



# **3<sup>rd</sup> Quarter of Fiscal 2014 Financial Results Conference Call**

**February 2, 2015**



# Summary of 3<sup>rd</sup> Quarter FY2014

**Sales and operating income on track**

**Ordinary income and net income are exceeding our plan**

- Ordinary income: higher than the levels achieved in the Apr. to Dec. period of any prior fiscal year

**Accelerating global development of high-priority compounds through clear priorities and focused resourcing (NDA submission for S-888711 and Cymbalta in Japan, etc.)**

**Implemented share buyback demonstrating Shionogi's strong commitment to increase its shareholder returns**

# Overview of 3<sup>rd</sup> Quarter FY2014 Financial Results

# Financial Results (Consolidated)

(Units: B yen)

|                  | FY2014 forecasts | FY2014 Apr-Dec results | Progress vs. forecasts (%) | FY2013 Apr-Dec results | Y on Y     |        |
|------------------|------------------|------------------------|----------------------------|------------------------|------------|--------|
|                  |                  |                        |                            |                        | change (%) | change |
| Sales            | 273.5            | 200.3                  | 73.2                       | 218.1                  | (8.2)      | (17.8) |
| Operating income | 49.5             | 36.1                   | 72.9                       | 48.8                   | (26.1)     | (12.7) |
| Ordinary income  | 58.0             | 51.7                   | 89.2                       | 50.0                   | 3.5        | 1.7    |
| Net income       | 30.0             | 26.3                   | 87.5                       | 36.2                   | (27.4)     | (9.9)  |
| Net income       | -                | * 39.8                 | -                          | 36.2                   | -          | -      |

- Ordinary income from Apr. to Dec. 2014 is higher than the levels achieved in the Apr. to Dec. period of any prior fiscal year

**Note:**

All numerical values are rounded to the nearest unit.

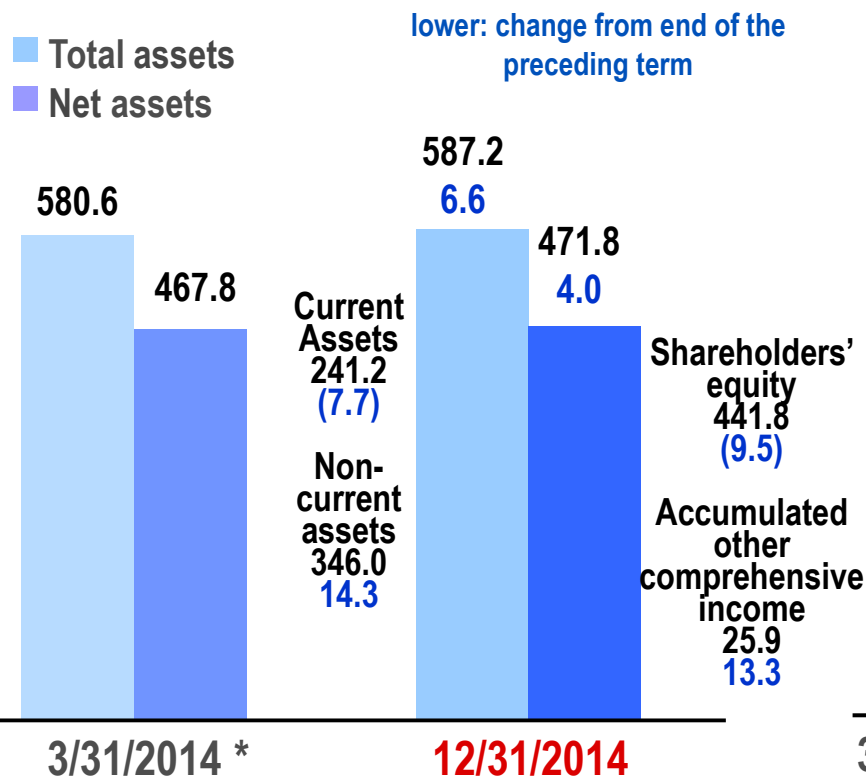
The accounting policy for R&D expenses was changed effective Apr. 1, 2014. Figures for FY2013 have been restated to reflect this change.

| Exchange rate (average) | FY2014 forecasts | FY2014 3Q results |
|-------------------------|------------------|-------------------|
| USD (\$) – JPY (¥)      | 105              | 106.73            |
| EUR (€) – JPY (¥)       | 140              | 140.21            |
| GBP (£) – JPY (¥)       | 170              | 175.45            |

# Financial Position and Cash Flow (Consolidated)

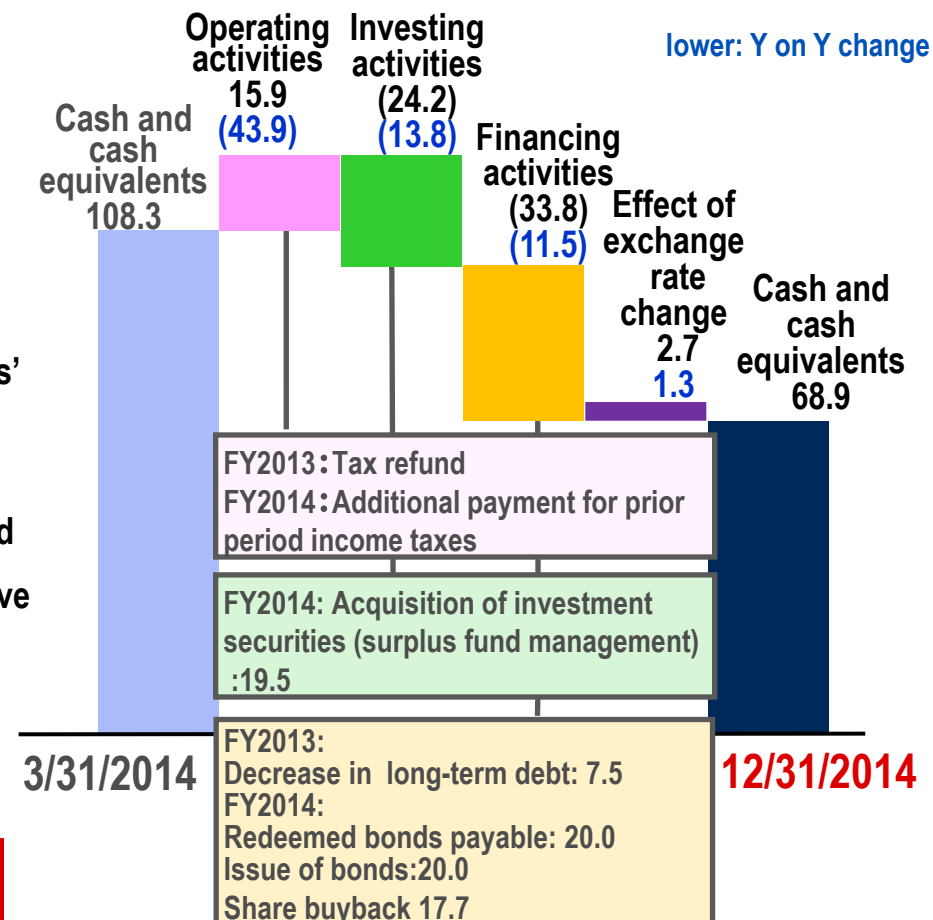
(Units: B yen)

