



**3rd Quarter of Fiscal 2013
Financial Results
Conference Call**

February 3, 2014



Overview of 3rd Quarter FY2013 Financial Results

Financial Results (Consolidated)

(Units: B yen)

	FY2013 forecasts	FY2013 Apr-Dec results	Progress vs. forecasts (%)	FY2012 Apr-Dec results	Y on Y	
					change (%)	change
Sales	284.8	218.1	76.6	211.4	3.1	6.7
Operating income	62.0	50.5	81.5	43.7	15.7	6.8
Ordinary income	61.0	51.7	84.8	42.6	21.4	9.1
Net income	43.0	37.2	86.6	28.3	31.4	8.9

- All income levels from Apr. to Dec. 2013 are 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

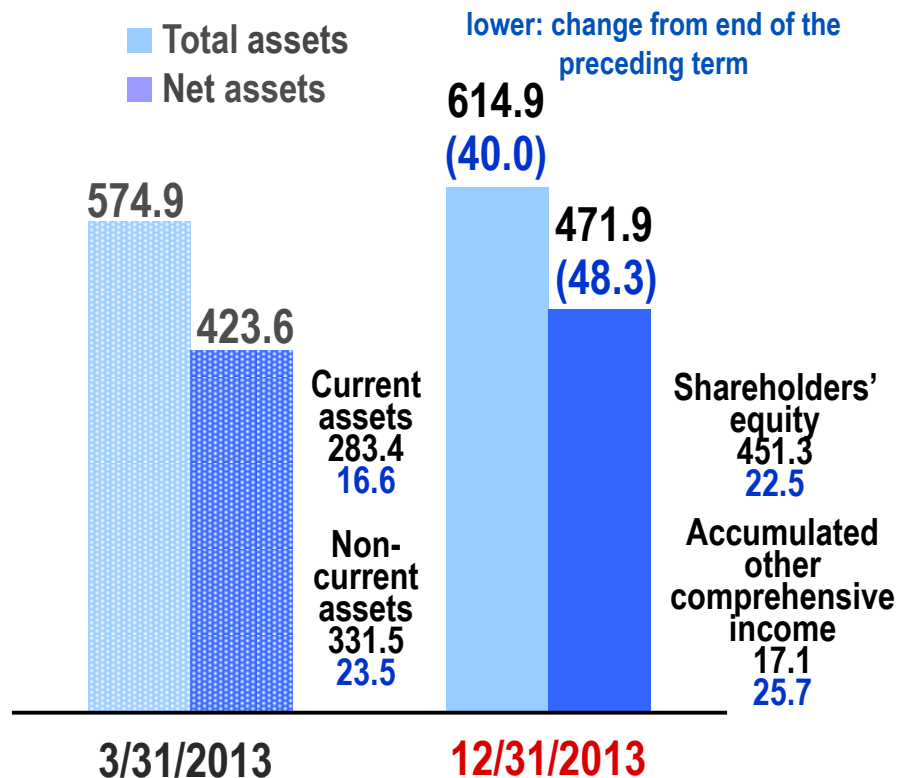
Litigation expenses have been recognized under non-operating expenses since FY2013. We have restated the consolidated statements of income for the prior fiscal year to reflect this change

Exchange rate (average)	FY2013 forecasts	FY2013 Apr-Dec results
USD(\$)	95 yen	99.36 yen
EUR(€)	120 yen	132.17 yen

