1st Quarter of Fiscal 2014 Financial Results

Conference Call

August 1, 2014

SHIONOGI

New Medium-Term Business Plan of SHIONOGI

Growth Strategy toward 2020

Shionogi Growth Strategy (SGS2020)

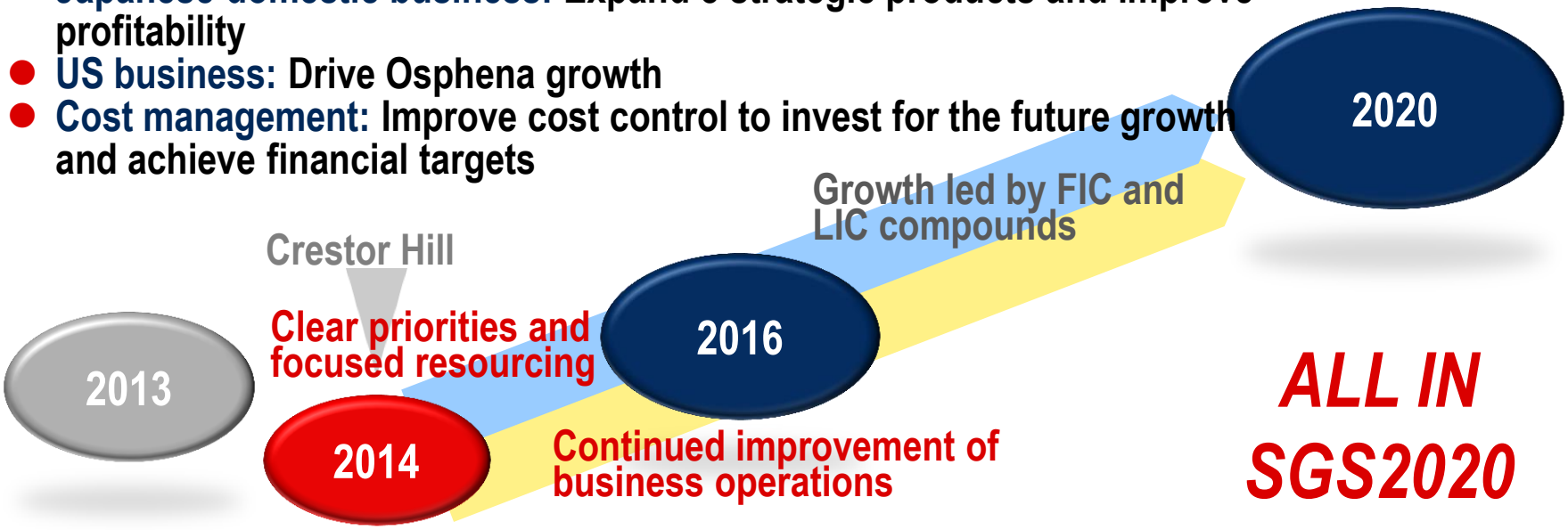
Position of FY2014 Business Plan

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 by "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 the future growth and achieve financial targets



Research & Development

Clear Priorities and Focused Resourcing in FY2014

◆ Accelerate development of high-priority compounds in Japan

- S-524101 (Sublingual tablets of house-dust mite allergen extracts for immunotherapy): submitted NDA in Apr. 2014
  - ➢ S-525606 (Sublingual tablets of Japanese cedar allergen extracts for immunotherapy): initiated Phase I study
- Cymbalta (Fibromyalgia): submitted NDA in Jun. 2014, (Chronic low back pain): plan to submit NDA in FY2014
- S-888711(Thrombocytopenia): Phase III code-break, plan to submit NDA in FY2014

◆ Focus on global compounds

- S-297995 (Alleviation of opioid-induced adverse effects): Ongoing global Phase III
- S-888711: Plan to initiate global clinical trials after discussion with EMA and FDA
- S-649266 (Infection): initiated global Phase II study
- S-222611 (Malignant tumor): initiated Phase I/II study in EU

◆ Clear priorities and focused resourcing in development

- Maximization of the potential of our assets in development, using a combination of partnering, licensing-in and licensing-out
- Janssen received FDA Fast Track designation for the out-licensed BACE inhibitor

S-888711 (Lusutrombopag): Phase III Code-break in Japan

◆ Phase III code-break

[Summary of results]

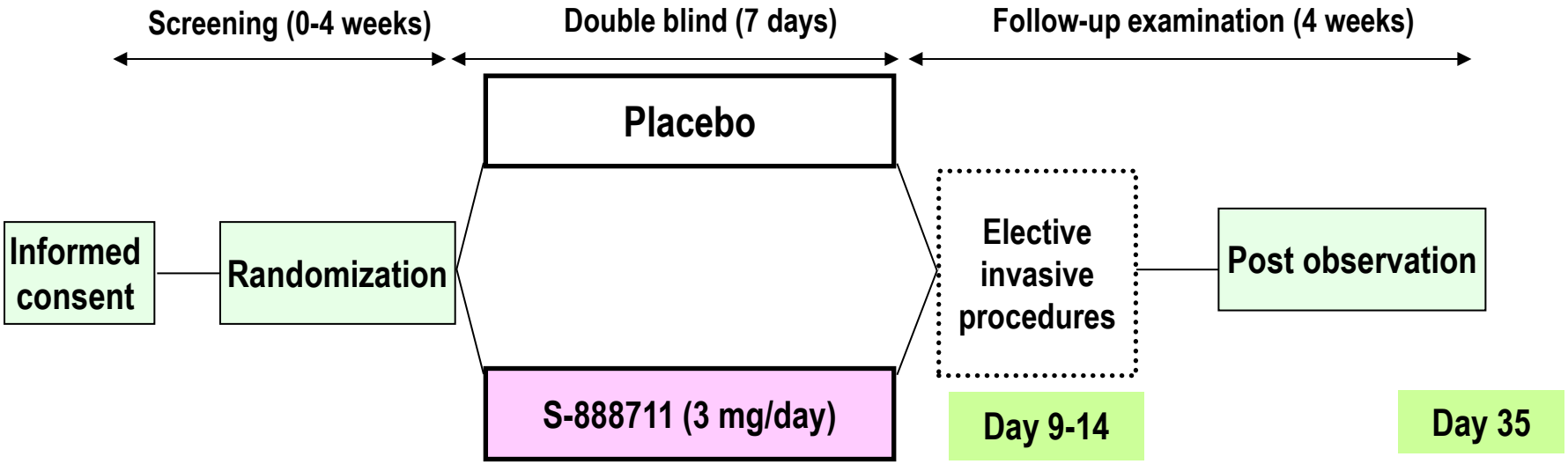
- Proportion of patients not requiring platelet transfusion: the S-888711 group showed statistically higher percentage than the placebo group