## ◆ Financial Position



|              | 3/31/2014 * | 12/31/2014 |
|--------------|-------------|------------|
| Equity ratio | 79.9%       | 79.7%      |

## ◆ Cash Flow



\* The accounting policy for R&D expenses was changed effective Apr. 1, 2014.  
Figures for FY2013 have been restated to reflect this change

# Statements of Income (Consolidated)

(Units: B yen)

|                               | FY2014          |                    | Progress vs.<br>forecasts<br>(%) | FY2013<br>Oct-Dec<br>results | Y on Y        |              | FY2014<br>Apr-Dec<br>results | FY2013<br>Apr-Dec<br>results | Y on Y<br>change<br>(%) |
|-------------------------------|-----------------|--------------------|----------------------------------|------------------------------|---------------|--------------|------------------------------|------------------------------|-------------------------|
|                               | 2H<br>forecasts | Oct-Dec<br>results |                                  |                              | change<br>(%) | change       |                              |                              |                         |
| Prescription drugs            | 86.5            | 43.8               | 50.6                             | 46.5                         | (5.8)         | (2.7)        | 120.8                        | 127.4                        | (5.2)                   |
| Total of 3 key products       | 38.0            | 17.9               | 47.3                             | 17.6                         | 1.7           | 0.3          | 52.0                         | 50.1                         | 3.7                     |
| Total of 8 strategic products | 53.6            | 25.5               | 47.6                             | 25.1                         | 1.6           | 0.4          | 71.2                         | 69.5                         | 2.4                     |
| Overseas subsidiaries/export  | 16.7            | 8.1                | 48.1                             | 12.0                         | (32.7)        | (3.9)        | 22.6                         | 27.3                         | (17.3)                  |
| Shionogi Inc.                 | 10.3            | 4.6                | 44.6                             | 8.3                          | (44.9)        | (3.7)        | 12.0                         | 17.9                         | (32.7)                  |
| <i>Osphena</i>                | 5.3             | 1.4                | 27.1                             | 0.4                          | 227.2         | 1.0          | 3.1                          | 0.5                          | 479.6                   |
| C&O                           | 4.2             | 1.7                | 41.4                             | 1.3                          | 31.4          | 0.4          | 5.0                          | 4.2                          | 18.7                    |
| Contract manufacturing        | 5.3             | 2.5                | 46.9                             | 0.8                          | 223.2         | 1.7          | 8.6                          | 5.8                          | 48.1                    |
| OTC and quasi-drugs           | 2.1             | 1.2                | 55.0                             | 1.1                          | 7.5           | 0.1          | 3.6                          | 3.4                          | 6.3                     |
| Royalty income                | 31.7            | 14.0               | 44.3                             | 18.1                         | (22.4)        | (4.1)        | 42.3                         | 51.5                         | (17.8)                  |
| <i>Crestor</i>                | 24.6            | 10.7               | 43.5                             | 16.7                         | (35.7)        | (6.0)        | 35.1                         | 47.9                         | (26.6)                  |
| Others                        | 1.2             | 0.8                | 70.3                             | 1.0                          | (11.1)        | (0.2)        | 2.3                          | 2.7                          | (12.2)                  |
| <b>Total</b>                  | <b>143.7</b>    | <b>70.4</b>        | <b>49.0</b>                      | <b>79.4</b>                  | <b>(11.3)</b> | <b>(9.0)</b> | <b>200.3</b>                 | <b>218.1</b>                 | <b>(8.2)</b>            |

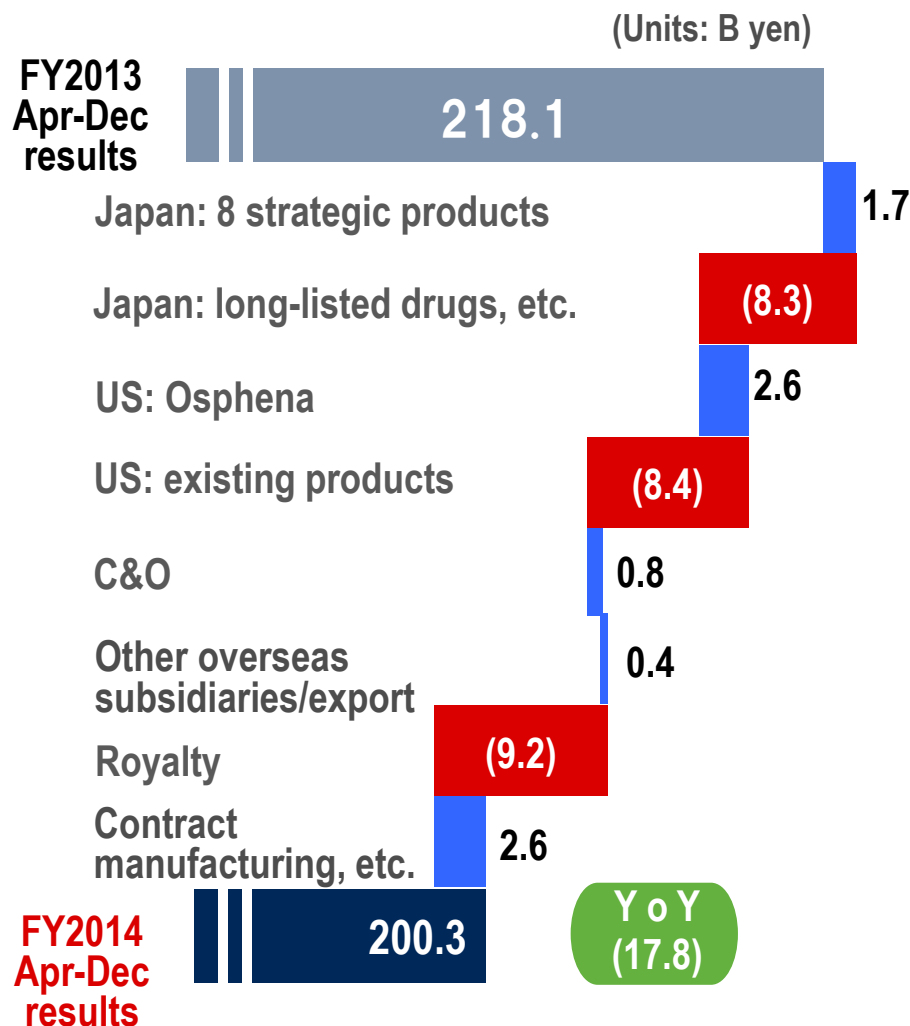
Eight strategic products: *Crestor*, *Irbetan* franchise, *Cymbalta* (3 key products), and *OxyContin* franchise, *Finibax*, *Differin*, *Pirespa*, *Rapiacta*

