



# The Growth Strategy of Shionogi

## The New Medium-Term Business Plan “SGS2020”

September 10, 2014

Isao Teshirogi, Ph.D.  
President and CEO



- **Rapidly-aging global society**

- ⇒ Expanded and segmented medical needs
- ⇒ Increased expectations for efficacy and safety of new drugs

- **Expanding range of therapeutic agents**

- ⇒ Creating biopharmaceuticals and large molecules in addition to small molecules to address unmet medical needs

- **Changes in the Japanese and global pharmaceutical markets**

- ⇒ Even greater financial pressure on the health insurance systems of developed countries
- ⇒ Uncertain economic conditions in emerging countries

- **Enhanced expectations for the pharmaceutical industry in Japan**

- ⇒ Contribution to economic growth as a high value-added industry
- ⇒ Strategic industry supported by the government

## New Medium-Term Business Plan of SHIONOGI

# **Shionogi Growth Strategy 2020** **(SGS2020)**

*(Announced on Mar. 28, 2014)*

### Our Vision

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

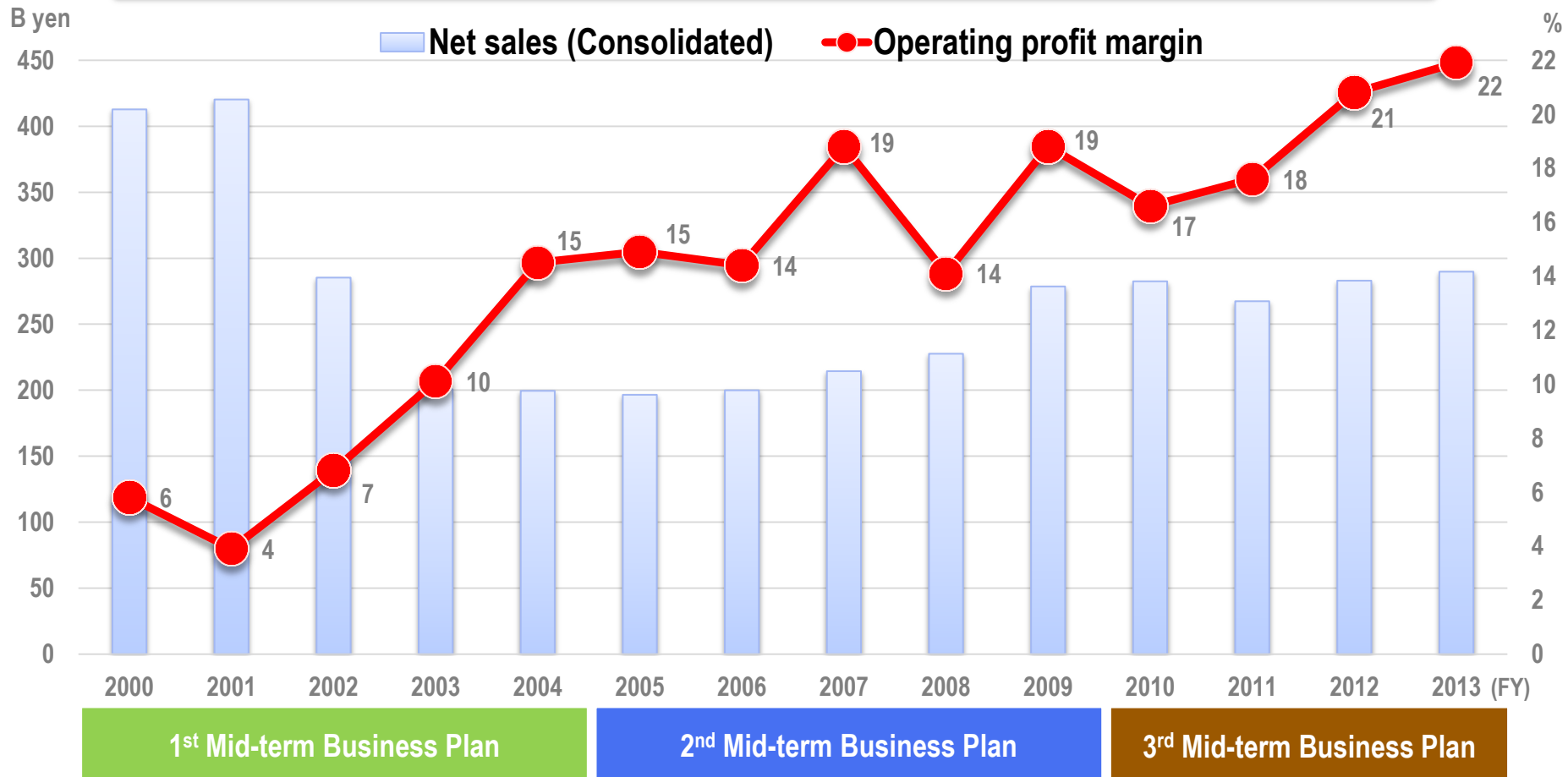
# **SHIONOGI's History**

**From the 1<sup>st</sup> Mid-term Business Plan to Now**

# Impact of Implementation of SHIONOGI's Medium-term Business Plans since FY2000



**Increased profitability while consistently maintaining R&D investment**



# Stages 1 through 3: FY2000 - FY2013



## 1<sup>st</sup> stage: Laying the foundation (FY2000 - 2004)

- ◆ Focused specifically on the prescription drug business
- ◆ Established infrastructure for global development

## 2<sup>nd</sup> stage: Accelerating toward significant strides (FY2005 - 2009)

- ◆ Focused R&D efforts on priority therapeutic areas (infectious diseases, pain, and metabolic syndrome)
- ◆ Acquired US-based Sciele Pharma, Inc.

## 3<sup>rd</sup> stage: SONG for the Real Growth (FY2010 - 2013)

- ◆ Shifted US business focus from 505(b)2s to innovative drugs while stabilizing business performance, and established business footholds in EU and China
- ◆ In Japan, increased sales of 8 strategic products, and expanded their share of Rx sales
- ◆ Launched Tivicay<sup>®</sup> and Osphena<sup>®</sup>
- ◆ Established a new business scheme for HIV integrase inhibitor franchise
- ◆ Modified the Crestor royalty structure

# Expansion of Global Presence and Capabilities

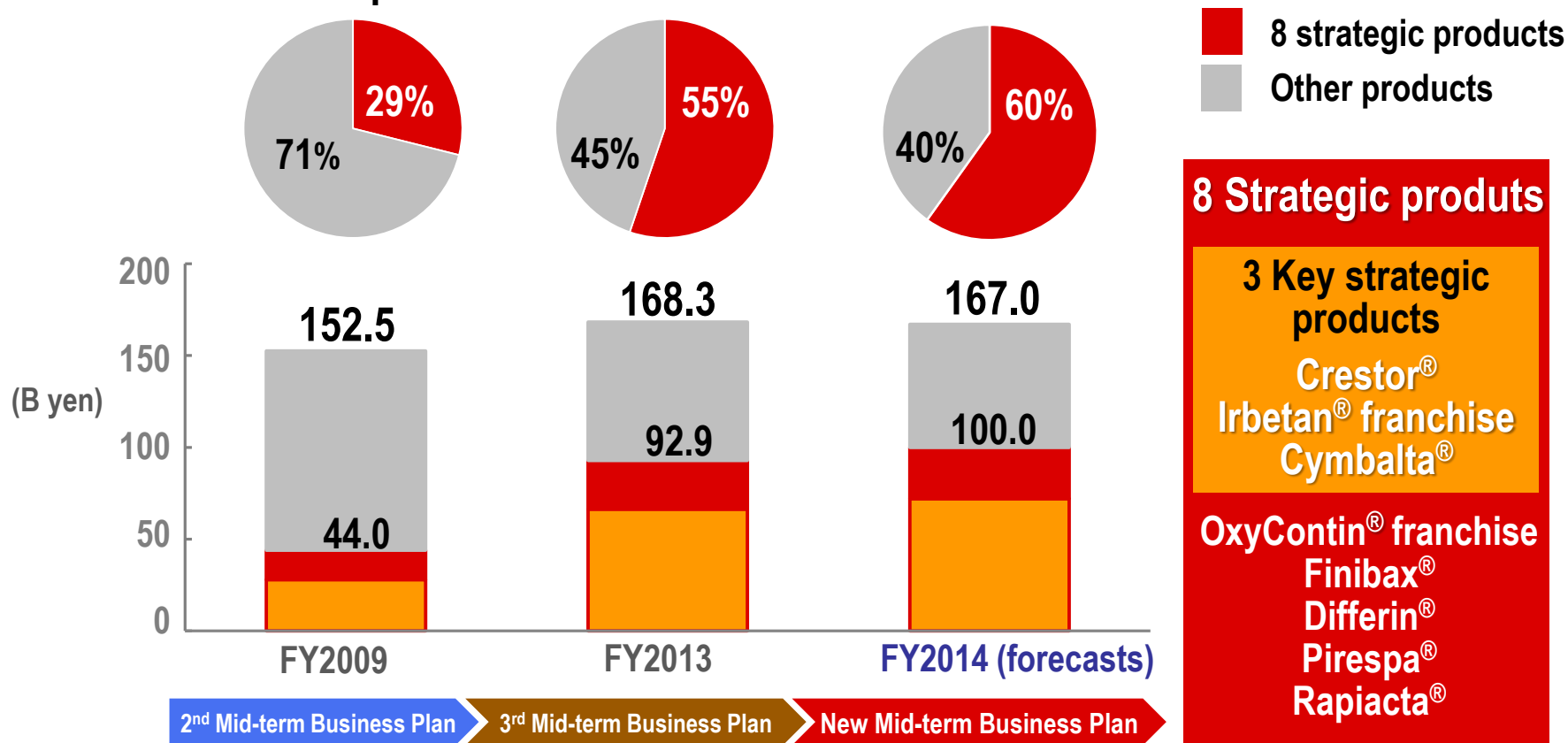
**A company capable of independent global development and, in the highest value markets, independent commercialization**



# Sales Growth of Strategic Products in Japanese Market

## ◆ Increase Sales of Eight Strategic Products by Improving Sales Force Impact

- Increase profitability by deploying SG&A funds in a new way
- Blunt the impact of NHI Price revisions





# US Launch of Ospheña



## ◆ Shionogi's First NCE in the US

- US brand name: Ospheña
- Approval: Feb. 26, 2013  
(Launch: Jun. 2013)
- Indication: Moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA), due to menopause

*Ospheña*®  
(ospemifene) tablets  
60 mg

## ◆ Ospheña is the **First and Only Oral Non-Estrogen** Treatment Alternative for Women with Dyspareunia, a Symptom of VVA due to Menopause

- Represents an important advancement in the treatment of dyspareunia, providing a alternative treatment option of the millions of women living with this condition



# Global Launch of Tivicay

## ◆ Demonstrated drug discovery capabilities for anti-infectives

- Tivicay was discovered via collaborative research and development with ViiV (former Shionogi-GlaxoSmithKline joint venture)
- Approval: US (Aug. 12, 2013), EU, Canada, Japan, etc.
- Launched by a highly experienced team at ViiV, a global specialist HIV company
- Indication: For use in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection
- Characteristics: Oral, 50mg tablet, once-daily