- One subject in each of the S-888711 group and the placebo group experienced portal thrombosis

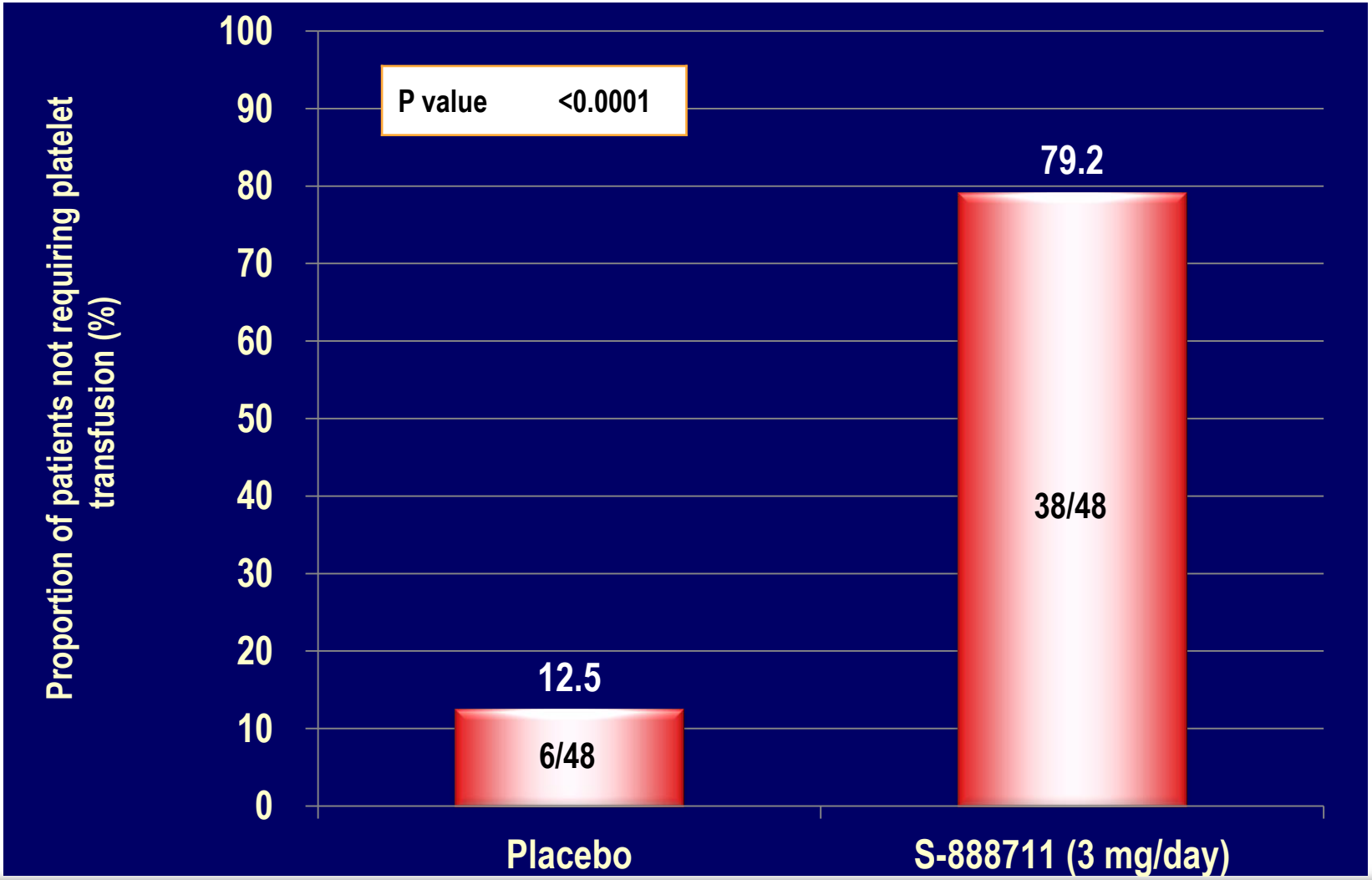
⇒ In FY2014, plan to submit the NDA in Japan, and to proceed to regulatory consultations with Western authorities

S-888711 (Lusutrombopag): Summary of Phase III Design

Purpose	Evaluate superiority to placebo after 7-day multiple dose administration of S-888711 in subjects for thrombocytopenia with chronic liver diseases prior to elective invasive procedures
Primary endpoint	Proportion of patients who did not require platelet transfusion before elective invasive procedures



S-888711 (Lusutrombopag): Primary Endpoint (FAS)



FAS: Full analysis set

S-888711 (Lusutrombopag): Safety

	Placebo	S-888711 (3 mg/day)
Number of patients	48	48
Patients with adverse events (AEs)	48	45
Patients with AEs related to study drug	1	4
Patients with significant AEs	20	20
Patients with serious AEs	4	1
Patients with thromboembolic AEs	1	1
Patients with bleeding-related AEs	13	7