# Japan: Sales of 8 Strategic Products

(Units: B yen)

|                               | FY2014       |                 | Progress vs. forecasts (%) | FY2013<br>Oct-Dec results | Y on Y     |        | FY2014<br>Apr-Dec results | FY2013<br>Apr-Dec results | Y on Y change (%) |
|-------------------------------|--------------|-----------------|----------------------------|---------------------------|------------|--------|---------------------------|---------------------------|-------------------|
|                               | 2H forecasts | Oct-Dec results |                            |                           | change (%) | change |                           |                           |                   |
| Prescription drugs            | 86.5         | 43.8            | 50.6                       | 46.5                      | (5.8)      | (2.7)  | 120.8                     | 127.4                     | (5.2)             |
| Crestor                       | 21.5         | 11.1            | 51.5                       | 10.6                      | 4.4        | 0.5    | 32.1                      | 31.2                      | 3.0               |
| Irbetan franchise             | 9.0          | 3.9             | 43.1                       | 3.9                       | (0.8)      | (0.0)  | 11.4                      | 10.6                      | 7.9               |
| Cymbalta                      | 7.4          | 3.0             | 40.3                       | 3.1                       | (4.2)      | (0.1)  | 8.5                       | 8.4                       | 1.1               |
| Total of 3 key products       | 38.0         | 17.9            | 47.3                       | 17.6                      | 1.7        | 0.3    | 52.0                      | 50.1                      | 3.7               |
| OxyContin franchise           | 5.4          | 2.9             | 54.0                       | 3.1                       | (6.6)      | (0.2)  | 8.2                       | 8.5                       | (3.5)             |
| Finibax                       | 2.3          | 1.1             | 48.3                       | 1.3                       | (18.4)     | (0.2)  | 3.0                       | 3.6                       | (16.2)            |
| Differin                      | 2.6          | 1.1             | 40.9                       | 1.2                       | (13.9)     | (0.1)  | 2.9                       | 3.1                       | (8.8)             |
| Pirespa                       | 2.9          | 1.4             | 48.3                       | 1.4                       | 3.3        | 0.0    | 4.0                       | 3.7                       | 8.0               |
| Rapiacta                      | 2.4          | 1.1             | 44.2                       | 0.4                       | 172.9      | 0.7    | 1.1                       | 0.5                       | 139.6             |
| Total of 8 strategic products | 53.6         | 25.5            | 47.6                       | 25.1                      | 1.6        | 0.4    | 71.2                      | 69.5                      | 2.4               |
| [percent of sales]            | 61.9%        | 58.2%           |                            | 54.0%                     |            |        | 59.0%                     | 54.6%                     |                   |

# Change in Sales vs. Previous Year



## ◆ Domestic business

- Negative impact of NHI drug price revisions averaged approx. 2%
  - Expanded sales of Crestor and Irbetan franchise
  - Decreased sales of long-listed drugs

## ◆ Shionogi Inc. (existing products)

- Sales of FY2013 included Naprelan® and divestitures of pediatric products around (9.0)

## ◆ C&O

- Expanded sales of *Amolin*

## ◆ Royalty income

- Reduced royalty rate of Crestor due to the new agreement with AstraZeneca around (13.0)
- Began receiving royalties on Tivicay franchise sales
- Milestone payments from business partners