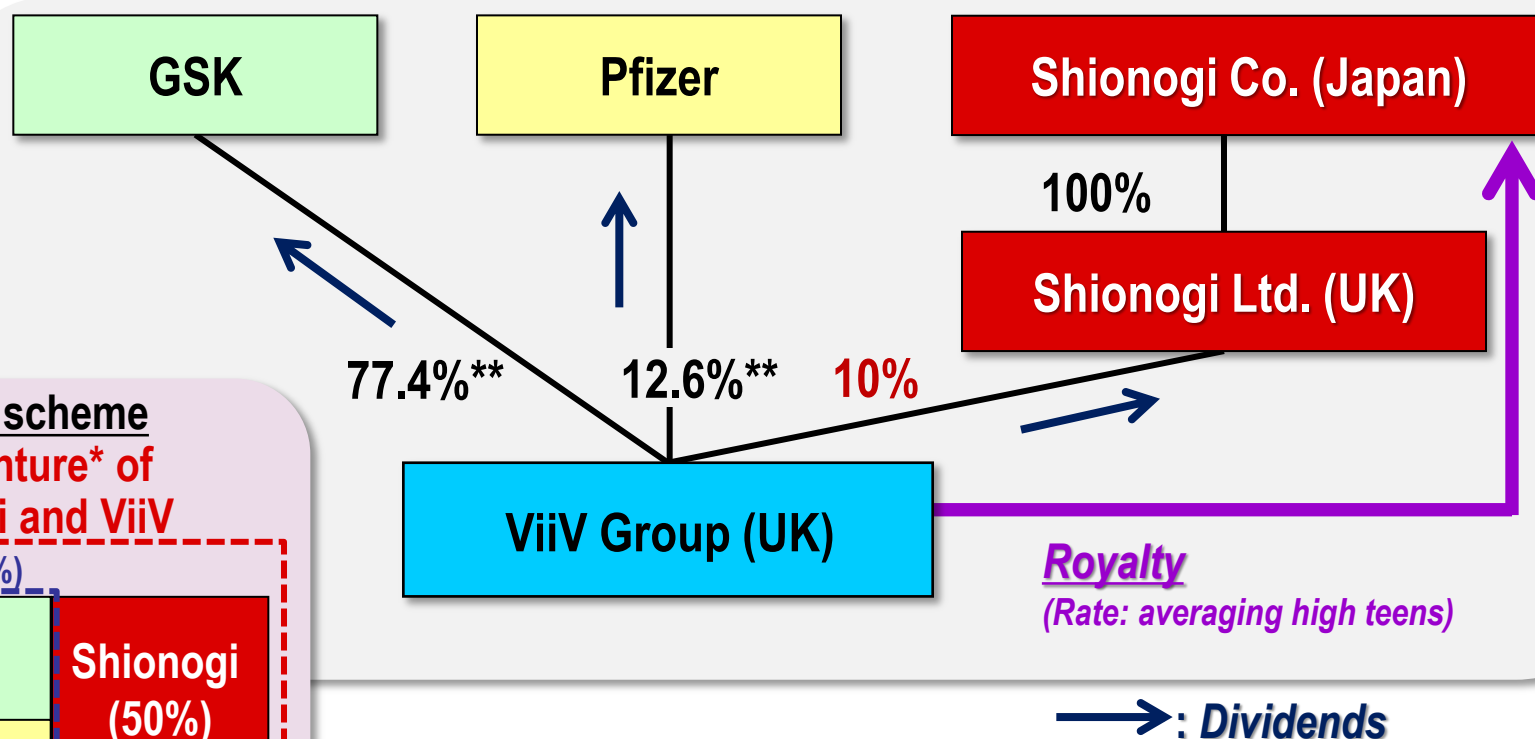
## ◆ Tivicay, with its **Strong Efficacy and Safety Profile**, is an important New option for all lines of HIV treatment

- Tivicay can be used in treatment-naïve and treatment-experienced patients including children ages 12 years and older weighing at least 40kg  
(For children, excluding those who have previously taken other integrase inhibitors)
- US HHS panel recommended both Tivicay and Epzicom® and Tivicay plus Truvada® as preferred regimens for ART-naïve patients

# Stable Earnings from HIV Integrase Inhibitor Portfolio

## ◆ New Arrangement with ViiV Healthcare Ltd. (announced on Oct. 29, 2012)

- JV's rights\* to the integrase inhibitor franchise products were transferred to ViiV., and Shionogi became a 10% shareholder with Board representation



# Realizing the Potential of HIV Franchise by ViiV Healthcare

## ◆ Global HIV Market: over US\$18B

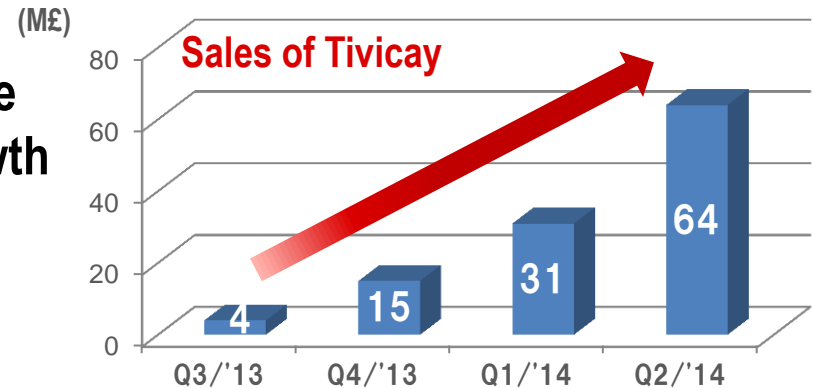
- Integrase inhibitors and their fixed-dose combinations are accelerating the growth of HIV market

## ◆ Tivicay Shows Strong Growth

- Global sales (Jan.-Jun., 2014): £95M (US\$159M)

## ◆ Ongoing Efforts to Maximize HIV Franchise by ViiV

- Triumeq® (dolutegravir/abacavir/lamivudine single-pill regimen)
  - Approval: **Aug. 22, 2014 (US), Sep. 3, 2014 (EU)**
- ViiV Healthcare and Janssen have entered into an agreement for the development and commercialization of a single pill combining dolutegravir as a standard therapy and Janssen's NNRTI rilpivirine in Jun. 2014
- S/GSK1265744LAP: Phase II study



# Modification of the Crestor Royalty Structure

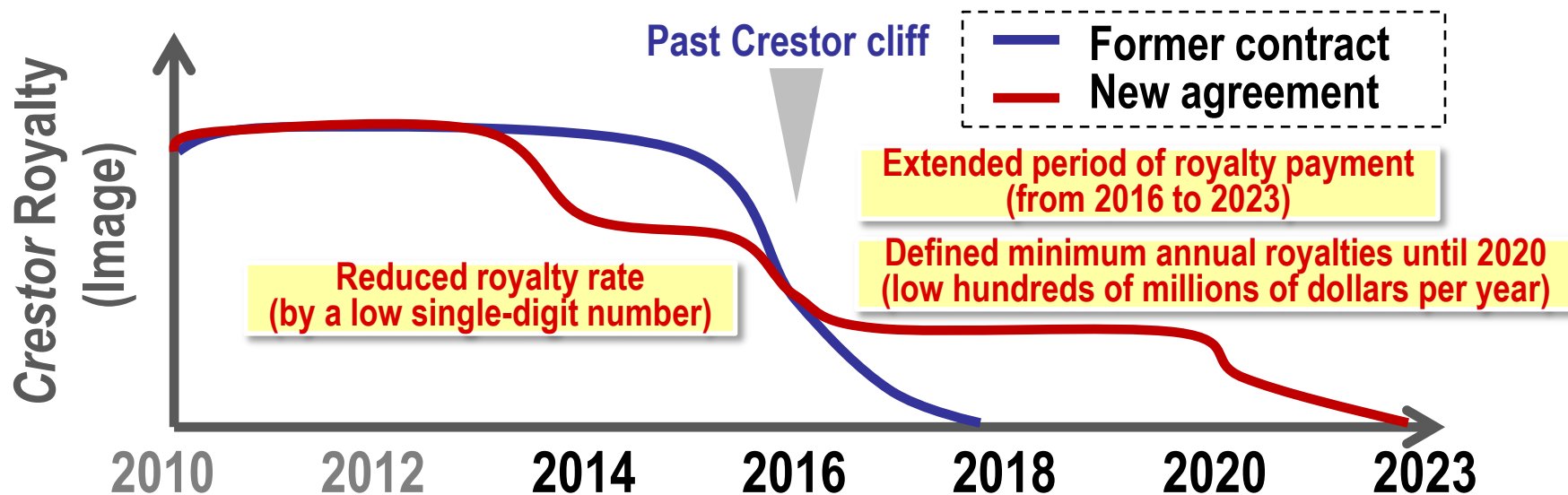
- ◆ The Biggest Business Challenge of the 3<sup>rd</sup> Mid-Term Business Plan was to Overcome the Crestor Cliff

| Crestor               | 2010 | 2011 | 2012 | 2013 |
|-----------------------|------|------|------|------|
| Global sales (B\$)    | 5.7  | 6.6  | 6.3  | 5.6  |
| Royalty income (M\$*) | 729  | 810  | 791  | 682  |



Lose all of Crestor royalty due to its patent expiration in 2016 and 2017

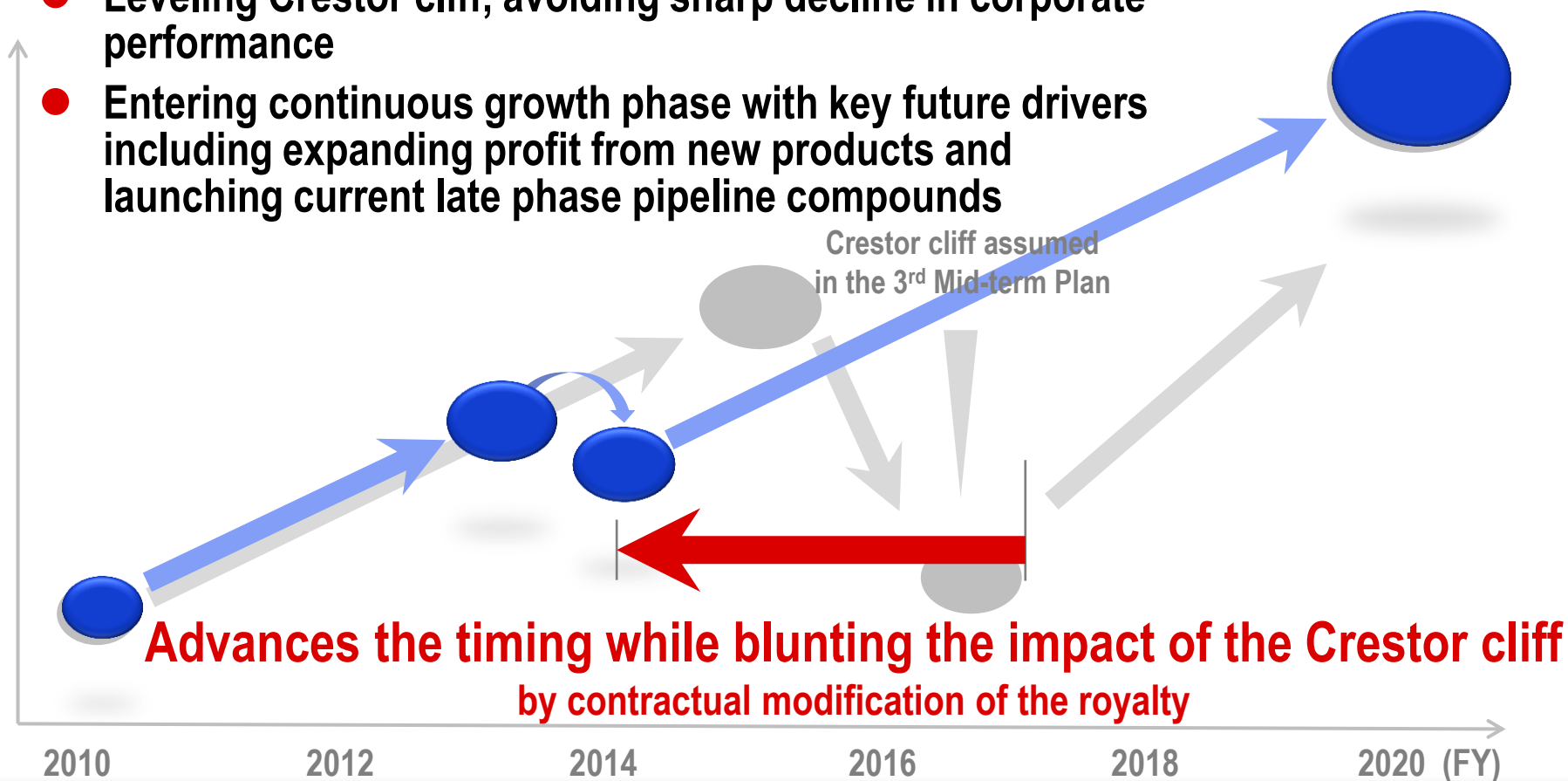
- ◆ New License Agreement with AstraZeneca (announced on Dec. 25, 2013)