S-297995 (Naldemedine): Phase III Update

- **COMPOSE Program (7 studies)**
  - Global: Chronic non-malignant pain patients (3 studies)
    - Two ongoing confirmatory studies (12-week), and long-term safety study (52-week)
  - Japan: Cancer patients and chronic non-malignant pain patients (2 studies, including safety studies, in each patient category)
  - Recruitment proceeding on target
- **The meeting of the Anesthetic and Analgesic Drug Products Advisory Committee was held in Jun. 2014**
  - Considered the necessity of long-term evaluation of cardiovascular adverse reactions for peripherally active mu-opioid antagonists
  - Voted that a large CV outcomes randomized trial is not required pre-approval, but substantial long-term safety data is still required pre-approval
  - FDA is seeking input from an Advisory Committee on Salix's sNDA for Relistor®
  - With this positive Advisory Committee outcome as background, Shionogi plans to discuss our NDA package for S-297995 with FDA

S-649266: Accelerate Global Development

Development Progress

- After completing Phase I studies in Japan and the US, initiated Phase II study for infectious disease in the US in 4Q FY2013
- Progress development in the US and Japan, expanding development into EU, after discussion with each regulatory authority

Discussions with regulators are ongoing

- Find common ground on approvable MDR (multi-drug resistant organism)-focused development plan based on "Antimicrobial Stewardship*" in Japan, the US and Europe

Future plan

- Expected indication: aerobic gram-negative (MDR) bacterial infections
- Plan to initiate global efficacy and safety study for MDR

* Antimicrobial stewardship refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. The Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America announced the guidelines in 2007

Realizing the Potential of Dolutegravir by ViiV Healthcare

- **Single-pill regimen combining dolutegravir with abacavir and lamivudine**
  - Submitted NDA in the US and EU in Oct. 2013
    - The CHMP of the EMA has issued a positive opinion recommending marketing authorization for Triumeq® as a single-pill regimen in Jun. 2014
- **New therapeutic regimen containing dolutegravir**
  - 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
  - The two-drug fixed-dose combination therapy could offer people living with HIV, who need long-term therapy, a new NRTI-free option as maintenance therapy, once a stable suppressed viral load has been achieved

CHMP: Committee for Medicinal Products for Human Use EMA: the European Medicines Agency
NNRTI: Non-nucleoside reverse transcriptase inhibitor NRTI: Nucleoside reverse transcriptase inhibitor

Overview of
1Q FY2014 Financial Results

Summary of 1Q FY2014

Sales and operating income are on track

Ordinary income increased
(Higher than the levels achieved in 1Q of any prior fiscal year)

Net income increased, excluding extraordinary factors, from 1Q FY2013

Financial Results (Consolidated)

(Units: B yen)

	FY2014 forecasts	FY2014		Progress vs. forecasts (%)	FY2013 Apr-Jun results	Y on Y	
		1H forecasts	Apr-Jun results			change (%)	change
Sales	269.0	130.0	62.7	48.3	67.3	(6.7)	(4.6)
Operating income	45.0	18.5	8.0	43.5	12.1	(33.6)	(4.1)
Ordinary income	50.0	24.0	13.6	56.8	12.6	8.4	1.0
Net income	33.0	16.0	10.3	64.5	10.8	(4.6)	(0.5)

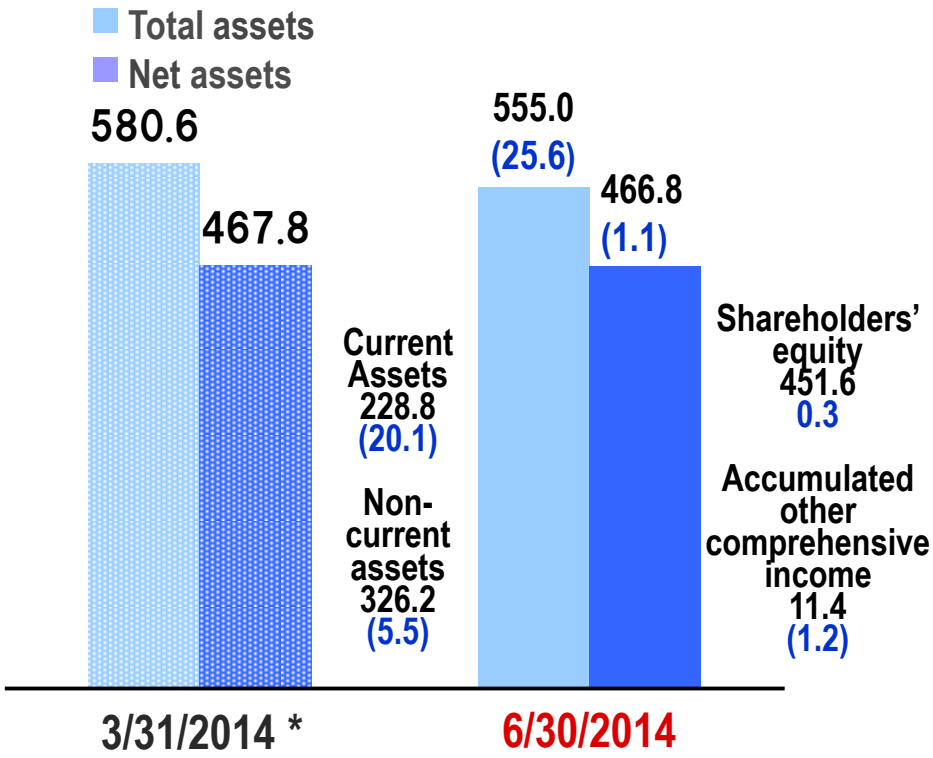
Note: All numerical values are rounded to the nearest unit
The accounting policy for R&D expenses was changed effective Apr. 1, 2014. Figures for FY2013 have been restated to reflect this change

Exchange rate (average)	FY2014 forecasts	Apr-Jun results
USD ($) – JPY (¥)	100	102.17
EUR (€) – JPY (¥)	140	140.06