## ◆ Other businesses on track



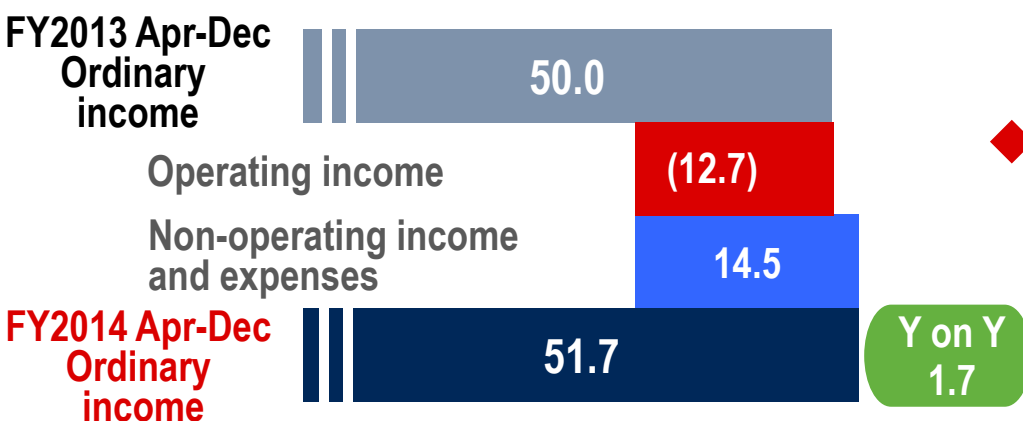
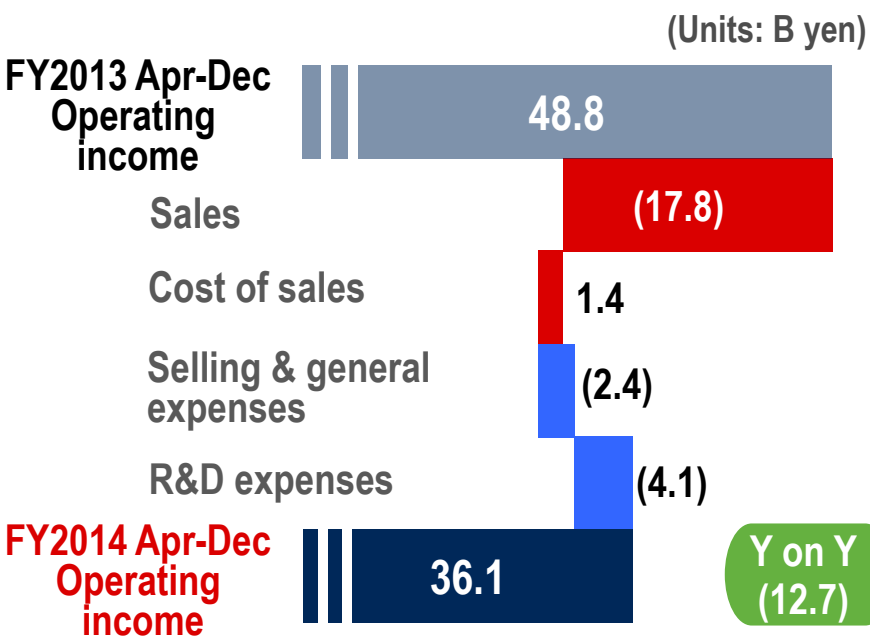
# Statements of Income (Consolidated)

(Units: B yen)

|                                   | FY2014          |                    | Progress<br>vs.<br>forecasts<br>(%) | FY2013             | Y on Y        |                | FY2014             | FY2013             | Y on Y<br>change<br>(%) |
|-----------------------------------|-----------------|--------------------|-------------------------------------|--------------------|---------------|----------------|--------------------|--------------------|-------------------------|
|                                   | 2H<br>forecasts | Oct-Dec<br>results |                                     | Oct-Dec<br>Results | change<br>(%) | change         | Apr-Dec<br>results | Apr-Dec<br>results |                         |
| Sales                             | 143.7           | 70.4               | 49.0                                | 79.4               | (11.3)        | (9.0)          | 200.3              | 218.1              | (8.2)                   |
| [Royalty income]                  | 31.7            | 14.0               | 44.3                                | 18.1               | (22.4)        | (4.1)          | 42.3               | 51.5               | (17.8)                  |
| Cost of sales                     | 28.1<br>[36.0]  | 29.3<br>[36.6]     |                                     | 25.4<br>[32.9]     |               |                | 29.3<br>[37.2]     | 26.3<br>[34.5]     |                         |
|                                   | 40.4            | 20.6               | 51.1                                | 20.2               | 2.2           | 0.4            | 58.8               | 57.4               | 2.3                     |
| Gross profit                      | 103.3           | 49.8               | 48.2                                | 59.2               | (15.9)        | (9.4)          | 141.5              | 160.7              | (11.9)                  |
| SG&A expenses                     | 53.3            | 51.8               |                                     | 48.3               |               |                | 52.6               | 51.3               |                         |
|                                   | 76.5            | 36.5               | 47.6                                | 38.4               | (5.0)         | (1.9)          | 105.4              | 111.9              | (5.8)                   |
| Selling & general expenses        | 47.7            | 24.1               | 50.4                                | 24.8               | (2.9)         | (0.7)          | 69.8               | 72.2               | (3.3)                   |
| R&D expenses                      | 28.8            | 12.4               | 43.0                                | 13.6               | (8.7)         | (1.2)          | 35.6               | 39.7               | (10.3)                  |
| Operating income                  | 18.6            | 19.0               |                                     | 26.3               |               |                | 18.0               | 22.4               |                         |
| [Excluding royalty income]        | 26.8<br>(4.9)   | 13.3<br>(0.7)      | 49.8<br>-                           | 20.8<br>2.7        | (36.0)<br>-   | (7.5)<br>(3.4) | 36.1<br>(6.3)      | 48.8<br>(2.7)      | (26.1)<br>-             |
| Non-operating income and expenses | L0.2            | P7.0               | -                                   | P1.8               | 282.2         | 5.2            | P15.7              | P1.2               | 1,216.7                 |
| Ordinary income                   | 26.6            | 20.3               | 76.4                                | 22.7               | (10.4)        | (2.4)          | 51.7               | 50.0               | 3.5                     |
| Net income                        | 20.3            | 16.6               | 81.6                                | 15.1               | 9.8           | 1.5            | 26.3               | 36.2               | (27.4)                  |

Extraordinary income and loss (Oct-Dec result): Gain on sales of the former research laboratory site (Osaka city) etc. ; 4.3B yen

# Change in Earning Structure vs. Previous Year



## ◆ Cost of sales

- Negative impact of NHI price revisions, exchange rate, etc.

## ◆ Selling & general expenses

- Further cost optimization in all group companies
  - Japan: Preferential investment in high-priority products and activities
  - Shionogi Inc.: Continued investment in Osphena while reducing other costs

## ◆ R&D expenses

- Invested in high-priority development programs and utilized alliances with partners (including NovaQuest)

- Reviewed fixed costs

## ◆ Non-operating income and expenses

- Increased dividends from ViiV
- Accounted for increase in value of foreign-currency assets due to the weak yen
- Reduced interest cost by repayment of bond and debt

# Key Actions in 2H FY2014, Looking Ahead towards Mid- to Long-term Growth



# To Achieve the FY2014 Targets in Japan and the US

## ◆ Japanese domestic business

- Constructing a business base for a changing Japanese market
  - Tighter focus on region-specific sales and marketing needs
- Continued focus on 3 key strategic products while laying the groundwork for the mid- to long-term product portfolio
  - Continue to strengthen the patient-based cross-disciplinary info-service
  - Strategic investment and resource allocation