# Impact of “Accelerating the Crestor Cliff”

## Secures our mid- to long-term revenue base

- Leveling Crestor cliff, avoiding sharp decline in corporate performance
- Entering continuous growth phase with key future drivers including expanding profit from new products and launching current late phase pipeline compounds



## *Rapid changes in external environment*

- Difficult global economic conditions
- Challenging competitive environment
- Fluctuation in exchange rates

## *Reaction to environmental changes*

- Shifted to innovative drug-driven business in the US
- Established new scheme for anti-HIV drugs
- Modified Crestor royalty contract

## **Solid platform in changing environment**

**In order to drive growth from this strengthened base,  
Shionogi prepared the New Mid-term Business Plan:  
“SGS2020”**

# **SHIONOGI's Future**

## **New Medium-Term Business Plan**

### **- Shionogi Growth Strategy 2020**



# What is Our Vision in SGS2020?



Corporate Mission “Shionogi’s purpose”

**Shionogi strives constantly to supply the best possible medicine to protect the health and wellbeing of the patients we serve**



- **Focus research efforts on discovery of First-in-Class<sup>\*1</sup> and Last-in-Class<sup>\*2</sup> compounds**
- **Expand sales in Japan and the US, establish development footholds in the EU and Asia**
- **Ensure that people around the world benefit from the new drugs and medical innovation generated from Shionogi’s R&D**

\*1 First in Class (FIC) : Innovative medicines with particularly high novelty and therapeutic value that can significantly change the existing therapeutic paradigm

\*2 Last in Class (LIC) : Unrivaled medicines with clear superiority over others with the same mechanism of action

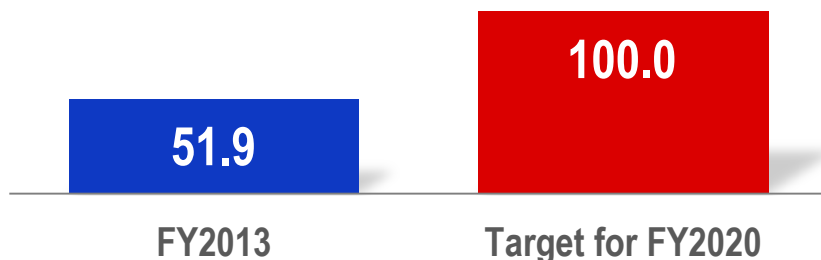
**R&D expenses: More than 100 B yen    R&D expense ratio: 20%**

# Consolidated Financial Target in SGS2020

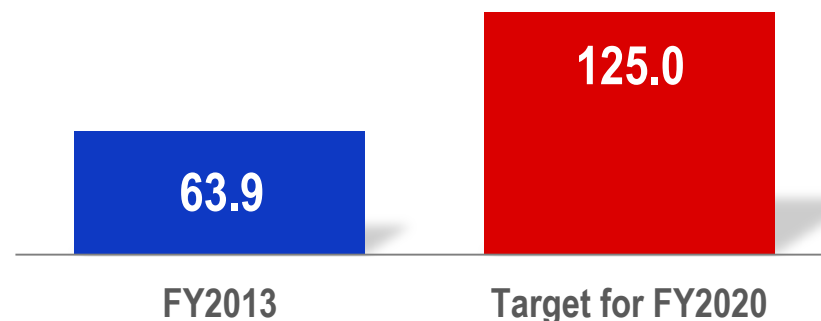


**Grow as a drug discovery-based pharmaceutical company**

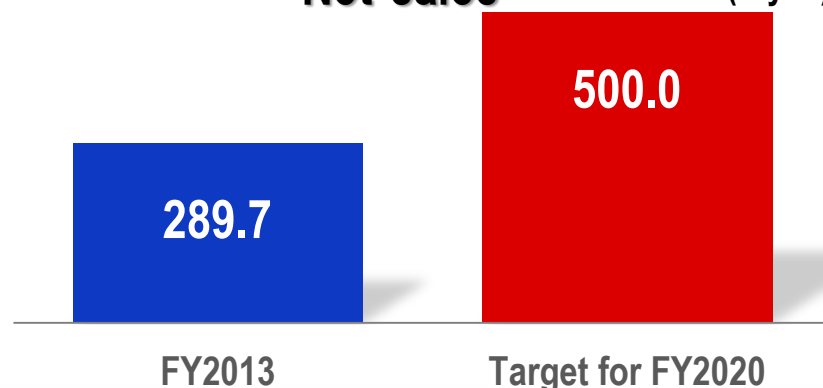
**R&D expenses** (B yen)



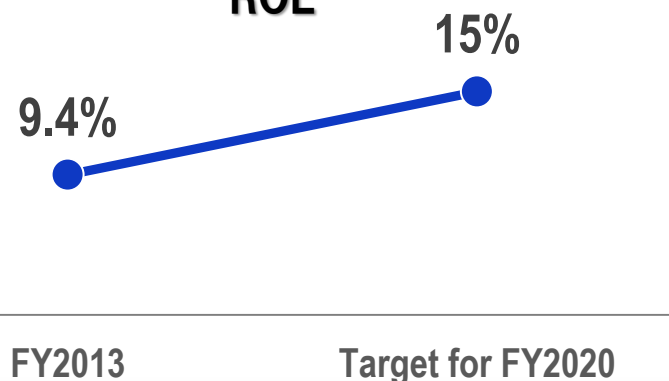
**Ordinary income** (B yen)



**Net sales** (B yen)



**ROE**



- Clear priorities and focused resourcing
- Growth driven by FIC and LIC compounds
- Continued improvement of business operations

## Growth of Top-line

Sales area, Therapeutic area

***Clear priorities  
and focused  
resourcing***

***Growth driven by FIC  
and LIC compounds***

## Growth of Bottom-line

***Continued improvement of business operations***

2014

2020

## Rapid response and rapid communication (Three-year rolling plan; communicate targets and results annually)

### Targets for FY2016 (the next three years)

#### Qualitative objectives

1. Focus on key growth driver products and high-priority late-stage pipeline compounds
2. Continue to enhance business operations

#### Quantitative targets

|                 |                  |              |                 |
|-----------------|------------------|--------------|-----------------|
| Net sales       | <b>320 B yen</b> | R&D expenses | <b>63 B yen</b> |
| Ordinary income | <b>75 B yen</b>  | ROE          | <b>11%</b>      |

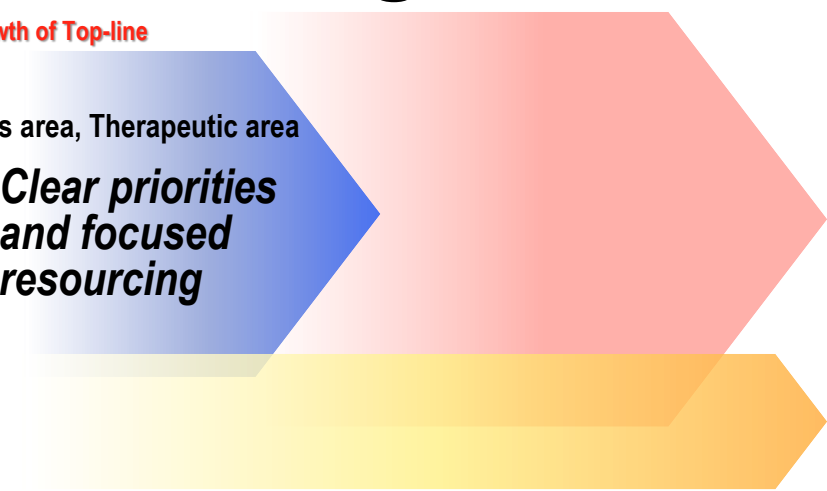
Sales area, Therapeutic area

## ***Clear Priorities and Focused Resourcing***

Growth of Top-line

Sales area, Therapeutic area

***Clear priorities  
and focused  
resourcing***

A diagram consisting of three overlapping arrows pointing to the right. The top arrow is red, the middle arrow is blue, and the bottom arrow is yellow. The blue arrow is the largest and is positioned in the center, overlapping the red and yellow arrows. The text "Growth of Top-line" is positioned above the red arrow, "Sales area, Therapeutic area" is positioned above the blue arrow, and "Clear priorities and focused resourcing" is positioned inside the blue arrow.