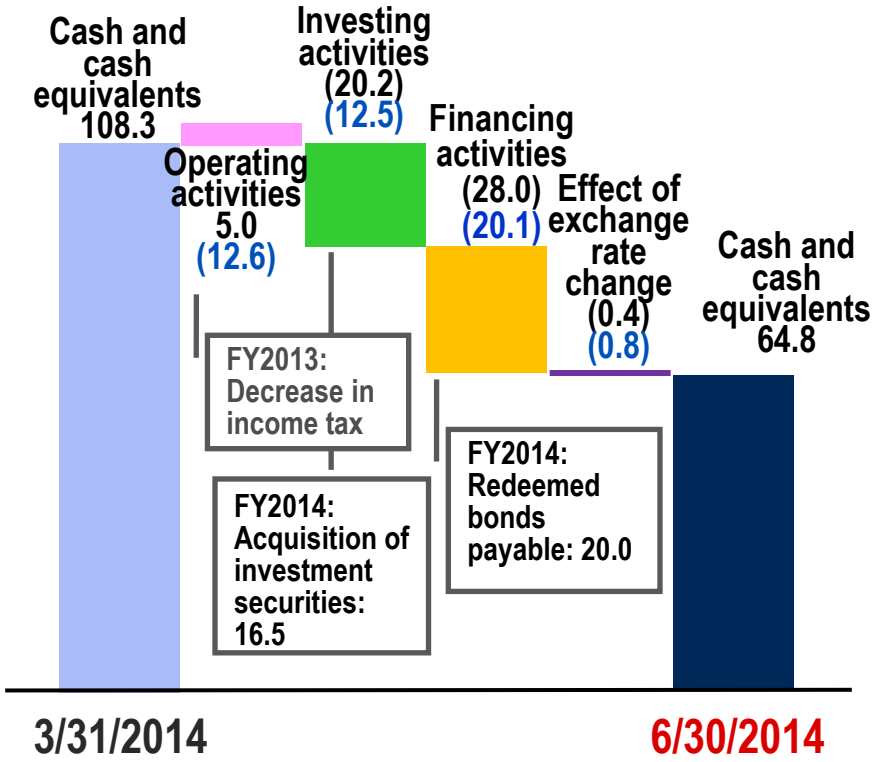
Financial Position and Cash Flow (Consolidated)

(Units: B yen)
lower: Y on Y change

Financial Position



Cash Flow



	3/31/2014 *	6/30/2014
Equity ratio	79.9%	83.4%

* 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. forecasts (%)	FY2013 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Prescription drugs	80.5	38.7	48.1	40.4	(4.3)	(1.7)
Total of 3 key products	34.5	17.1	49.6	15.5	10.5	1.6
Total of 8 strategic products	47.3	22.9	48.4	21.6	6.0	1.3
Overseas subsidiaries/export	15.0	6.7	44.7	8.4	(19.6)	(1.7)
Shionogi Inc.	7.9	2.8	36.0	5.4	(47.0)	(2.6)
Osphena®	2.5	0.8	30.4	-	-	0.8
C&O	3.4	1.8	52.0	1.3	37.6	0.5
Contract manufacturing	4.8	2.8	58.0	2.4	17.2	0.4
OTC and quasi-drugs	2.4	1.1	46.2	1.0	11.3	0.1
Royalty income	26.0	12.7	48.7	14.0	(9.8)	(1.3)
Crestor®	24.2	11.8	48.6	13.1	(10.1)	(1.3)
Others	1.3	0.7	56.9	1.0	(29.9)	(0.3)
Total	130.0	62.7	48.3	67.3	(6.7)	(4.6)

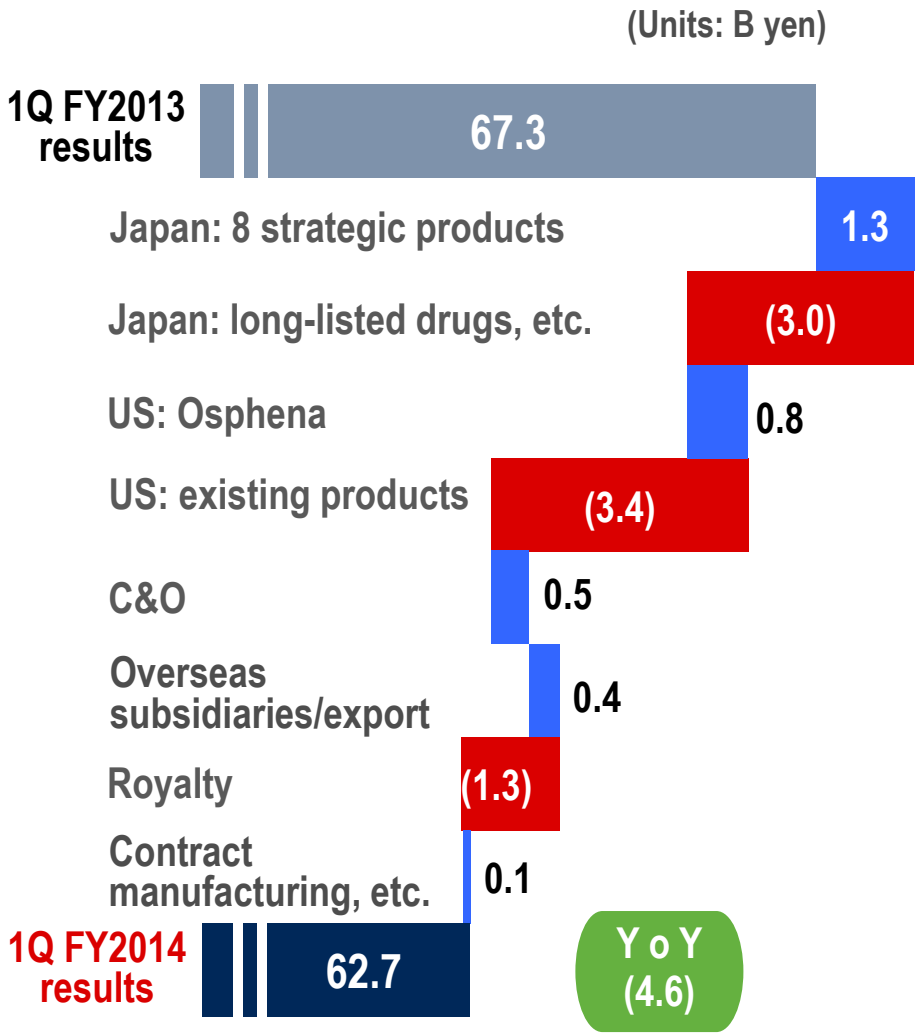
Eight strategic products: Crestor®, Irbetan® franchise, Cymbalta® (3 key products), and OxyContin® franchise, Finibax®, Differin®, Pirespa®, Rapiacta®