## ◆ US business

- Strengthen commercial approach to drive Osphena's growth
  - Broadening the physician audience and updating key messages
  - Provide stronger support for patients throughout their treatment journey
  - Improve adherence of patients taking Osphena
- Pursue alliances and partnerships to
  - Expand our Women's Health portfolio
  - Strengthen platform for our next wave of products, including S-297995 and S-649266

# Continued Enhancement of Business Operations

## ◆ Optimizing cost of sales and management of inventory

- Strengthening collaboration amongst purchasing, manufacturing, distribution and sales divisions
- Cross-functional projects to improve profitability and cash flow



## ◆ Optimization of selling & general expenses

- Managing the total cost throughout the Shionogi group to invest in future growth and achieve profit targets

**Maximize profitability by strengthening business operations**

# Parallel Actions to Drive Mid- to Long-Term Growth

## R&D

- Focus resources on innovative development programs to meet the needs of patients and society,
- Maximize the value of products through innovative alliances
- Implement truly global development plans ( JPN, US, EU and Asia)

## Japanese domestic business

- Strengthen customer-facing activities and respond in real-time to changes in the market environment
- Maintain continuous ROI improvement for profit growth
- Establish the business base to support the mid- to long-term product portfolio

## US business

- US business to contribute to group profit by expanding Osphena sales
- Strengthen the women's health area and prepare for entry into the pain and infectious disease areas (including via alliances)

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

**Maximize profitability by strengthening business operations**

2014

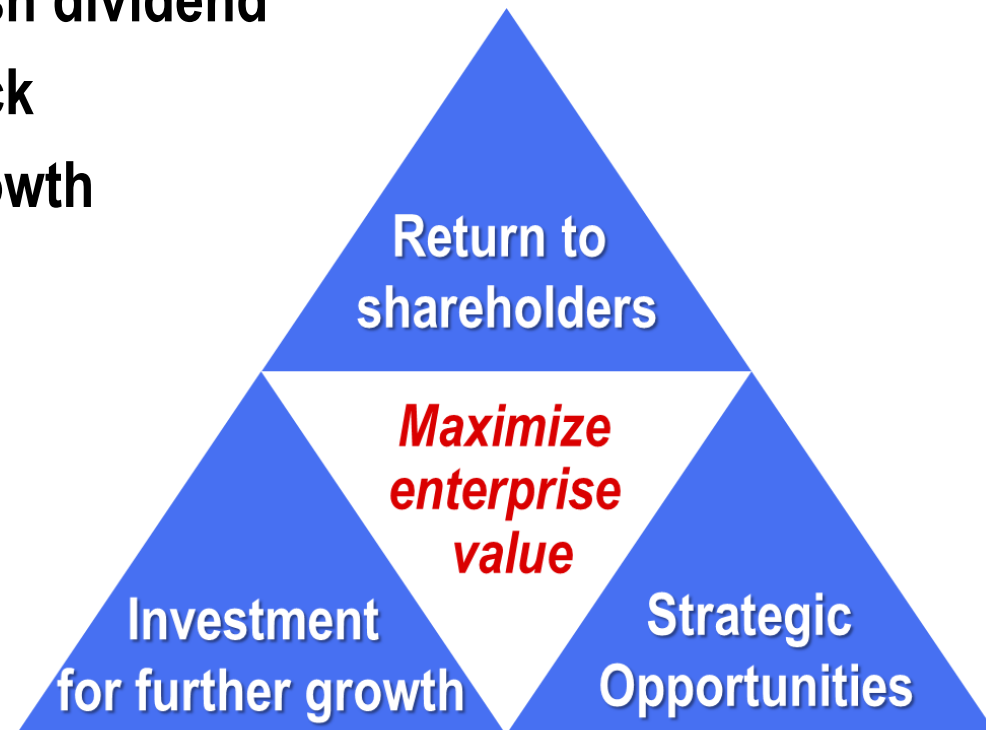
2016

2020

**FY2014 focus on steady operations while preparing for mid- to long-term growth in the first year of SGS2020**

# Financial Strategy in SGS2020

- ◆ **Financial strategy: Advance our business objectives with a focus on capital efficiency (Improvement in ROE)**
  - **Strong commitment to increase shareholder returns**
    - **Stable increase in cash dividend**
    - **Flexible share buyback**
  - **Investment for further growth**
  - **Strategic opportunities**



# Flexible Share Buyback

## Share Buyback

### Upper limits

Total cost: 30 billion yen

Number of shares:  
10 million shares



### Results

Total cost: 30.0 billion yen

Number of shares:  
9,329,900 shares

Period: Dec. 2, 2014 – Jan. 22, 2015

Shionogi Funds (10 billion yen)