# Clear Priorities and Focused Resourcing



## *External environmental factors*

- Rapidly-aging global society
- Even greater financial pressure on the health insurance systems of developed countries
- Uncertain economic conditions in emerging countries

## *Internal challenges*

- Intensify efforts supporting growth drivers
- Strengthen sales capabilities in Japan and US
- Secure royalty-independent earning capacity

## **Territories**

Focus on the highest-value territories for Shionogi

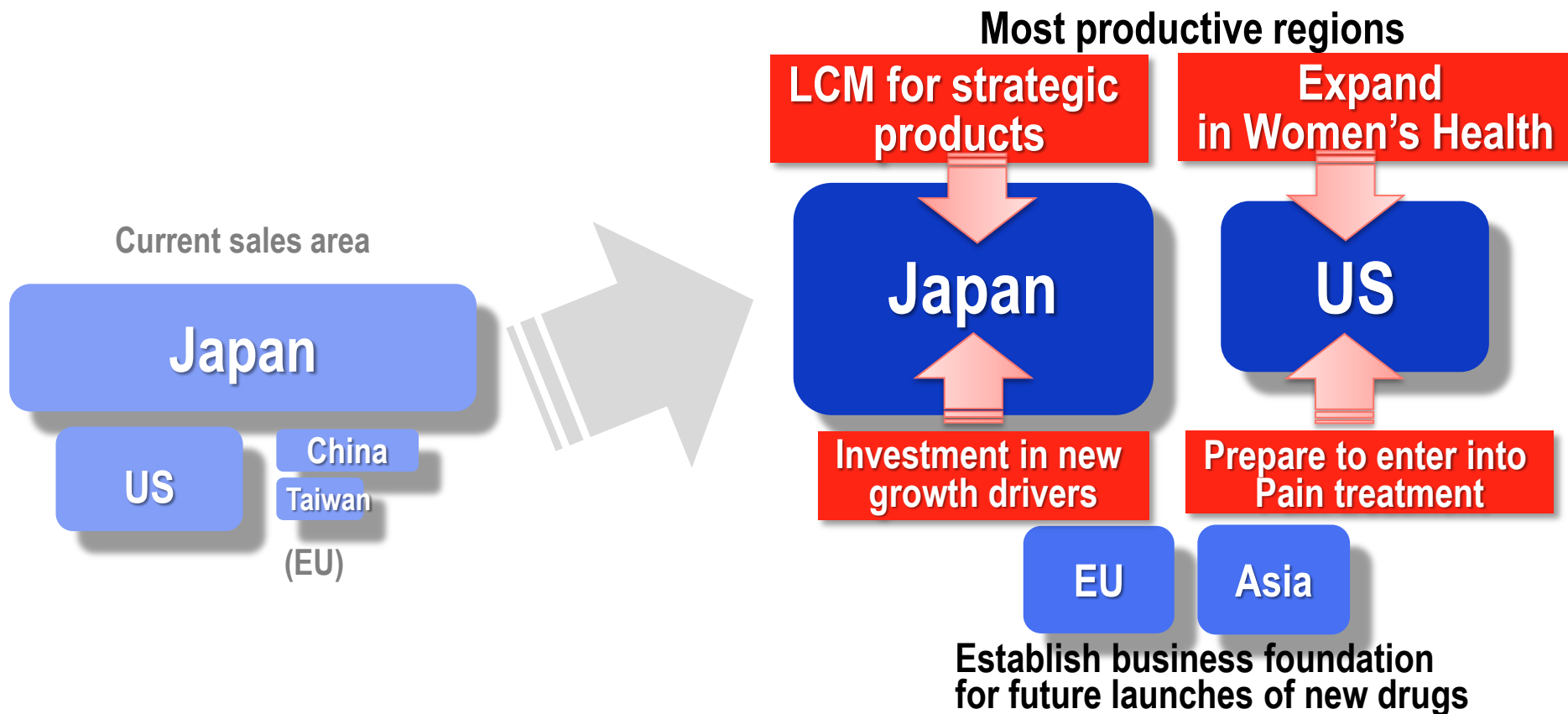
## **Therapeutic area**

Focus on unmet medical needs of the present, near future and future

- Therapeutic area priorities for research, development and sales activities selected on the above basis
- Drive pipeline forward and continue to strengthen it

# Clear Priorities and Focused Resourcing: Sales

- Focus on regions with the highest growth potential
- Maximize existing products while expanding pipeline



# Clear Priorities and Focused Resourcing: Therapeutic Areas



- Reorganized to effectively focus on our target therapeutic areas
- Utilizing the strengths of Shionogi's R&D capabilities to generate FIC and LIC compounds in these areas

**Needs of a rapidly-aging society**  
(extension of HALE, ability to return to productive activities)

Discovery Research Laboratory  
for Core Therapeutic Areas

*Needs of the  
near future*

Previous span of therapeutic areas

Infectious  
disease

Pain

MS

Frontier

**Infectious  
disease**

**Pain/CNS**

**Obesity/Geriatric  
metabolic disease**

**Oncology/  
Immunological  
disease**

Discovery Research Laboratory  
for Innovative Frontier Medicines

*Needs of the  
future*



# Continued Discovery of Future Growth Drivers

- Maximize synergy with existing products
- Cultivate our future growth areas from the frontier research programs

Anti-flu drug (new mechanism)  
Enhancement of HIV franchise

Anti-viral drugs

Infectious  
disease

Drugs for severe infection

S-649266

Antibody drug for *Pseudomonas*

Neuropathic pain, Inflammatory pain

Chronic pain drugs

Pain/CNS

Opioid pain relievers

S-297995

Abuse-deterrent formulation

Out-licensed  
Co-development

Alzheimer's  
drugs

ADHD  
drugs

Frontier

S-888711, Obesity, etc.

# S-297995 (Naldemedine): Front-Runner in Pain/CNS Area

## ◆ Indication

- Treatment of opioid-induced constipation

## ◆ Development Status

- **Global Phase III study** (Global: 3 studies, Japan: 4 studies)
  - Recruitment proceeding on target

## ◆ Global opioid market\*: US\$14.8B

Top 5 markets  
(US, UK, Germany, Canada and France)  
Account for up to 80% of total markets  
(70M chronic opioid patients)

x

40 - 50% of chronic opioid  
patients experience  
opioid-induced  
constipation  
(28-35M patients)

<50% of patients taking laxative  
report a satisfactory results

- Show efficacy at a low, once-daily, dose
- Improve treatment satisfaction of cancer and non-cancer chronic pain patients

# S-888711 (Lusutrombopag): Meet an Unmet Medical Need

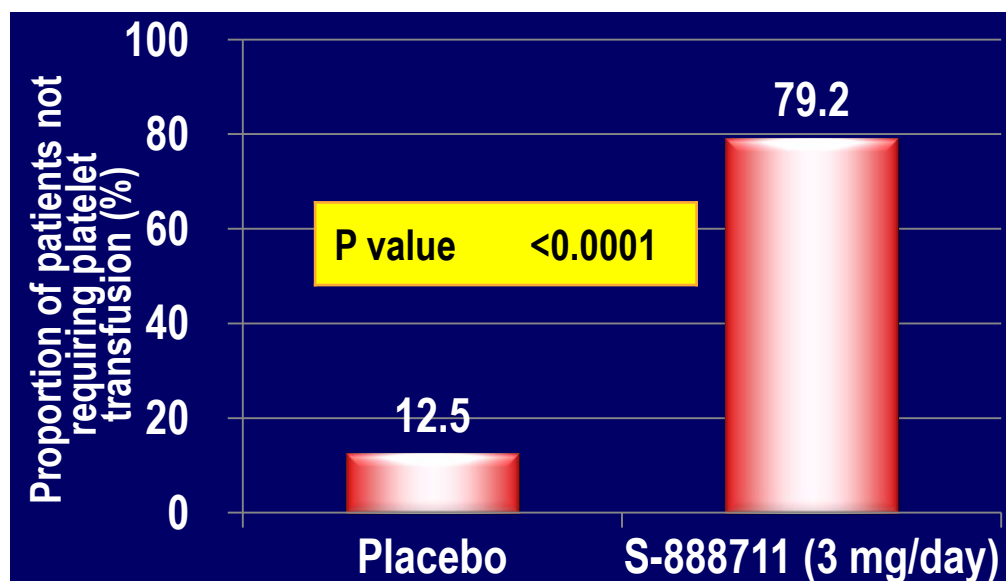
## ◆ Indication

- Thrombocytopenia

## ◆ Development Status

- Japan: Phase III code-break, **plan to submit NDA in 2014**
- Global: Plan to initiate global clinical trials after discussion with EMA and FDA

## ◆ Result of Phase III Study in Japan



- S-888711 can be a new alternative to platelet transfusion before elective invasive procedures
- Considering global clinical trials

Note:

Drug price of blood derivative for platelet transfusion

- JP¥77,270 (Irradiated platelet concentrate, leukocytes reduced, NISSEKI Unit: 10, 200mL)

# S-649266: Targeting Severe Infectious Diseases

## ◆ Expected indication

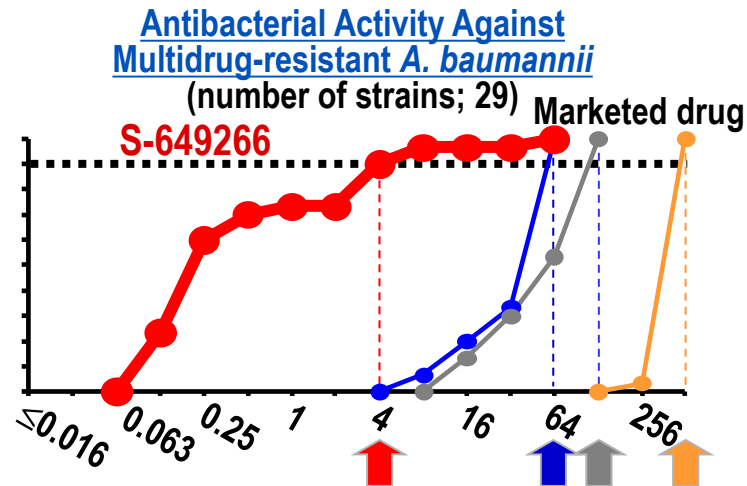
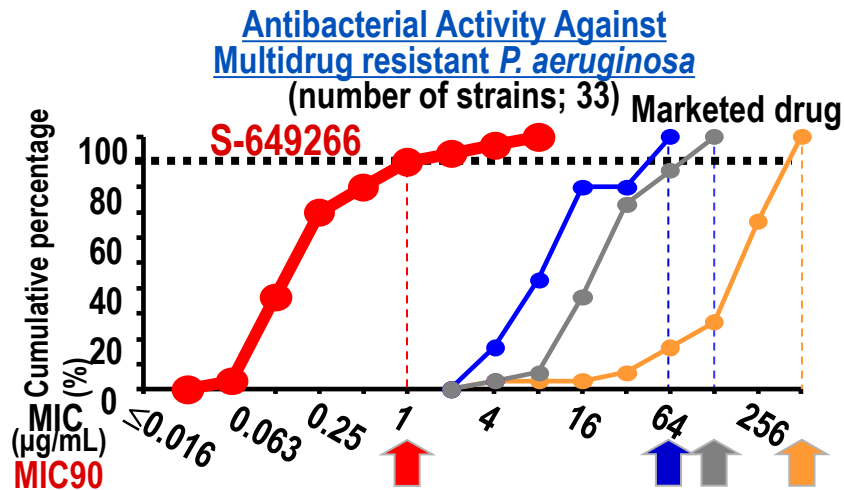
- Aerobic gram-negative (MDR) bacterial infections

## ◆ Development Status

- Global Phase II study (discussion with regulators are ongoing)