Japan: Sales of 8 Strategic Products

(Units: B yen)

	FY2014		Progress vs. forecasts (%)	FY2013 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Prescription drugs	80.5	38.7	48.1	40.4	(4.3)	(1.7)
Crestor	21.0	10.8	51.6	10.0	8.2	0.8
Irbetan franchise	7.3	3.7	51.2	2.9	30.4	0.8
Cymbalta	6.2	2.5	41.0	2.6	(2.5)	(0.1)
Total of 3 key products	34.5	17.1	49.6	15.5	10.5	1.6
OxyContin franchise	5.5	2.7	49.0	2.7	(1.7)	(0.0)
Finibax	2.3	0.9	37.9	1.1	(22.0)	(0.2)
Differin	2.1	0.9	42.0	0.9	(5.8)	(0.0)
Pirespa	2.7	1.3	46.7	1.2	2.9	0.1
Rapiacta	0.2	0.1	26.1	0.1	(30.7)	(0.0)
Total of 8 strategic products	47.3	22.9	48.4	21.6	6.0	1.3
[percent of sales]	58.8%	59.1%	-	53.3%	-	-

Change in Sales vs. Previous Year



- **Japanese domestic business**
  - Negative impact of NHI drug price revisions by an average of approx. 2%
    - Expanded sales of Crestor and Irbetan franchise
    - Decreased sales of Cymbalta and Differin due to increase in temporary demand in 4Q FY2013 before the consumption tax increase around (1.0)
    - Decreased long-listed drugs due to generic penetration
- **Shionogi Inc.**
  - Sales of FY2013 included divestitures of pediatric products and Naprelan around (3.0)
- **C&O**
  - Expand sales of Amolin and Flumarin
- **Royalty income (Crestor)**
  - Reduced royalty rate due to the new license agreement with AstraZeneca
    - Global Crestor sales are flat as previous year
- **Other businesses on track**

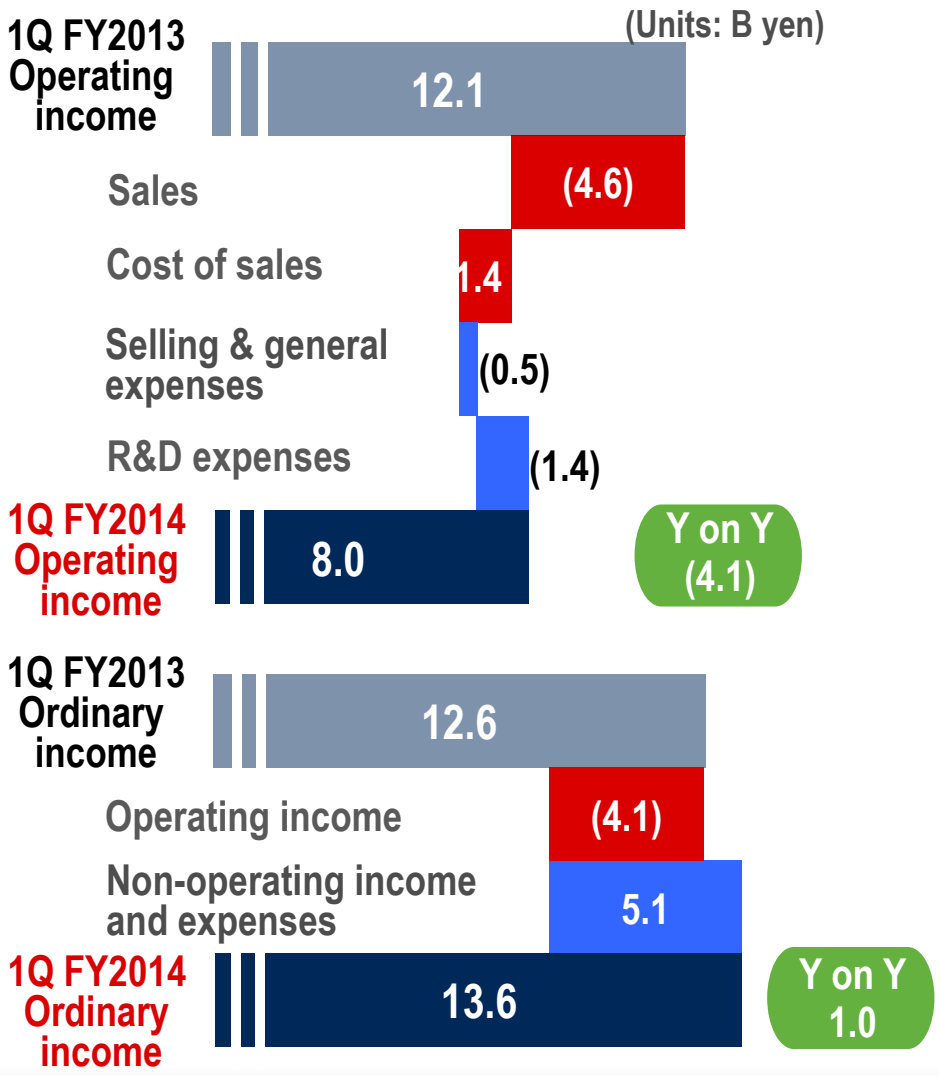
Statement of Income (Consolidated)

