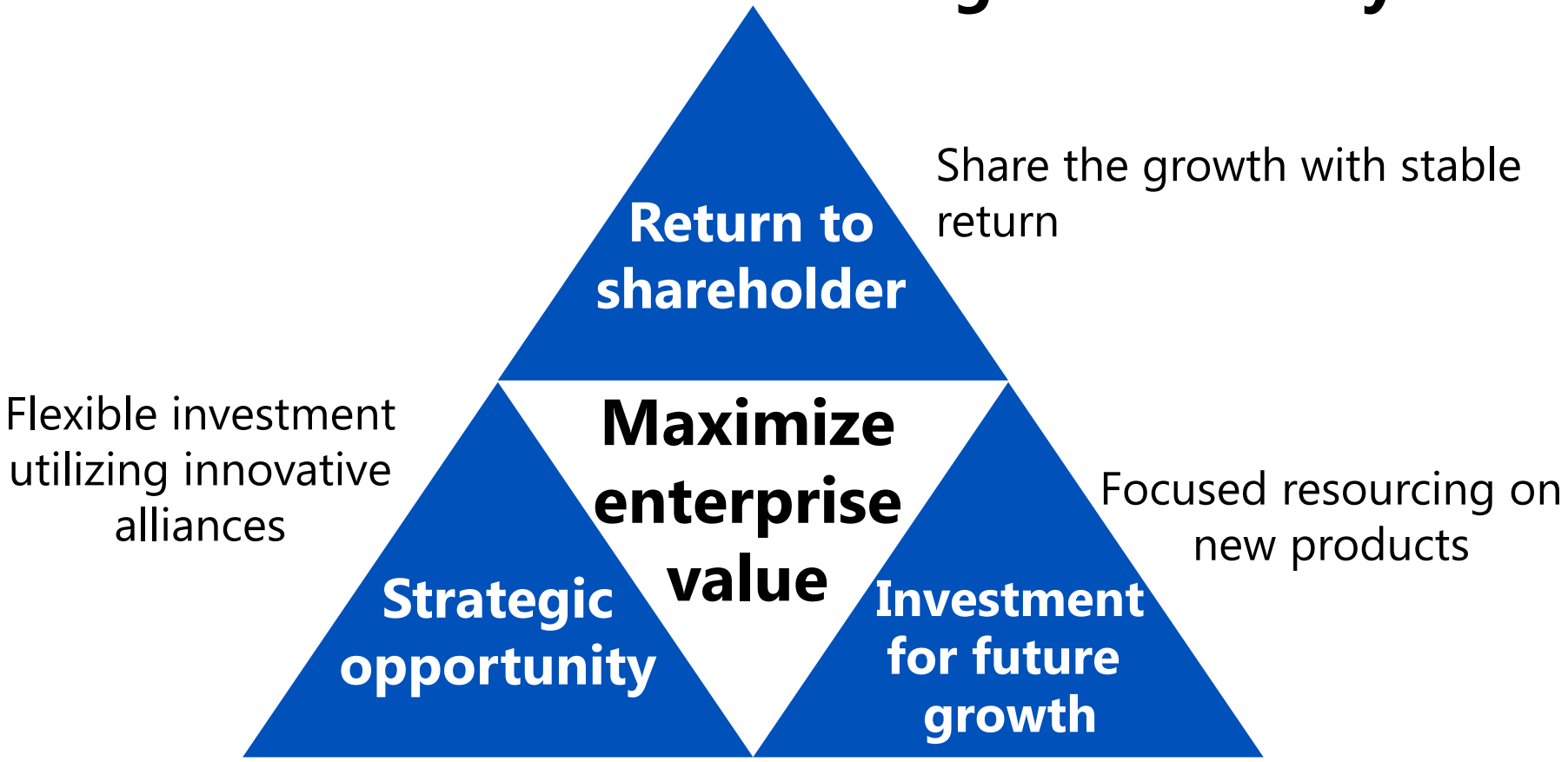


- Leveraging our capabilities in small molecule drug discovery
- Open innovation: Identify novel drug seeds and develop them