## ◆ Severe Infections

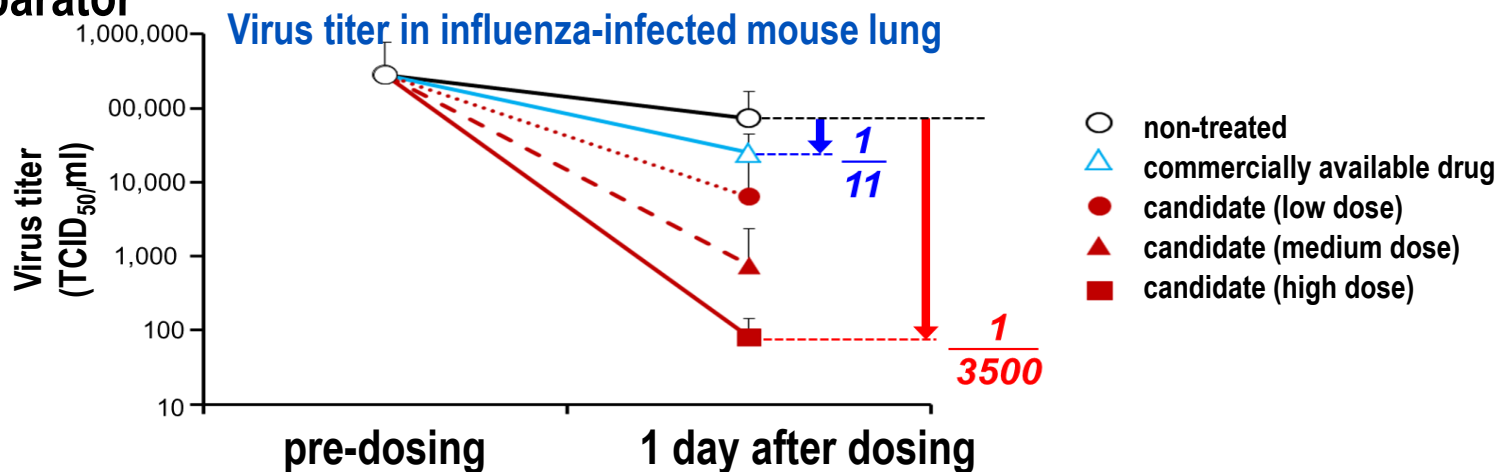
- Each year in the US, about 2 million people acquire serious infections with “resistant bacteria” and about 20,000 people die each year <sup>\*4</sup>
- The increase of bacterial resistance is a serious problem in Eastern Europe, Latin-America and Asia



Antibacterial activity shown against multidrug-resistant *P. aeruginosa* and multidrug-resistant *A. baumannii*, which are problematic in clinical settings

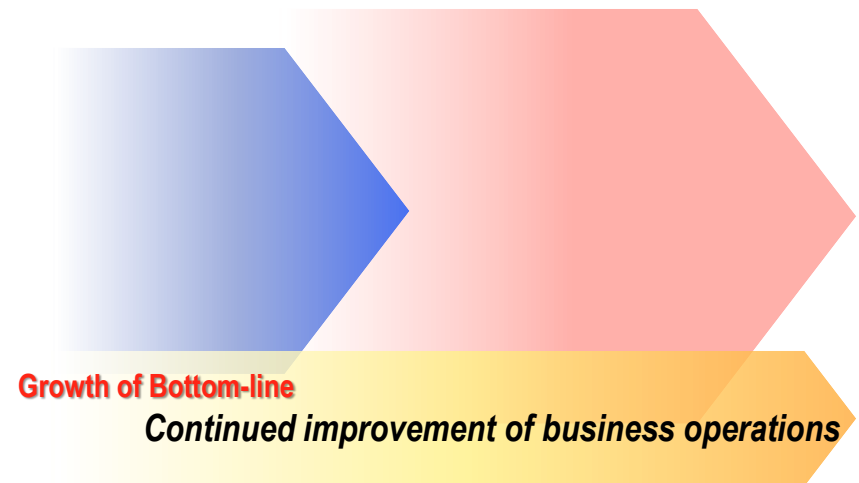
# Discovery of an Anti-Flu Drug Candidate

- ◆ Applying our know-how in anti-viral drug discovery to discover an oral anti-flu drug candidate, aiming at “innovative First-in-Class”
  - Discovered a candidate with strong anti-flu activity and a **novel mechanism** of action
  - **Much greater decline in viral load** in mouse model compared to that achieved with a commercially available comparator
  - Showed potent in vitro inhibitory activity against both seasonal and highly pathogenic bird influenza strains resistant to a commercially available comparator



Expanding and applying our knowledge base built in anti-HIV drug discovery to other viral infections

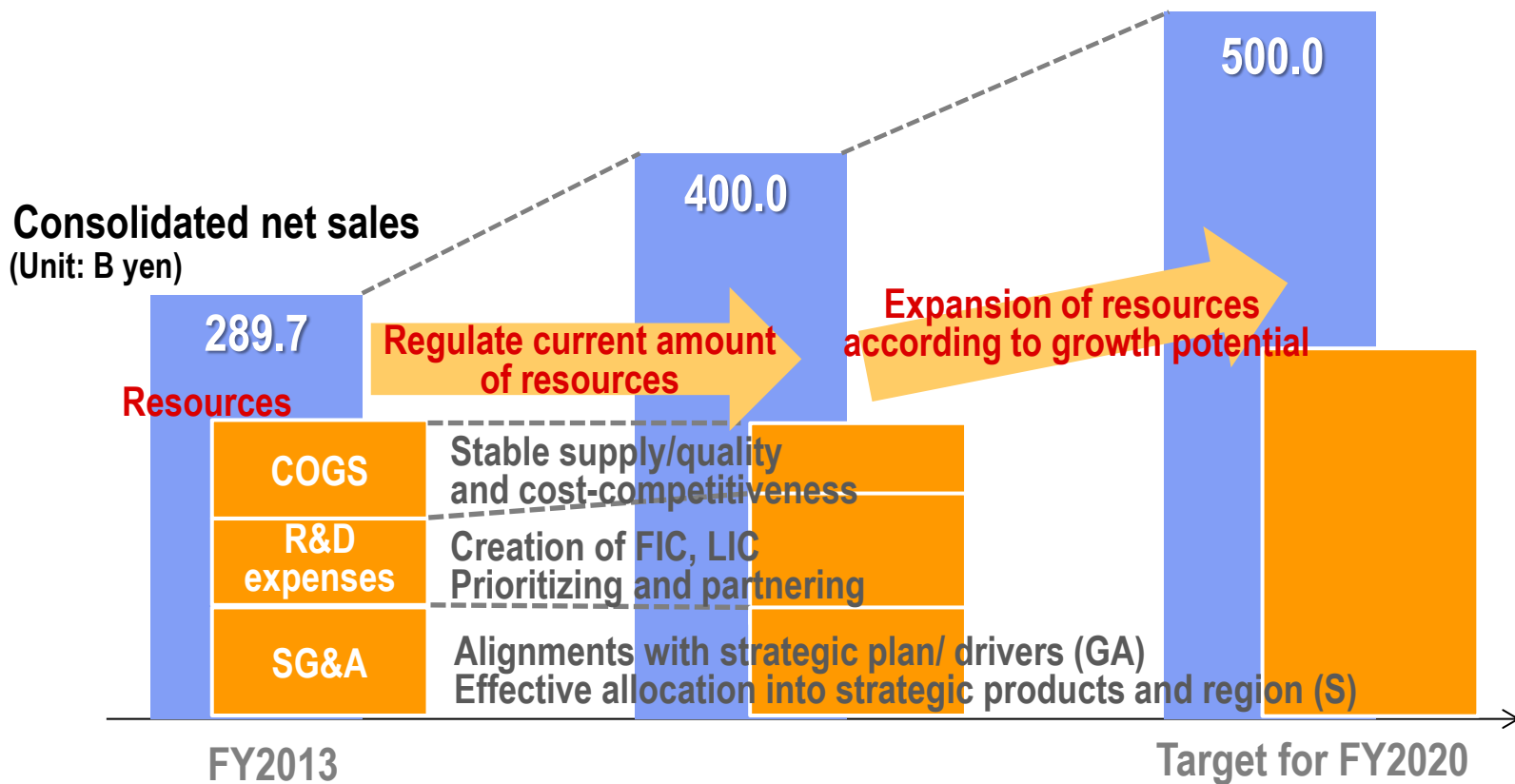
## ***Continued Improvement of Business Operations***