(Units: B yen)

	FY2014		Progress vs. forecasts (%)	FY2013 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Sales	130.0	62.7	48.3	67.3	(6.7)	(4.6)
[Royalty income]	26.0	12.7	48.7	14.0	(9.8)	(1.3)
Cost of sales	29.2 (36.5) 38.0	31.6 (39.6) 19.8	52.2	27.3 (34.5) 18.4	8.1	1.4
Gross profit	92.0	42.9	46.6	48.9	(12.3)	(6.0)
SG&A expenses	56.5 73.5	55.6 34.9	47.4	54.7 36.8	(5.3)	(1.9)
Selling & general expenses	46.5	23.1	49.7	23.6	(2.2)	(0.5)
R&D expenses	27.0	11.7	43.5	13.2	(10.7)	(1.4)
Operating income	14.2 18.5	12.8 8.0	43.5	18.0 12.1	(33.6)	(4.1)
[Excluding royalty income]	(7.5)	(4.6)	-	(1.9)	-	(2.7)
Non-operating income and expenses	P5.5	P5.6	-	P0.5	-	5.1
Ordinary income	18.5 24.0	21.7 13.6	56.8	18.7 12.6	8.4	1.0

Note: Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalties

Change in Earning Structure vs. Previous Year

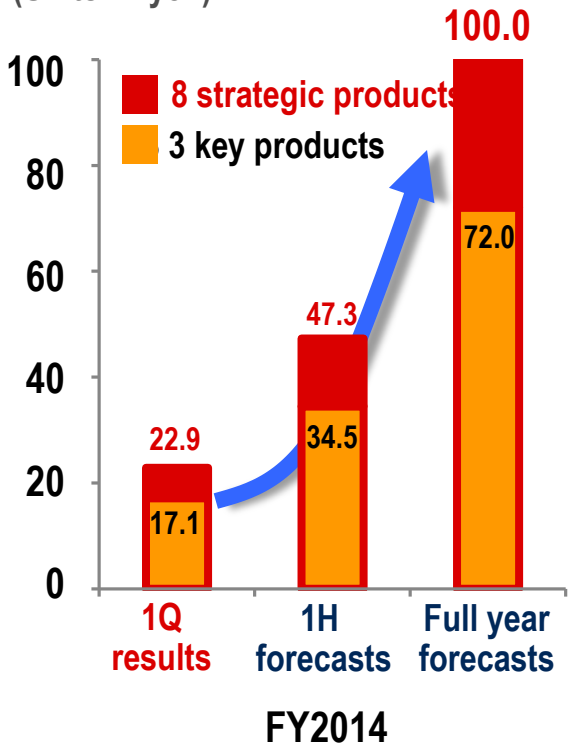


- **Cost of sales**
  - Negative impact of NHI price revisions, exchange rate, and 2013 extraordinary factors
    - Product divestitures at Shionogi Inc. in FY2013
- **Selling & general expenses**
  - Optimized costs in all group companies
    - Japan: Appropriate investment based on know-how accumulated in FY2013
    - Shionogi Inc.: Continue to invest in Osphena
- **R&D expenses**
  - Invested in high-priority development programs
    - Review fixed costs
- **Non-operating income and tax**
  - Increased dividends from ViiV
  - Reduced interest cost by repayment of debt

Key Next Actions to Achieve FY2014 Business Plan Targets Building on the Results of 1Q FY2014

Japanese Domestic Business Actions to Drive Growth

[Sales of 8 strategic products]



To achieve the FY2014 targets

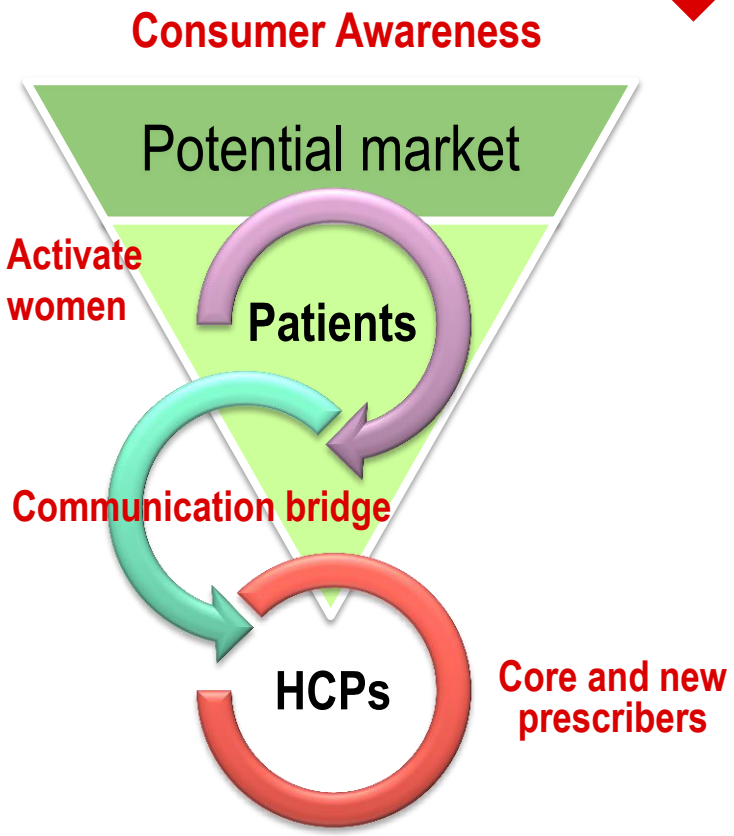
- Increased the 1Q sales of 3 key products by 10.5% vs. previous year
  (1H forecasts: +6.2%, full year forecasts: +8.5%)
- Negative impact of temporary spike in demand before consumption tax increase is resolving
- Substantial drop in sales of long-listed drugs was more than expected