Euro Yen Convertible Bonds

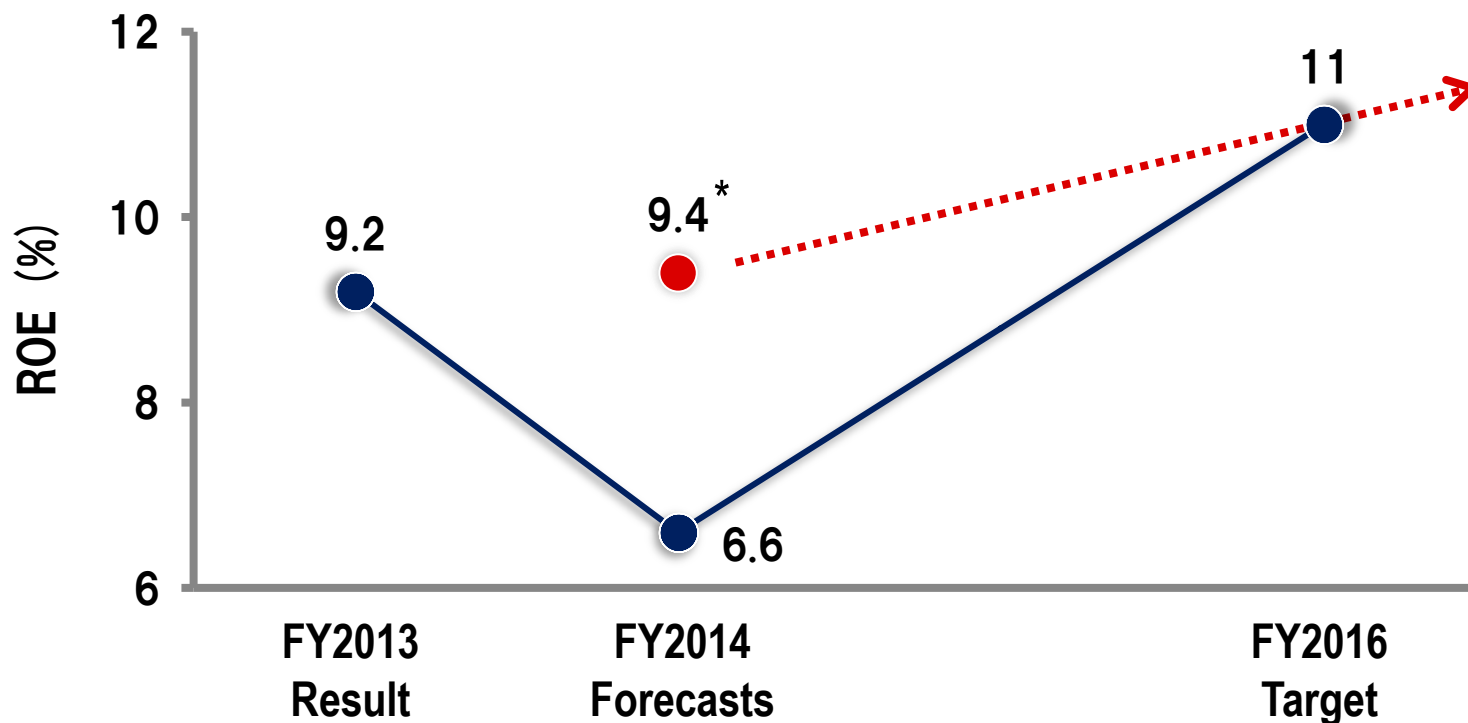
Total amount of issue:  
20 billion yen

Interest rate: 0%

Conversion price: 4,180 yen  
(Premium to closing price on Dec. 2, 2014:  
37.05%)



# Commitment to increasing ROE



FY2014 forecast was calculated based on projected net income of 30 billion yen

\* Hypothetical ROE excluding the payment for prior period income taxes

**Focus on the capital efficiency targets in SGS2020**

# Research & Development

## Clear Priorities and Focused Resourcing on Medical Needs



# Focusing Targets in FY2014

## ◆ High-priority compounds in Japan

- Cymbalta<sup>®</sup> (Fibromyalgia pain): [NDA submission \(Jun. 2014\)](#),  
(Chronic low back pain): [NDA submission \(Dec. 2014\)](#)
- S-888711 (Thrombocytopenia): [NDA submission \(Dec. 2014\)](#)
- S-524101 (Sublingual tablets of house-dust mite allergen extracts for immunotherapy):  
[NDA submission \(Apr. 2014\)](#)
  - S-525606 (Sublingual tablets of Japanese cedar allergen extracts for immunotherapy):  
Phase I initiation

## ◆ Global development compounds

- S-297995 (Alleviation of opioid-induced adverse effects): Ongoing global Phase III
  - [Modification of global Phase III study package agreed with FDA](#)
- S-718632 (hydrocodone tamper resistant extended-release formulation):  
[Phase I in preparation](#)
- S-888711: Global Phase III study package under discussion with EMA and FDA
- S-649266 (Infection): [Global Phase II initiation](#)
- Senshio<sup>®</sup> (ospemifene, post-menopausal vaginal atrophy): [Approved in EU \(Jan. 2015\)](#)

**Consistently meeting FY2014 development milestones**

# Japan: S-888711 and Cymbalta

## ◆ S-888711 (lusutrombopag)

- Indication (planned)
  - Increase platelet production in patients with chronic liver disease prior to invasive procedures
    - ✓ The world's first such indication for a thrombopoietin receptor agonist
- Avoid platelet transfusion prior to invasive procedures in patients with chronic liver disease and resulting severe thrombocytopenia
- Submitted NDA (Dec. 2014)

## ◆ Cymbalta® (duloxetine)

- Development for additional indications
  - Fibromyalgia pain: Submitted NDA (development for new indications with high medical need, requested by Review Committee\*)
  - Chronic low back pain: Submitted NDA (Dec. 2014)
  - Osteoarthritic pain: Phase III study
- Joint development and co-promotion with Eli Lilly Japan

\* A committee convened by the Ministry of Health, Labor and Welfare to promote new development and applications of drugs which have not yet been approved for use in Japan but that have already been approved for use in the US and Europe.

# Pipeline for Future Growth in the Domestic Market

## Pipeline in Japan

S-524101

Frontier

S-888711

Frontier

Cymbalta®

(Fibromyalgia pain, chronic low back pain)

Pain/CNS

Cymbalta® (Osteoarthritic pain)

Pain/CNS

OxyContin® (Moderate to severe chronic pain;  
tamper resistant formulation)

Pain/CNS

S-297995

Pain/CNS

ADHD (S-877503, S-877489)