# Continued Enhancement of Business Operations



- Resource level to be aligned to growth stage
- Strategic resource allocation



# Shareholder Return and Investment for Our Future



# Balancing Shareholder Return and Investment for Our Future

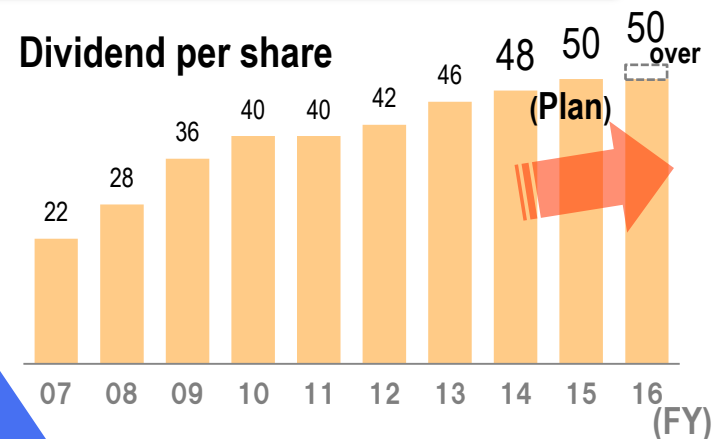


**Maximize enterprise value by balancing three key factors**

**Share the growth**

DOE: More than 3.5% in FY2016  
Further shareholder return

**Return to  
shareholders**



**Clear priorities and  
focused resourcing**

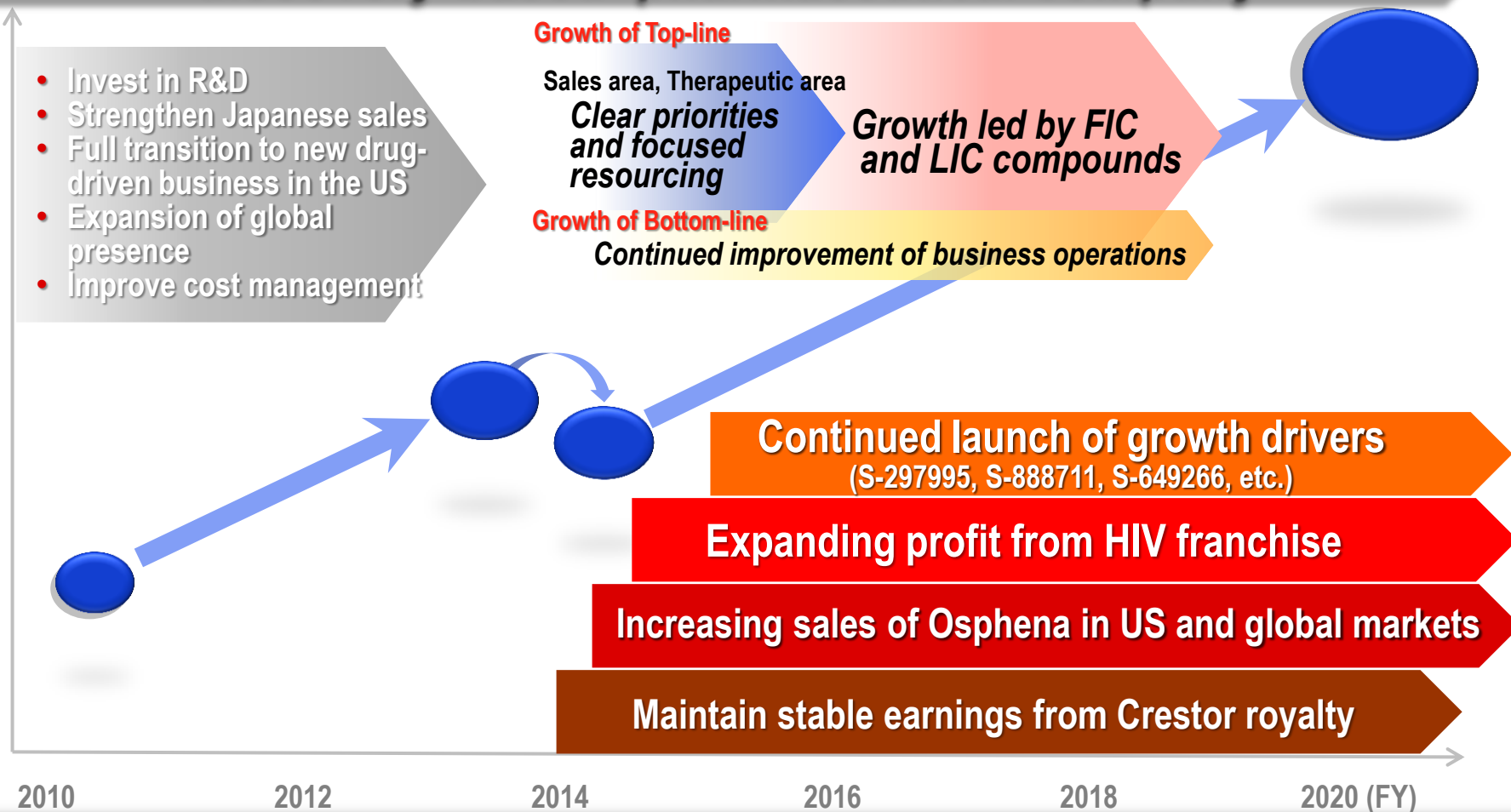
***Maximize  
enterprise  
value***

**Increase flexibility while  
remaining highly selective**  
Nearly debt-free in FY2014

**Investment  
for further growth**

**Strategic  
Opportunities**

## Achieve SGS2020, and continue to grow as a drug discovery-based pharmaceutical company



# End of File

# Appendix

## FY2014 Business Plan and 1Q FY2014 Results

# Position of FY2014 Business Plan

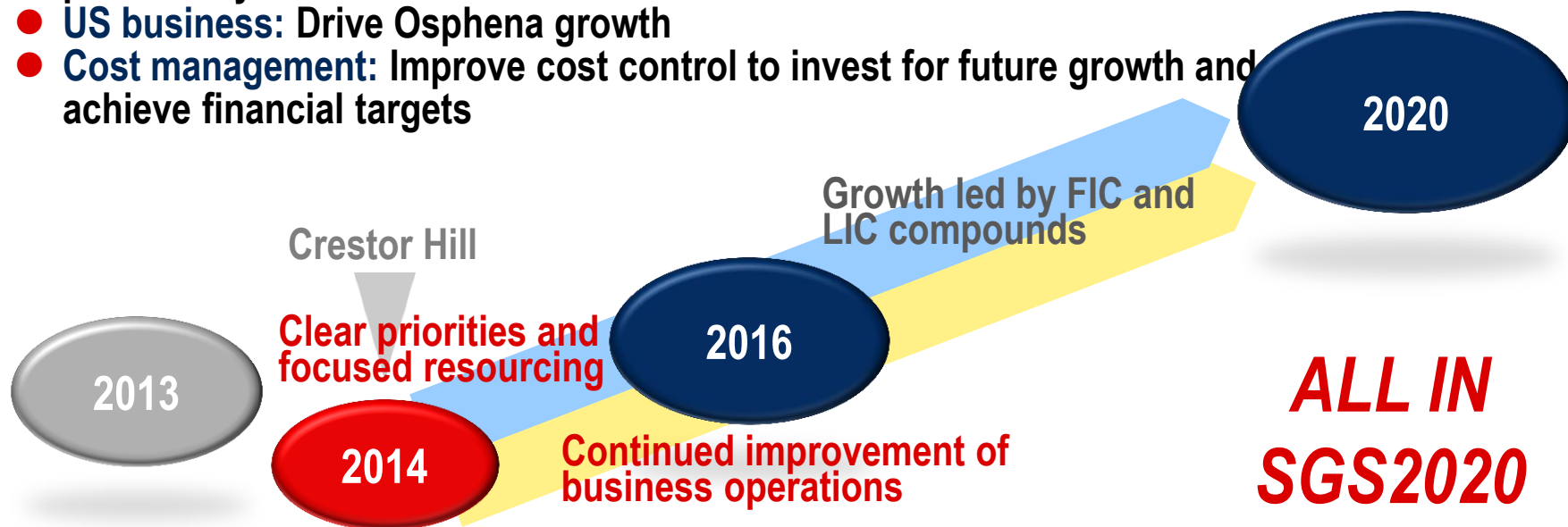


Business operation from FY2014 to FY2016

**Enter into a true growth phase, with a gentler “Crestor Hill”**

**Establish a stable foundation for our mid- to long-term growth through  
“Clear priorities and focused resourcing”**

- **R&D:** Select high-priority compounds and accelerate global development
- **Japanese domestic business:** Expand 8 strategic products and improve profitability
- **US business:** Drive Osphena growth
- **Cost management:** Improve cost control to invest for future growth and achieve financial targets



# FY2014 Forecast and 1Q Results (Consolidated)



| (Unit: B yen)                     | FY2014                 |                 |                    | Progress<br>vs. 1H<br>forecasts<br>(%) | FY2013<br>Apr-Jun<br>results | Y on Y<br>change<br>(%) |
|-----------------------------------|------------------------|-----------------|--------------------|--|------------------------------|-------------------------|
|                                   | Full year<br>forecasts | 1H<br>forecasts | Apr-Jun<br>results |  |                              |                         |
| Sales                             | 269.0                  | 130.0           | 62.7               | 48.3                                   | 67.3                         | (6.7)                   |
| Domestic prescription drugs       | 167.0                  | 80.5            | 38.7               | 48.1                                   | 40.4                         | (4.3)                   |
| - 8 strategic products            | 100.0                  | 47.3            | 22.9               | 48.4                                   | 21.6                         | 6.0                     |
| Crestor royalty                   | 47.5                   | 24.2            | 11.8               | 48.6                                   | 13.1                         | (10.1)                  |
| Overseas sales/export             | 31.3                   | 15.0            | 6.7                | 44.7                                   | 8.4                          | (19.6)                  |
| - Shionogi Inc.                   | 17.7                   | 7.9             | 2.8                | 36.0                                   | 5.4                          | (47.0)                  |
| Osphena                           | 7.0                    | 2.5             | 0.8                | 30.4                                   | -                            | -                       |
| - C&O                             | 7.5                    | 3.4             | 1.8                | 52.0                                   | 1.3                          | 37.6                    |
| Cost of sales                     | 79.0                   | 38.0            | 19.8               | 52.2                                   | 18.4                         | 8.1                     |
| SG&A expenses                     | 145.0                  | 73.5            | 34.9               | 47.4                                   | 36.8                         | (5.3)                   |
| Selling & general expenses        | 93.0                   | 46.5            | 23.1               | 49.7                                   | 23.6                         | (2.2)                   |
| R&D expenses                      | 52.0                   | 27.0            | 11.7               | 43.5                                   | 13.2                         | (10.7)                  |
| Operating income                  | 45.0                   | 18.5            | 8.0                | 43.5                                   | 12.1                         | (33.6)                  |
| [Excluding royalty income]        | (7.0)                  | (7.5)           | (4.6)              | -                                      | (1.9)                        | -                       |
| Non-operating income and expenses | P5.0                   | P5.5            | P5.6               | -                                      | P0.5                         | -                       |
| Ordinary income                   | 50.0                   | 24.0            | 13.6               | 56.8                                   | 12.6                         | 8.4                     |

## Domestic Rx sales

- 8 new products: Steady growth
- Long listed products: Decreased due to NHI price revision and generic penetration

## Crestor royalty

- Decreased based on modification of royalty structure
- AZN's sales on track

## Overseas sales

- Shionogi Inc.(US): Gradual progress of Osphena
- Contribution from divestments in FY2013
- C&O (China) sales on track

## Cost

- Cost of sales: weak yen and extraordinary factors
- SG&A expenses were decreased

## Ordinary income

- Higher than 1Q of any prior fiscal year due to dividend from ViV

# Appendix

# Dolutegravir: Summary of Phase III/IV Results



| Study No.            | Patient Population                  | Study Design   | Results  |
|----------------------|-------------------------------------|--|--|
| <b>ING113086</b><br> | Treatment-naïve                     | ART-naïve pts (n=822)<br>DTG 50mg QD vs. RAL 400mg BID<br>(+ ABC/3TC or TDF/FTC)<br>non-inferiority design                   | Week 48<br><b>Non-inferior</b><br>(AIDS 2012)                      |
| <b>ING114467</b><br> |                                     | ART-naïve pts (n=833)<br>DTG 50 mg/ABC/3TC QD vs. <i>Atripla</i> QD<br>non-inferiority design                                | Week 48<br><b>Superior</b><br>(ICAAC 2012)                         |
| <b>ING112574</b><br> | INI-resistance patients             | INI-resistant pts (n=183)<br>Single cohort,<br>DTG 50mg BID + OBR  | Week 24<br>63% patients showed<br>HIV RNA <50c/mL<br>(HIV 11 2012) |
| <b>ING111762</b><br> | Treatment-experienced but INI-naïve | ART-experienced, INI-naïve pts (n=719)<br>DTG 50mg QD vs. RAL 400mg BID<br>(+ BR)<br>non-inferiority design                  | Week 24 (CROI 2013)<br>Week 48 (IAS 2013)<br><b>Superior</b>       |
| <b>ING114915</b><br> | Treatment-naïve                     | ART-naïve pts (n=468)<br>DTG 50mg QD vs. DRV/r 800/100mg QD<br>(+ ABC/3TC or TDF/FTC)<br>non-inferiority design (open label) | Week 48<br><b>Superior</b><br>(ICAAC 2013)                         |



# New Agreement for HIV Integrase Inhibitors with ViiV Healthcare Ltd.



## ◆ Difference between the Two Schemes (1/2)

|                                 | Former contract   | New scheme  |
|---------------------------------|---|---|
| Royalty and financial condition | <ul style="list-style-type: none"> <li>■ Royalty rate depends on sales amount and territories                             <ul style="list-style-type: none"> <li>• JV territory (US and potentially EU5); JV sells products, and the profit is shared on a 50/50 basis, in principle. An originator receives the royalty depending on the sales amount</li> <li>• Shionogi territory (Japan and Taiwan); were under discussion in former contract</li> <li>• ViiV territory (ROW); ViiV sells products in principle, and pays royalty</li> </ul> </li> <li>■ In case of combination products such as Triumeq, JV profit share and royalty is calculated by the proportion of DTG in the combination</li> <li>■ Shionogi holds call option for acquiring the JV. The option could be exercised anytime after 10 years since the JV established, or after 12 years since the first product was launched or sales exceed a certain amount</li> </ul> | <ul style="list-style-type: none"> <li>■ Shionogi receives royalty averaging high teens for the sales of DTG and its combo pills</li> <li>■ Shionogi becomes a 10% shareholder of ViiV and receives dividends on the basis of ViiV's net profit</li> <li>■ Royalty rate is the same for DTG and its combo pills</li> <li>■ Shionogi has no call option</li> </ul> |