Actions:

- Focus on 3 key products, especially Crestor and Cymbalta
- Promote 5 strategic products by focusing on their key differentiators to achieve the total sales target of 8 strategic products (over 100 B yen)
- Continue effective cost management

Diminish the negative impact of long-listed drugs by focusing on eight strategic products

Strengthen the US Business



To achieve the FY2014 targets

- Establish Osphena as one of the top 2 brands in the market
- Activate women to ask for Osphena

Actions:

- Strengthen the value proposition for HCPs
- Increase focus on new productive targets(e.g. selected PCPs as well as OB/GYNs)
- Support patients in communicating with HCPs
- Continue effective DTC campaigns using easy-to-understand and motivating messages to reach women who need Osphena, including those currently undiagnosed

Increase momentum of Osphena sales to make the product profitable after FY2015

Cost Management: Focused Resourcing on our Clear Priorities

Cost of sales

- 1Q slightly higher than 1H forecasts due to extraordinary factors

Action:

- Continue reducing cost of sales and maintain tight inventory control

Selling & general expenses

- Total costs are on track due to effective investment in high-priority products and activities

Action:

- Achieve FY2014 financial targets; continue to optimize cost management throughout the whole group from the perspective of mid- to long-term growth

R&D expenses

- Focus on high-priority compounds, continuously review costs and leverage alliance strategy

Action:

- Accelerate partnering and out-licensing to reduce costs and receive gain

Achieve financial targets while continuing growth-oriented investment by strategic cost management throughout the whole group

Continuous Operation for Mid- to Long-Term Growth

R&D

- Create innovative drugs to meet needs of patients and society
- Establish globally competitive development framework
- Select development programs and licensing activities to maximize the value of products

Japanese domestic business

- Improve profitability by strengthening customer-facing activities
- Maintain cost efficiency for consolidated profit growth
- Prepare for growth from mid- to long-term product portfolio

US business

- Establish strong presence in women's health area by maximizing the value of Osphena
- Prepare for pain market
- Global development in collaboration with Japan, EU and Asia

Grow as a drug discovery-based pharmaceutical company

Maximize profitability by strengthening business operations

2014 2016 2020

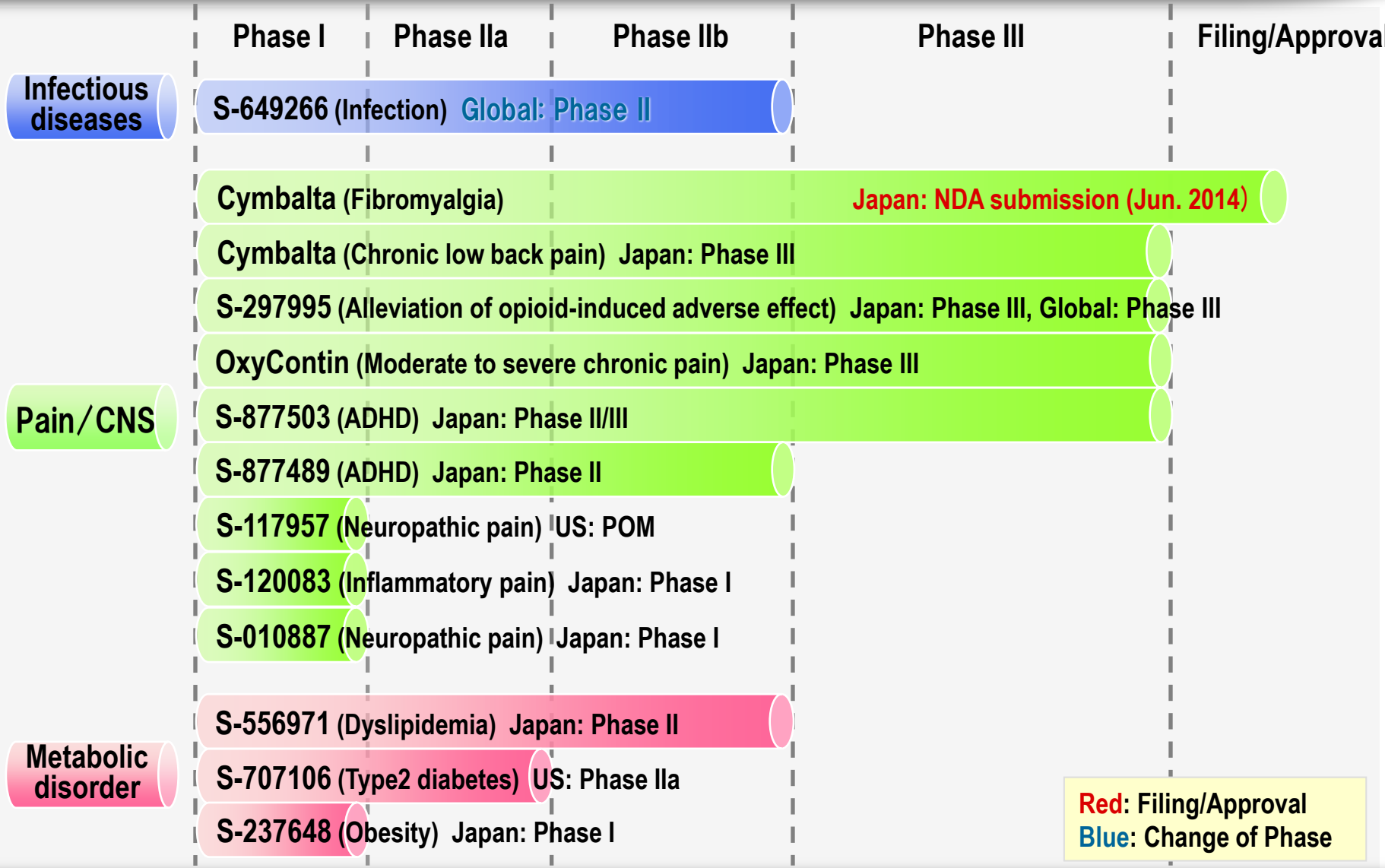
Appendix
- Pipeline -

Change of Phase (since May 2014)