Pain/CNS

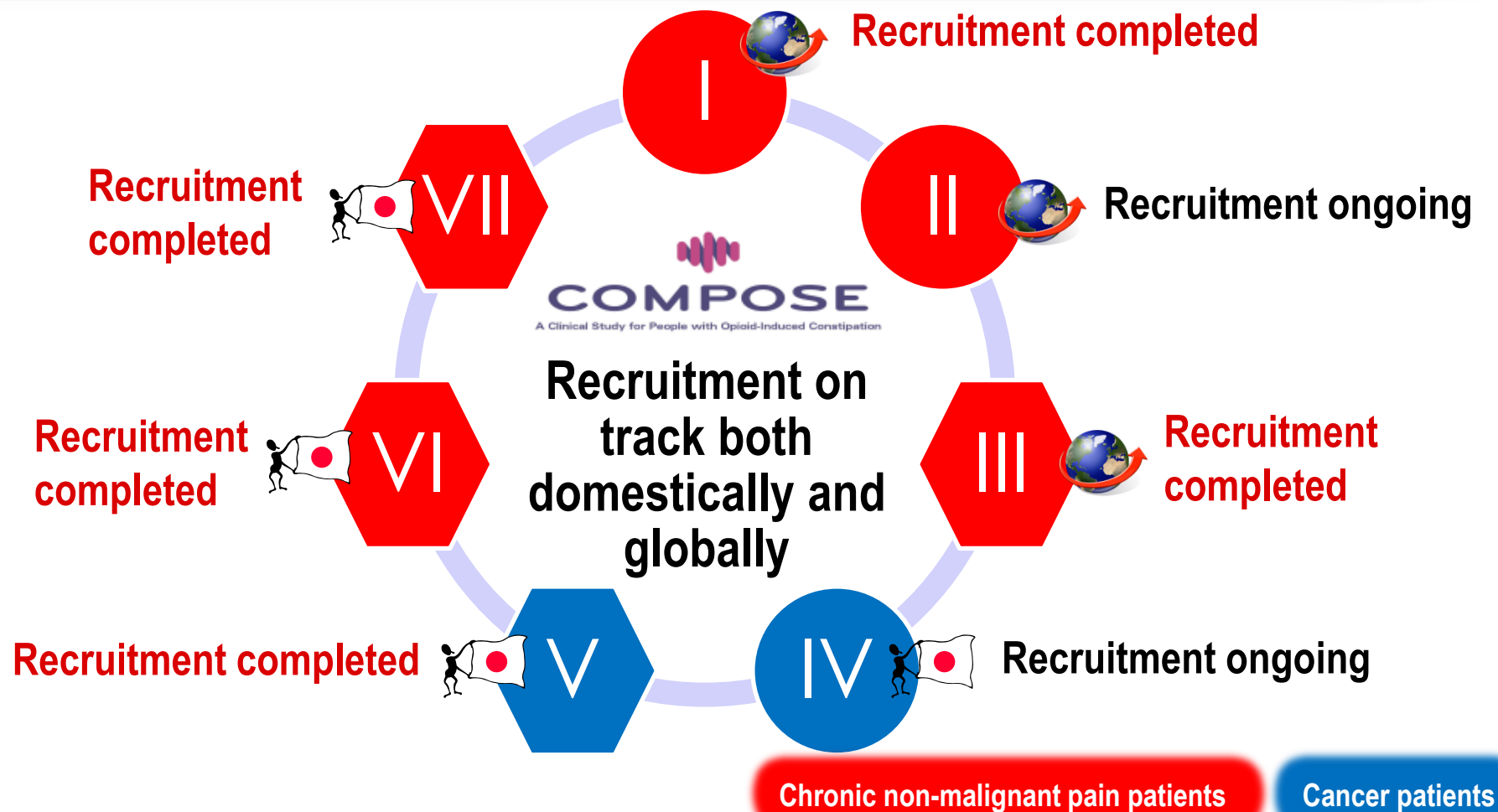
S-649266

Infection

**Steady  
series of  
launches  
in the  
Japanese  
Market**

**Strengthen the product portfolio by launching new drugs**

# S-297995 (Naldemedine): Phase III Studies



**Plan to submit NDAs in 1Q FY2016 in US and Japan**



# **Appendix**

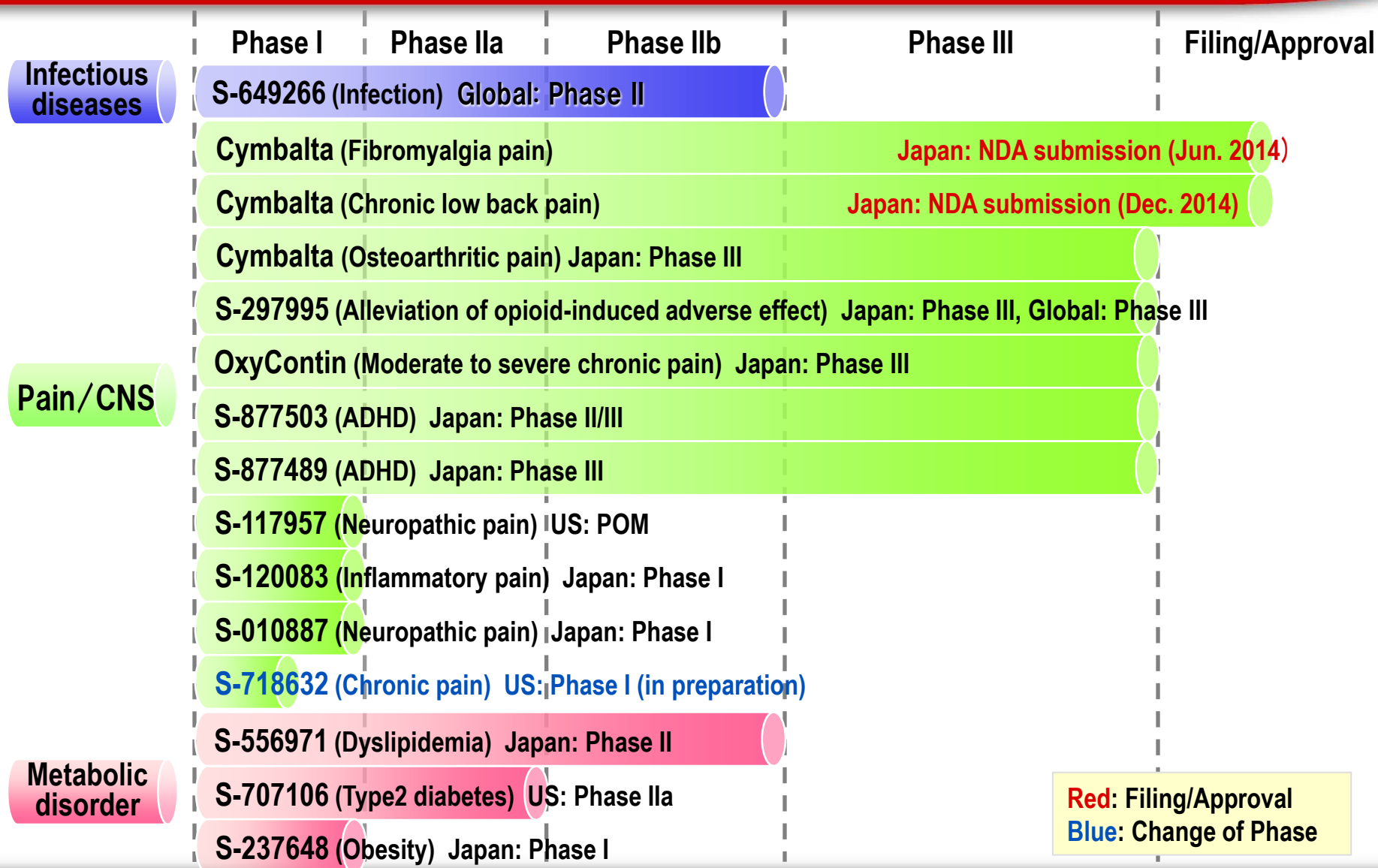
## **- Pipeline -**

# Change of Phase (since November 2014)

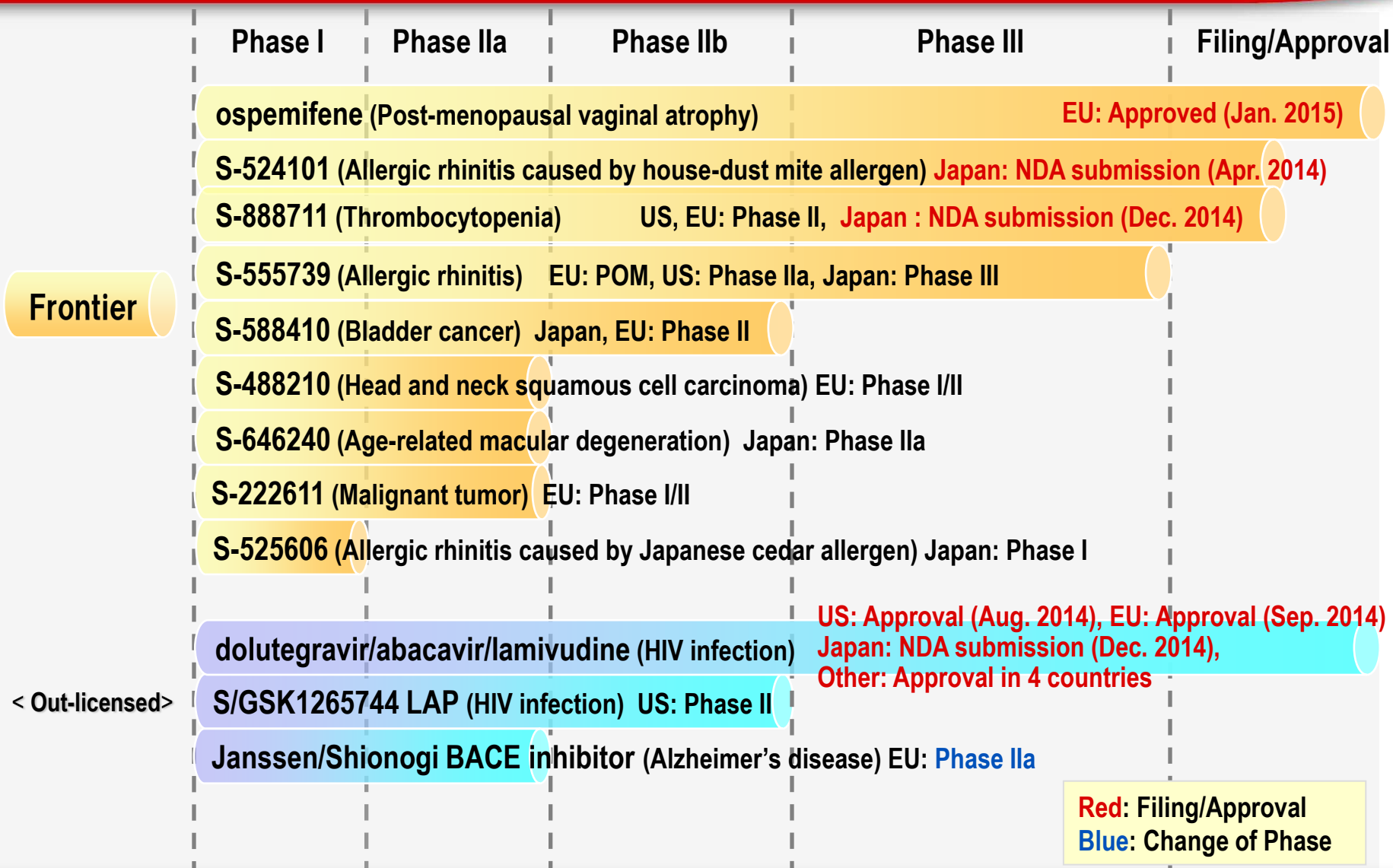
| Code No.<br>[Product/generic name]                  | Category<br>(Administration)   | Indication                      | Change of Phase   |
|---|--|---------------------------------|---|
| LY248686<br>Duloxetine hydrochloride<br>[Cymbalta®] | SNRI (Serotonin & noradrenaline reuptake inhibitor)<br>(Oral)              | Chronic low back pain           | Japan: NDA submission (in preparation)<br>⇒NDA submission (Dec. 2014) |
| S-718632  | Abuse-deterrent extended release hydrocodone<br>(Oral)                     | Chronic pain                    | USA: Phase I (in preparation)   |
| Ospemifene  | Selective estrogen receptor modulator<br>(Oral)                            | Post-menopausal vaginal atrophy | Europe: NDA submission (Mar. 2013)<br>⇒Approval (Jan. 2015)           |
| S-888711<br>[Lusutrombopag]                         | Small molecule TPO receptor agonist<br>(Oral)                              | Thrombocytopenia                | Japan: NDA submission (in preparation)<br>⇒NDA submission (Dec. 2014) |
| Dolutegravir/abacavir/<br>lamivudine                | Integrase inhibitor / Nucleoside reverse transcriptase inhibitor<br>(Oral) | HIV infection                   | Japan: NDA submission (Dec. 2014)                                     |
| Janssen/Shionogi BACE inhibitor                     | BACE inhibitor<br>(Oral)   | Alzheimer's disease             | Europe: Phase I<br>⇒Phase IIa   |



# Pipeline (as of February 2015)



# Pipeline (as of February 2015)



# 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.
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