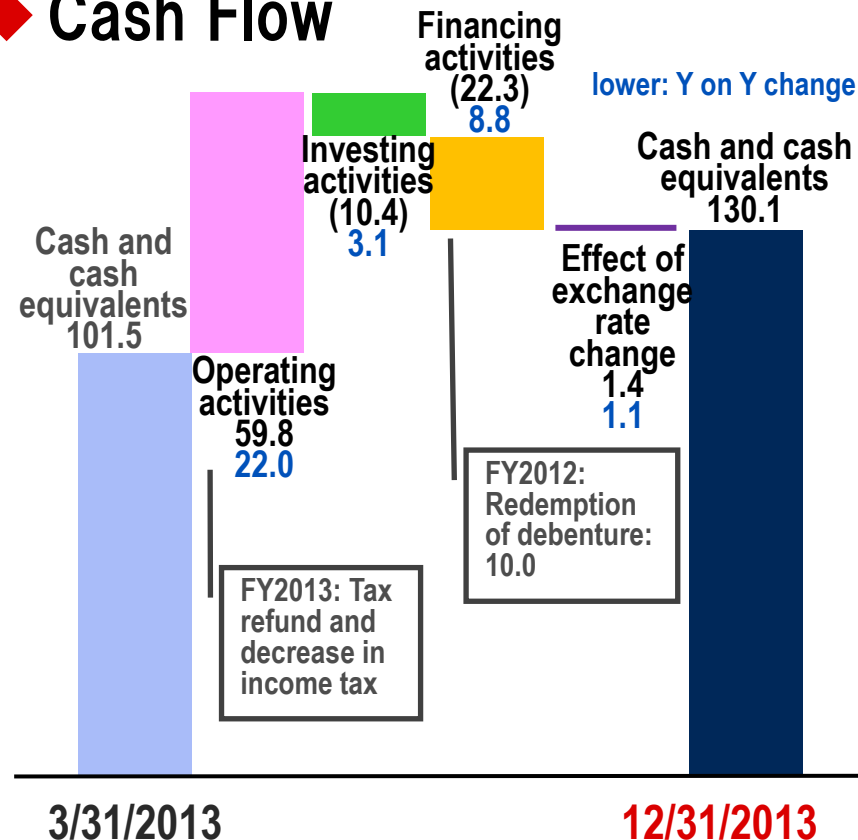
Financial Position and Cash Flow (Consolidated)

(Units: B yen)

◆ Financial Position



◆ Cash Flow



	3/31/2013	12/31/2013
Equity ratio	73.1%	76.2%

Statements of Income (Consolidated)

(Units: B yen)

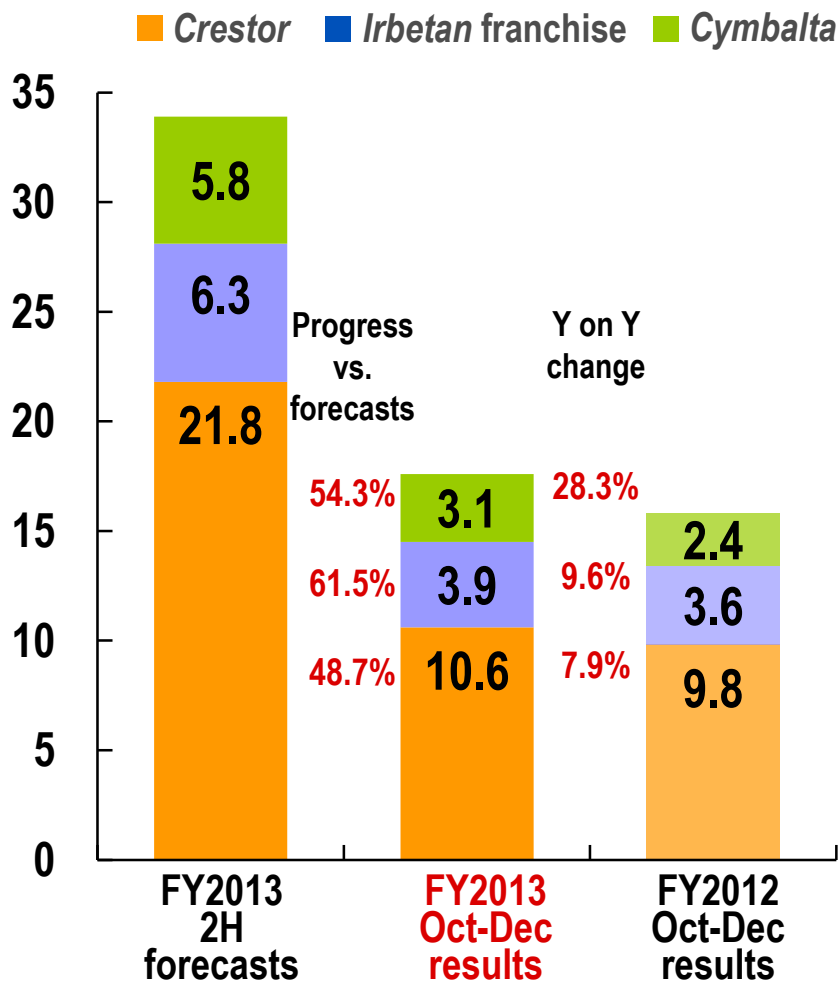
	FY2013		Progress vs. forecasts (%)	FY2012	Y on Y		FY2013	FY2012	Y on Y change (%)
	2H forecasts	Oct-Dec results		Oct-Dec results	change (%)	change	Apr-Dec results	Apr-Dec results	
Prescription drugs	87.5	46.5	53.1	45.2	2.9	1.3	127.4	124.9	2.0
Total of 3 key products	33.9	17.6	52.0	15.8	11.4	1.8	50.1	43.8	14.4
Total of 8 strategic products	48.5	25.1	51.8	22.8	9.8	2.3	69.5	62.6	11.0
Overseas subsidiaries/export	17.7	12.0	67.5	6.6	82.4	5.4	27.3	* 21.4	27.9
Shionogi Inc.	11.2	8.3	74.5	4.2	96.0	4.1	17.9	11.7	52.3
<i>Osphena</i>	5.4	0.4	8.1	-	-	0.4	0.5	-	-
C&O	3.1	1.3	43.0	1.3	2.7	0.0	4.2	4.2	0.4
Contract manufacturing	3.7	0.8	21.0	1.3	(41.8)	(0.5)	5.8	5.8	(0.0)
OTC and quasi-drugs	2.4	1.1	46.2	1.2	(8.3)	(0.1)	3.4	4.0	(14.4)
Diagnostics	1.1	0.5	43.5	0.5	(6.8)	(0.0)	1.3	1.6	(21.5)
Royalty income	32.6	18.1	55.5	18.8	(3.6)	(0.7)	51.5	52.2	(1.3)
<i>Crestor</i>	31.8	16.7	52.4	15.7	6.0	1.0	47.9	46.4	3.1
Others	1.1	0.5	43.6	0.6	(13.8)	(0.1)	1.4	1.6	(12.4)
Total	146.1	79.4	54.3	74.1	7.1	5.3	218.1	211.4	3.1