Code No. [Product name]	Category (Administration)	Indication	Change of Phase
S-649266	Cephem antibiotic (Injection)	Infection	US: Phase II, Japan: Phase I ⇒ Global: Phase II
S-525606	Sublingual tablet of Japanese cedar allergen extracts for immunotherapy	Allergic rhinitis caused by Japanese cedar allergen	Japan: Phase I (in preparation) ⇒ Japan: Phase I
Duloxetine hydrochloride [Cymbalta]	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Fibromyalgia	Japan: NDA submission (in preparation) ⇒Japan: NDA submission (Jun. 2014)
Vancomycin hydrochloride [Vancomycin]	Glycopeptide antibiotic (Drip infusion)	Septicemia, Infectious endocarditis, (Superficial) Secondary infections in trauma, Burns, Surgical wounds, etc., Osteomyelitis, Arthritis, Peritonitis, Bacterial meningitis	Japan: NDA submission (Nov. 2013) ⇒ Japan: Approval (May 2014)
		Febrile Neutropenia suspected of MRSA or MRCNS infection	
Interferon gamma-1a [Imunomax®-γ]	Interferon gamma-1a (Genetical recombination) (Injection)	Mycosis fungoides/Sezary syndrome	Japan: NDA submission (Aug. 2013) ⇒ Japan: Approval (May 2014)

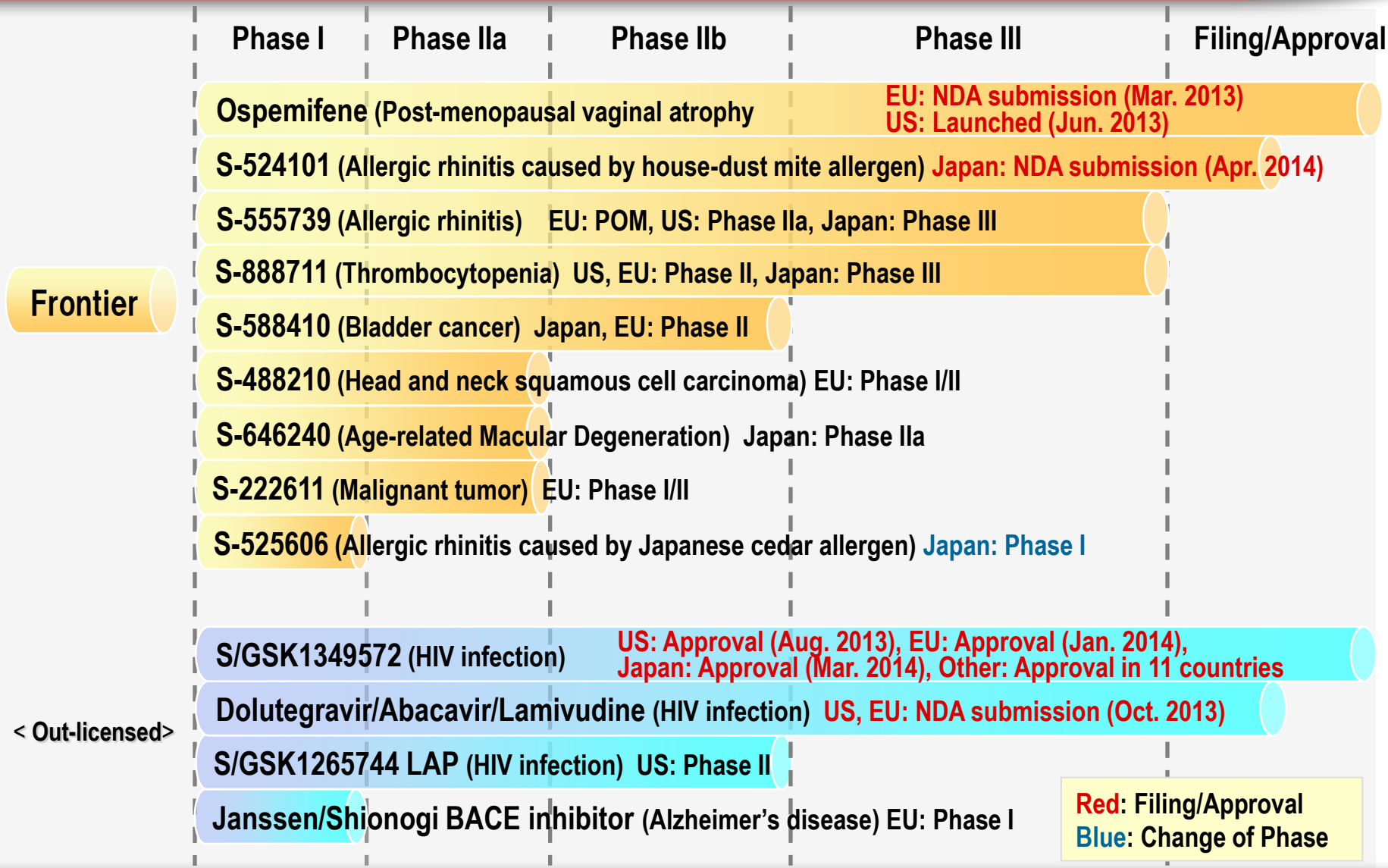
MRCNS: Vancomycin-sensitive Methicillin resistant coagulase negative Staphylococcus

Pipeline (as of August 2014)



ADHD: Attention deficit hyperactivity disorder POM: Proof of mechanism

Pipeline (as of August 2014)



LAP: Long acting parenteral formulation

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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