# New Agreement for HIV Integrase Inhibitors with ViiV Healthcare Ltd.

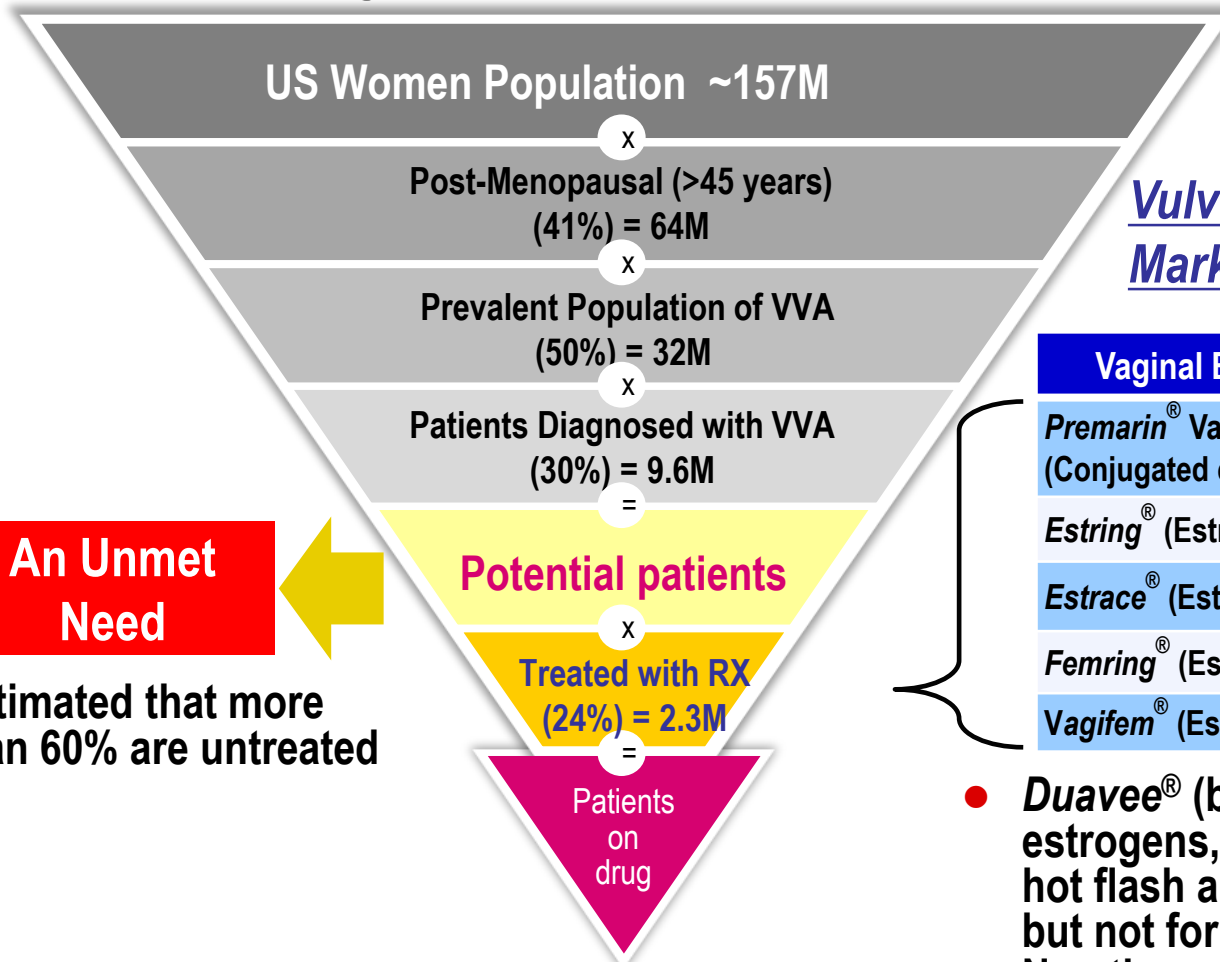


## ◆ Difference between the Two Schemes (2/2)

|                       | Former contract   | New scheme                     |
|-----------------------|---|--------------------------------|
| R&D and SG&A expenses | ■ Both Shionogi and ViiV pay on a 50/50 basis   | ■ ViiV pays all expenses       |
| Commercial scheme     | <ul style="list-style-type: none"><li>■ US; JV establishes its subsidiary</li><li>■ EU5; Option to establish a subsidiary for commercialization by JV. If not conducting the option, ViiV sells and royalty scheme applies</li><li>■ Japan and Taiwan; approach was under discussion</li><li>■ ROW; ViiV sells products</li></ul> | ■ ViiV sells products globally |

# Osphena – Market Opportunity

## ◆ Enhancing Awareness of Product, Focused on OB-GYN Physicians



**An Unmet Need**

Estimated that more than 60% are untreated

**Market Expansion Opportunity**

### Vulvar and Vaginal Atrophy (VVA) Market as of 2012

| Vaginal Estrogen Products                      | Company      |
|--|--------------|
| Premarin® Vaginal Cream (Conjugated estrogens) | Pfizer       |
| Estring® (Estradiol vaginal ring)              | Pfizer       |
| Estrace® (Estradiol vaginal cream)             | Actavis      |
| Femring® (Estradiol acetate ring)              | Actavis      |
| Vagifem® (Estradiol vaginal tablet)            | Novo Nordisk |

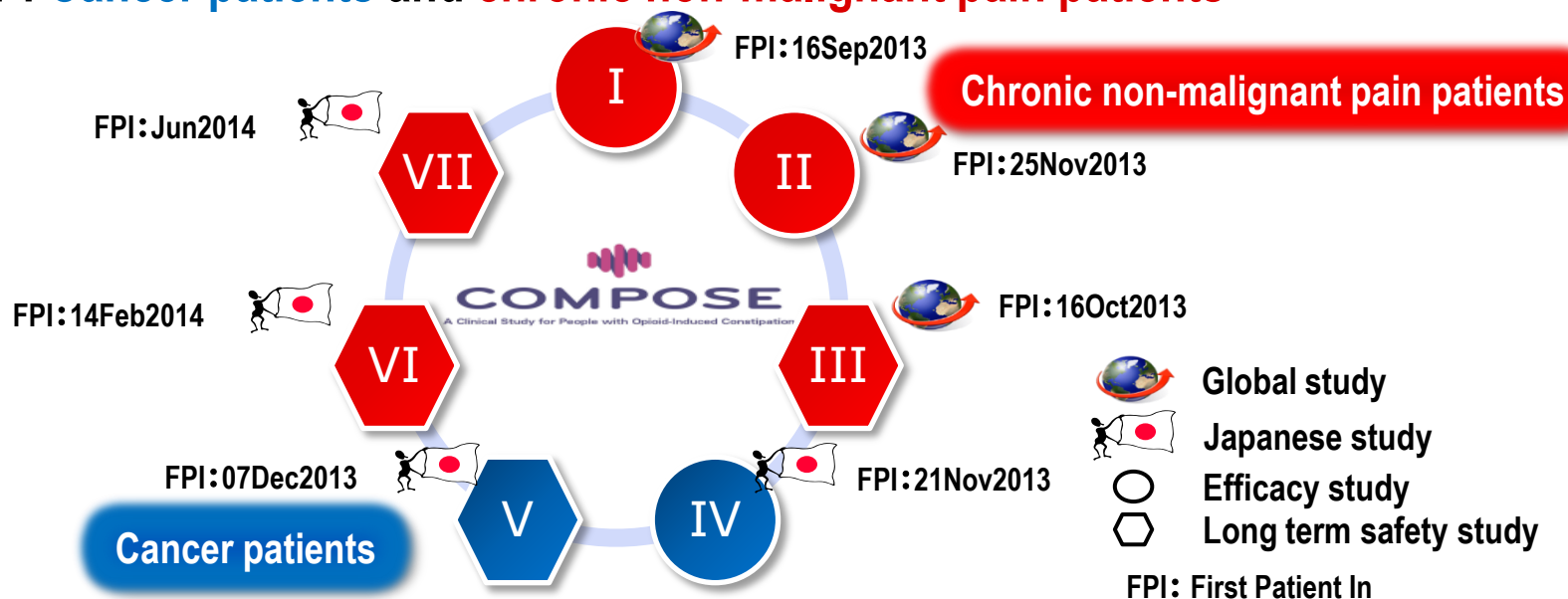
- Duavee® (bazedoxifene-conjugated estrogens, Pfizer) approved by FDA for hot flash and prevention of osteoporosis, but not for VVA
- No other new launches expected in the prescription cream market

# S-297995(Naldemedine): Phase III Studies (COMPOSE Program)



## ◆ Target Patients

- US: **Chronic non-malignant pain patients**
- JP: **Cancer patients** and **chronic non-malignant pain patients**



| Global Phase III Study | Subjects | Group            | Treatment period | Objectives           |
|------------------------|----------|------------------|------------------|----------------------|
| Confirmatory study I   | 540      | 0.2 mg / placebo | 12 wks           | Efficacy, Safety, PK |
| Confirmatory study II  | 540      | 0.2 mg / placebo | 12 wks           | Efficacy, Safety, PK |
| Long term safety study | 1,500    | 0.2 mg / placebo | 52 wks           | Safety, Efficacy     |

# S-649266: Market Opportunity (Severe Infections)



## ◆ Healthcare-associated Infections (Hospital-acquired Infections)

- The total annual incidence in the US, Europe and Japan is estimated at 6 million and has been increasing at 1.7% per year
- The additional healthcare cost related to healthcare-associated infections is estimated to be about US\$154,000 in the US (PHC4<sup>\*1</sup>)
- Global sales of carbapenem is US\$1.9 billion (2013, EvaluatePharma)

## ◆ Prevalence of Carbapenem Resistance (NHSN<sup>\*2</sup>, ECDC<sup>\*3</sup>)

|         | <i>E. coli</i> | <i>P. aeruginosa</i> | <i>A. baumannii</i>            | <i>K. pneumoniae</i> |
|---------|----------------|----------------------|--------------------------------|----------------------|
| US      | 2%             | 23%                  | 61%                            | 12%                  |
| France  | <1%            | 18%                  | 81%<br>(29 European countries) | <1%                  |
| Germany | <1%            | 11%                  |                                | <1%                  |
| Italy   | <1%            | 25%                  |                                | 29%                  |
| Spain   | <1%            | 21%                  |                                | <1%                  |
| UK      | <1%            | 6%                   |                                | <1%                  |