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

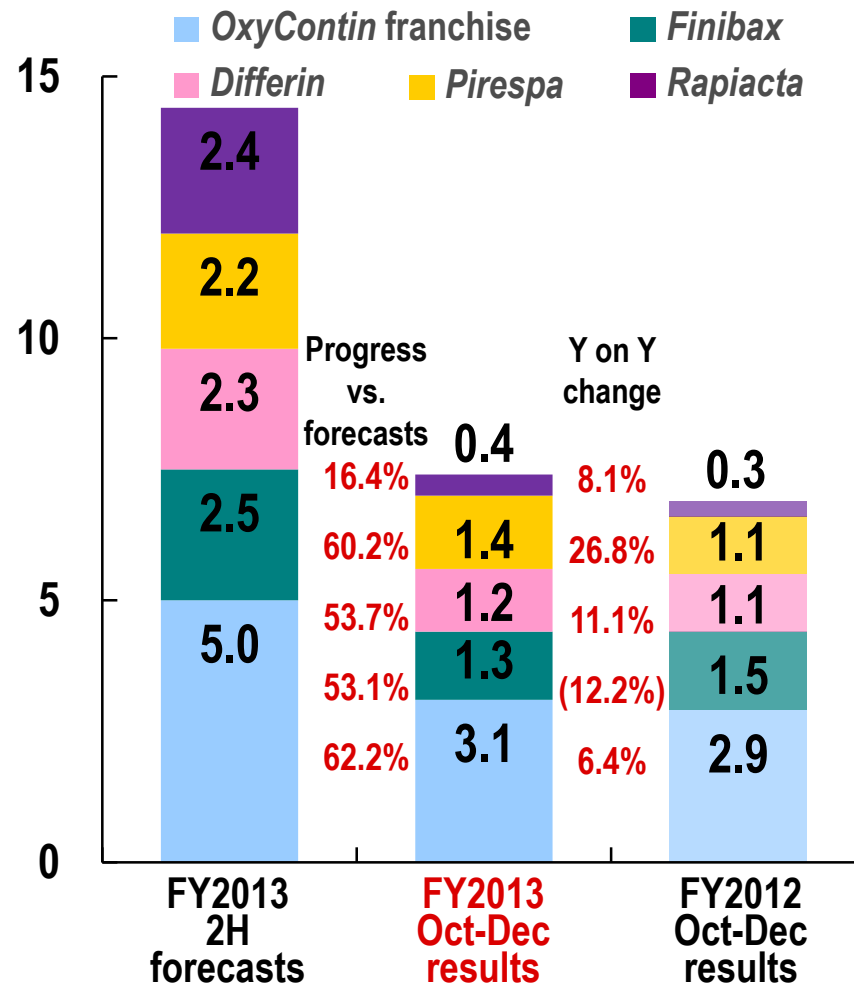
Japan: Sales of 8 Strategic Products (Oct-Dec)