* including collaboration products and internally selected drug candidates

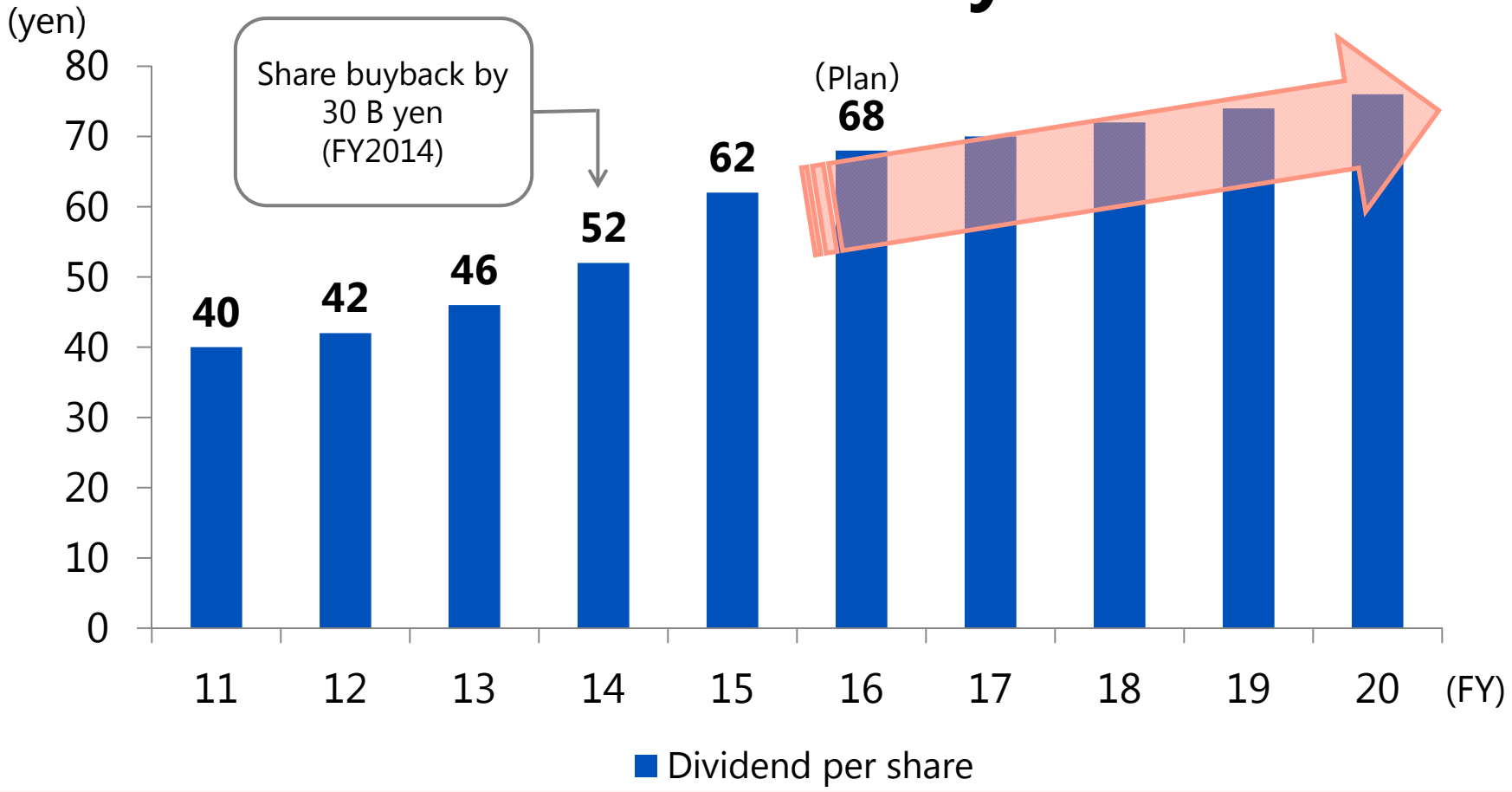
Balancing Shareholder Return and Investment for Our Future

Maximize enterprise value by balancing three key factors, reflecting growth commensurate with our contributions to a more vigorous society



Shareholder Return - Sharing the Growth

Continuous dividend increases and flexible share buybacks



KPIs for SGS2020

Growth	• Sales of new products: 200 B yen • Ordinary income: 150 B yen
Efficiency	• ROIC: Over 13.5% • CCC: 5.5 months • Original pipeline ratio: Over 50%
Shareholder return	• ROE: Over 15% • DOE: Over 4.0%

Vision for SGS2020

Grow sustainably as a drug discovery-based pharmaceutical company contributing to a more vigorous society through improved healthcare