## ◆ Severe Infections

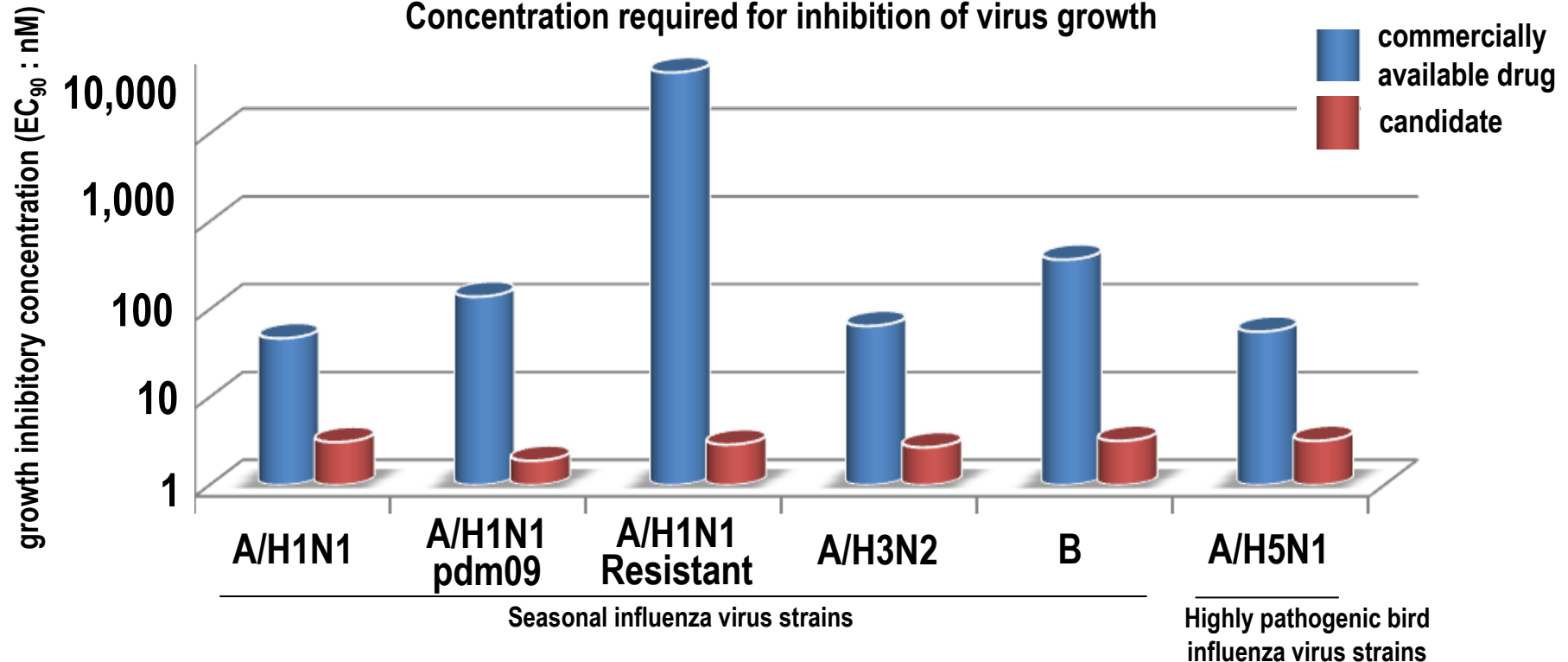
- Each year in the US, about 2 million people acquire serious infections with “resistant bacteria” and about 20,000 people die each year (CDC<sup>\*4</sup>)
- The increase of resistant bacteria is a serious problem in Eastern Europe, Latin-America and Asia

# Infectious Diseases: Discovery of an Anti-Flu Drug Candidate



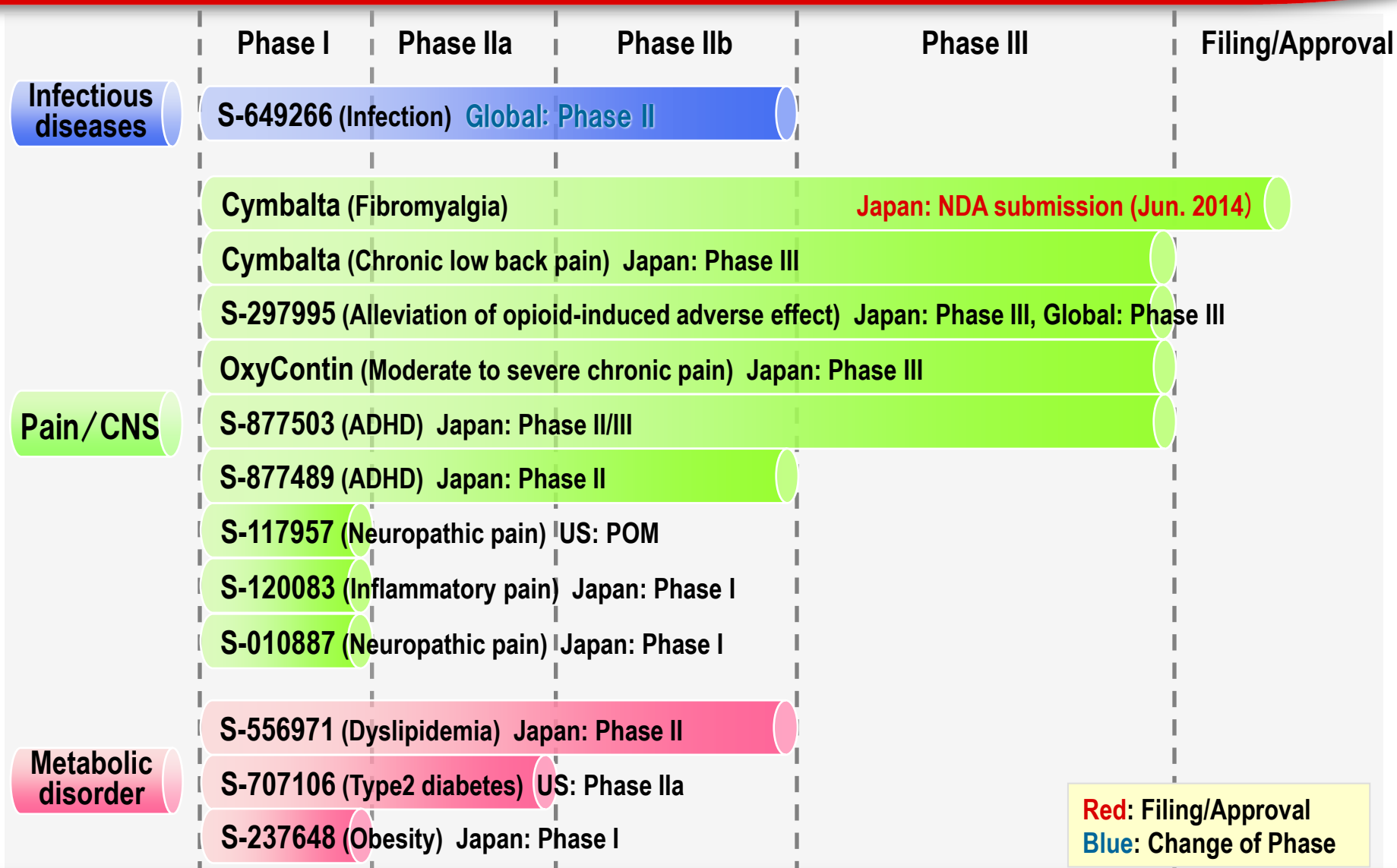
## Antiviral activity against various influenza virus strains

Concentration required for inhibition of virus growth

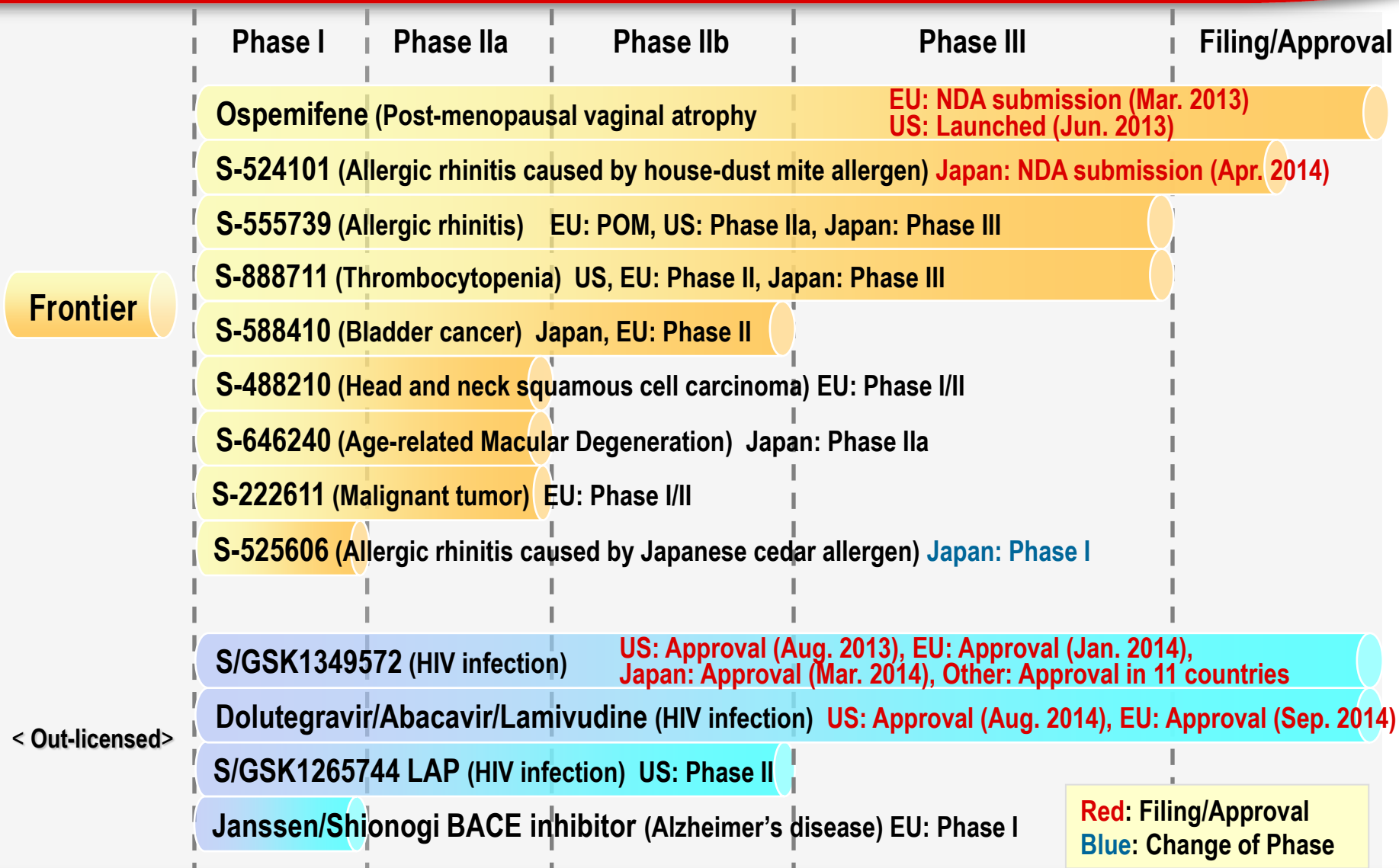


Shown potent *in vitro* inhibitory activity against both seasonal and highly pathogenic bird influenza strains resistant to a commercially available comparator

# Pipeline (as of September 2014)



# Pipeline (as of September 2014)





# Forward-Looking Statements



- Forecast or target figures in this material are neither official forecasts of earnings and dividends nor guarantee of target, achievement and forecasts, but present the midterm strategies, goals and visions. Official earnings guidance should be referred to in the disclosure of the annual financial report (*kessan tanshin*) in accordance with the rules set by Tokyo Stock Exchange.
- Materials and information provided during this presentation may contain so-called “forward-looking statements”. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination period, obtaining regulatory approvals; domestic and foreign healthcare reforms; trend toward managed care and healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- For products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and failure to gain market acceptance.
- Shionogi disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This material is presented to inform stakeholders of the views of Shionogi’s management but should not be relied on solely in making investment and other decisions.
- You should rely on your own independent examination of us before investing in any securities issued by our company. Shionogi shall accept no responsibility or liability for damage or loss caused by any error, inaccuracy, misunderstanding or changes of target figures or any other use of this material.
- This English presentation was translated from the original Japanese version. In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.