(Units: B yen)

◆ 3 Key Products



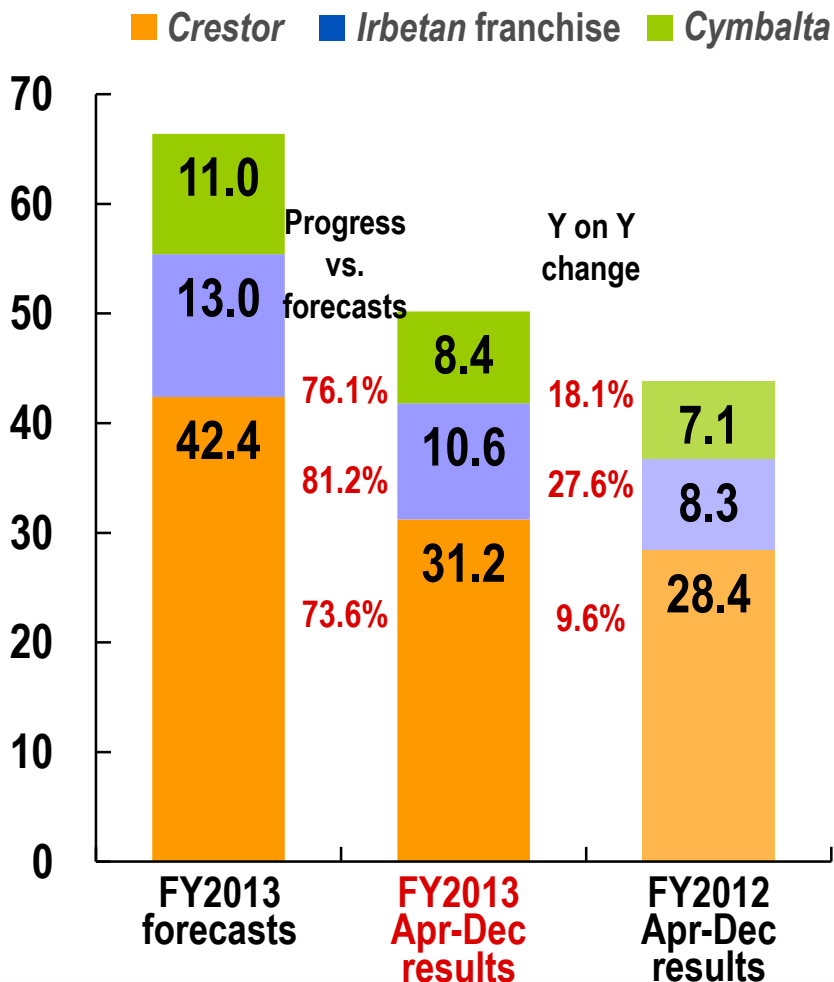
◆ 5 Strategic Products



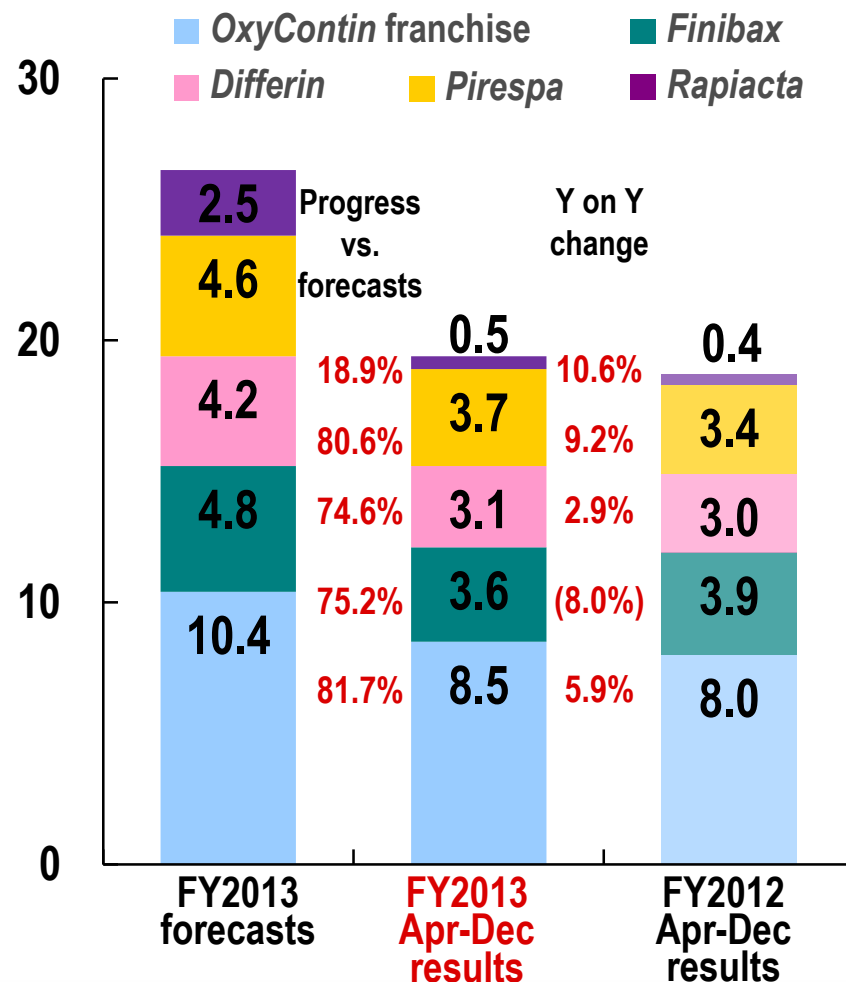
Japan: Sales of 8 Strategic Products (Apr-Dec)

(Units: B yen)

◆ 3 Key Products



◆ 5 Strategic Products



Statement of Income (Consolidated)

(Units: B yen)

	FY2013		Progress vs. forecasts (%)	FY2012	Y on Y		FY2013	FY2012	Y on Y change (%)
	2H forecasts	Oct-Dec results		Oct-Dec results	change (%)	change	Apr-Dec results	Apr-Dec results	
Sales	146.1	79.4	54.3	74.1	7.1	5.3	218.1	211.4	3.1
[Royalty income]	32.6	18.1	55.5	18.8	(3.6)	(0.7)	51.5	52.2	(1.3)
	27.8 (35.7)	25.4 (32.9)		26.4 (35.4)			26.3 (34.5)	28.3 (37.6)	
Cost of sales	40.6	20.2	49.8	19.6	3.0	0.6	57.4	59.8	(4.0)
Gross profit	105.5	59.2	56.1	54.5	8.6	4.7	160.7	151.6	6.0
SG&A expenses	49.3 72.0	46.8 37.1	51.6	50.3 37.3	(0.3)	(0.2)	50.5 110.1	51.1 107.9	2.0
Selling & general expenses	44.6	24.8	55.6	22.6	9.9	2.2	72.2	68.3	5.8
R&D expenses	27.4	12.4	45.1	14.7	(15.9)	(2.3)	38.0	39.7	(4.4)
Operating income	23.0 33.5	27.8 22.1	65.8	23.3 17.3	27.8	4.8	23.2 50.5	20.7 43.7	15.7
[Excluding royalty income]	0.9	4.0	-	(1.5)	-	5.5	(1.0)	(8.5)	-

Review of 3rd Quarter FY2013

◆ Overseas Business (Shionogi Inc.)

- Divested *Naprelan* and focused resources in Women's Health area
- Promotion of *Osphena* is proceeding smoothly
 - Increase in awareness and interest amongst healthcare providers
 - Re-allocated and refined approach of sales professionals
 - Data on Rx refill frequency is encouraging (currently about 40% per TRx*)
 - Started multimedia direct to consumer campaign, including print (magazine), digital, and television (commercial started in January)
 - Increase consumer awareness and encourage them to speak with their physicians

◆ Japanese Domestic Sales

- Increased Operating Income over 3Q FY2012 because sales of eight strategic products were up 9.8% Y on Y
- Direct to consumer education for pain caused by depression, acne and influenza, and promotion of newly launched *Irtra* as a high-priority

Modification of the *Crestor* Royalty Structure

◆ Changes in the License Agreement

- Reduction of the effective royalty rate in 2014-2016 by a low single-digit number
- Extension of the period of royalty payments from 2016 to 2023
- Provision of guaranteed defined minimum annual royalties from 2014 until 2020 in the low hundreds of millions of dollars per year
- Settlement of arbitration proceedings related to the treatment of certain excise taxes and other specific items in the calculation of royalties on *Crestor* sales

◆ Business Perspective

- Maintain stable profit foundation to support medium to long-term growth
 - Leveling *Crestor* cliff and avoid sharp decline in corporate performance
 - Shionogi is expected to enter continuous growth phase with key future drivers including expanding profit from the integrase inhibitor franchise and increasing sales of *Osphena*, and the approval and launch of current late phase pipeline compounds

Alliance Activities for Medium to Long-term Growth

◆ Overseas Business

- Development collaboration and license agreement with Egalet for abuse-deterrent oral hydrocodone opioid product
 - Strengthen our R&D pipeline in pain area
 - Synergy with S-297995 which is in Phase III globally
- Co-promotion agreement with Noven for *Brisdelle* capsules for the treatment of moderate to severe hot flashes associated with menopause
 - Healthcare providers with interest in *Brisdelle* are synergistically aligned to those interested in *Osphena*
 - Expand portfolio of non-hormonal oral treatments for menopause-related conditions and strengthen presence in Women's Health area

◆ Japanese Business

- License agreement with Mundipharma for *OxyContin* franchise
 - Expand our R&D pipeline with additional indication of *OxyContin* to the treatment of non-cancer pain
- Co-promotion agreement with ViiV for dolutegravir
 - Fully utilize the strengths of Shionogi and ViiV in the infectious disease area, maximizing the potential of dolutegravir, and benefiting from the HIV experience of ViiV

Pipeline

Summary of Late-phase Compounds

◆ S-555739

- Indication: Allergic rhinitis
- Completed Phase III in Japan
- Statistically significant difference between S-555739/AH and AH were observed in some symptom scores and some measures of QOL, but not in nasal symptom score, primary endpoint
- Review to further select target patients

◆ S-524101

- Indication: Allergic rhinitis caused by house-dust mite allergen
- Completed Phase II/III in Japan
- Statistical significance versus placebo was achieved for the primary endpoint, average adjusted symptom score for one year treatment. There were no significant safety concerns
- Schedule: NDA submission in 1H FY2014

New Chemical Entities

- ◆ **S-588410: Initiate Phase II (POC) in Japan/EU**
 - Indication: Bladder cancer
 - Combined with S-288310 and S-488410
 - Expect to improve efficacy and expand indication

- ◆ **S-237648: Initiate Phase I in Japan**
 - Indication: Obesity
 - Mechanism: Neuropeptide Y Y5 receptor antagonist
 - Planned for global development
 - Good efficacy and safety in preclinical studies

- ◆ **S-010887: Initiate Phase I in Japan**
 - Indication: Neuropathic pain
 - Planned for global development
 - In-house discovered compound with a novel mechanism for the treatment of pain

Dolutegravir (*Tivicay*)

◆ US: HHS Guidelines

- US HHS panel recommended both *Tivicay* plus *Epzicom* and *Tivicay* plus *Truvada* as preferred regimens for ART-naive patients
- NDA/MAA submissions of a STR combining *Tivicay/Epzicom* in US/EU in Oct. 2013

◆ Canada and EU

- Approved by Health Canada in Oct. 2013
- Received positive CHMP opinions in EU in Nov. 2013
⇒ Approved in Jan. 2014

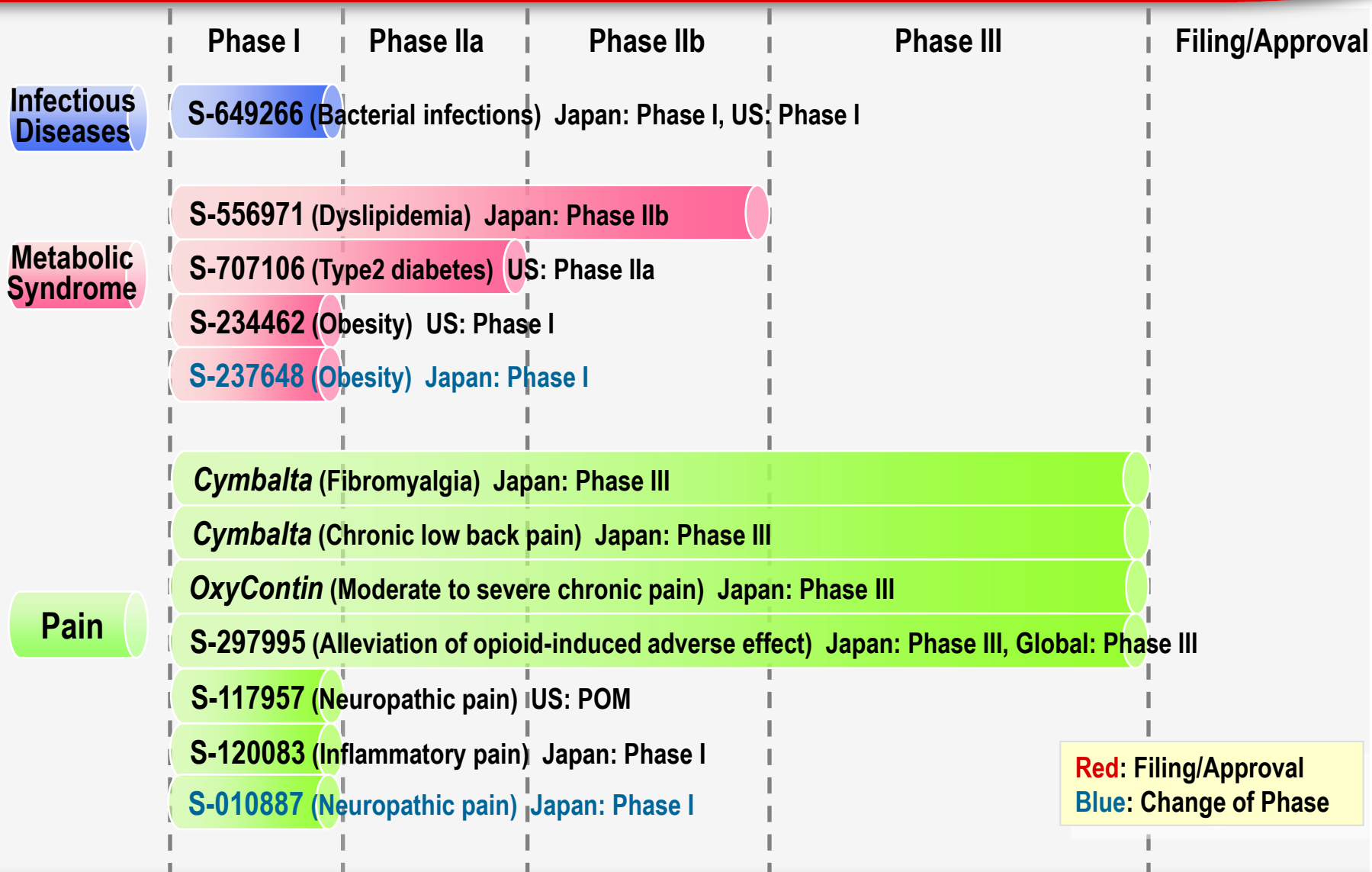
◆ Japan

- NDA submission in Dec. 2013 as orphan drug
- ViiV and Shionogi entered into a co-promotion agreement for dolutegravir

Change of Phase (since October 2013)

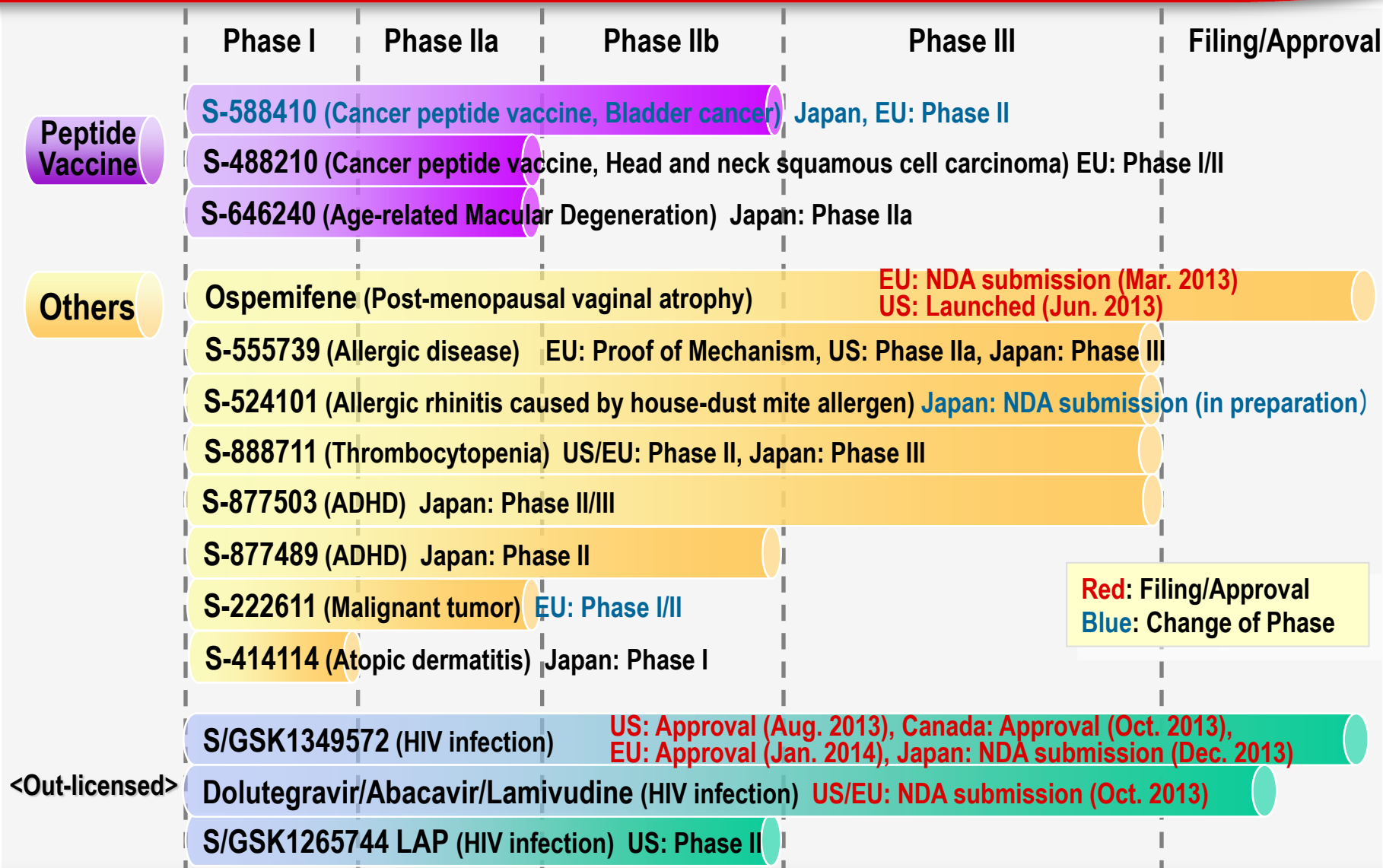
Code No. (Generic name) 【Product name】	Category (Administration)	Indication	Change of Phase
S-237648	Neuropeptide Y Y5 receptor antagonist (Oral)	Obesity	Japan: Phase I
S-010887	Analgesic agent for neuropathic pain (Oral)	Neuropathic pain	Japan: Phase I
S-524101	Sublingual tablet of house-dust mite allergen extracts for immunotherapy	Allergic rhinitis caused by house-dust mite allergen	Japan: Phase II/III ⇒NDA submission (in preparation)
S-588410	Cancer peptide vaccine (Injection)	Bladder cancer	Japan, Europe: Phase II (Combined with S-288310 and S-488410)
S-222611	HER2/EGFR dual inhibitor (Oral)	Malignant tumor	Europe: Phase Ib ⇒Phase I/II
S/GSK1349572 (Dolutegravir)	Integrase inhibitor (Oral)	HIV infection	Global: NDA submission (Dec. 2012) US: Approval (Aug. 2013) ⇒Canada: Approval (Oct. 2013) Europe: Approval (Jan. 2014) Japan: NDA submission (Dec. 2013)
Vancomycin hydrochloride 【Vancomycin】	Glycopeptide antibiotic (Drip infusion)	<Spectrum> MRCNS <Indication> Septicemia, Infectious endocarditis, (Superficial) Secondary infections in trauma, Burns, Surgical wounds, etc., Osteomyelitis, Arthritis, Peritonitis, Bacterial meningitis	Japan: NDA submission (in preparation) ⇒NDA submission (Nov. 2013)
		Febrile Neutropenia suspected to be MRSA or MRCNS infection	

Pipeline (as of February 2013)



Red: Filing/Approval
Blue: Change of Phase

Pipeline (as of February 2013)



Forward-Looking Statements



- This presentation contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements.
- Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products.
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