1st Quarter of Fiscal 2013 Financial Results

Conference Call

August 2, 2013

SHIONOGI & CO., LTD.

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.
- The company 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 contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.

Overview of 1st Quarter FY2013 Financial Results

Financial Results (Consolidated)

(Units: B yen)

	FY2013 forecasts	FY2013 1H forecasts	FY2013 Apr-Jun results	Progress vs. forecasts (%)	FY2012 Apr-Jun results	Y on Y change (%)	Y on Y change
Sales	287.0	138.0	67.3	48.7	67.8	(0.8)	(0.5)
Operating income	60.0	24.0	12.2	50.7	12.4	(1.7)	(0.2)
Ordinary income	59.0	24.0	12.6	52.6	12.1	4.6	0.5
Net income	37.0	14.5	10.8	74.8	6.9	56.9	3.9

- Ordinary income and net income from April to June 2013 are higher than the levels achieved in the first quarter of any prior fiscal year.

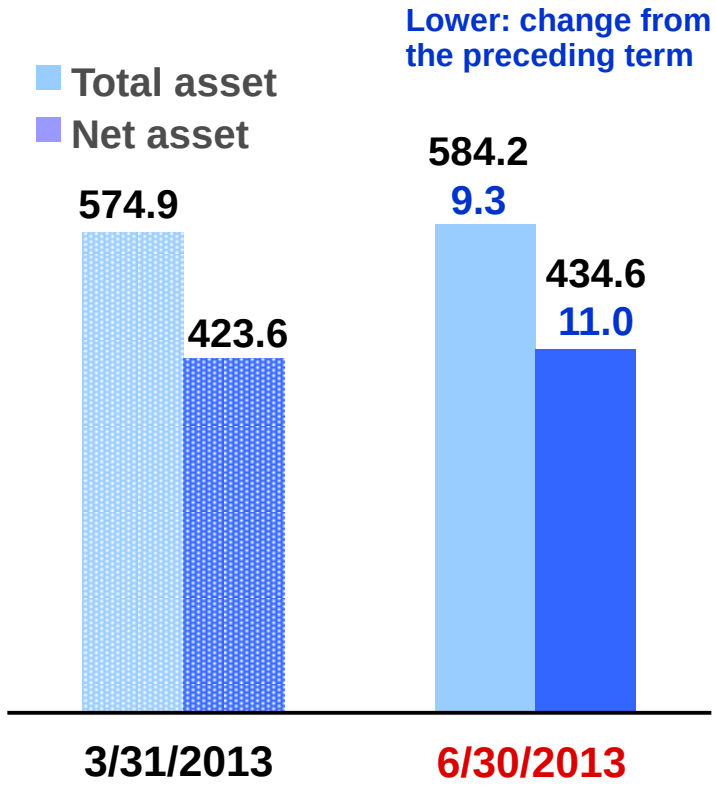
Note: All numerical values are rounded to the nearest unit.

Exchange rate (average)	FY2013 forecasts	Apr-Jun results
USD ($) – JPY (¥)	95	98.79
EUR (€) – JPY (¥)	120	128.97

Financial Position and Cash Flow (Consolidated)

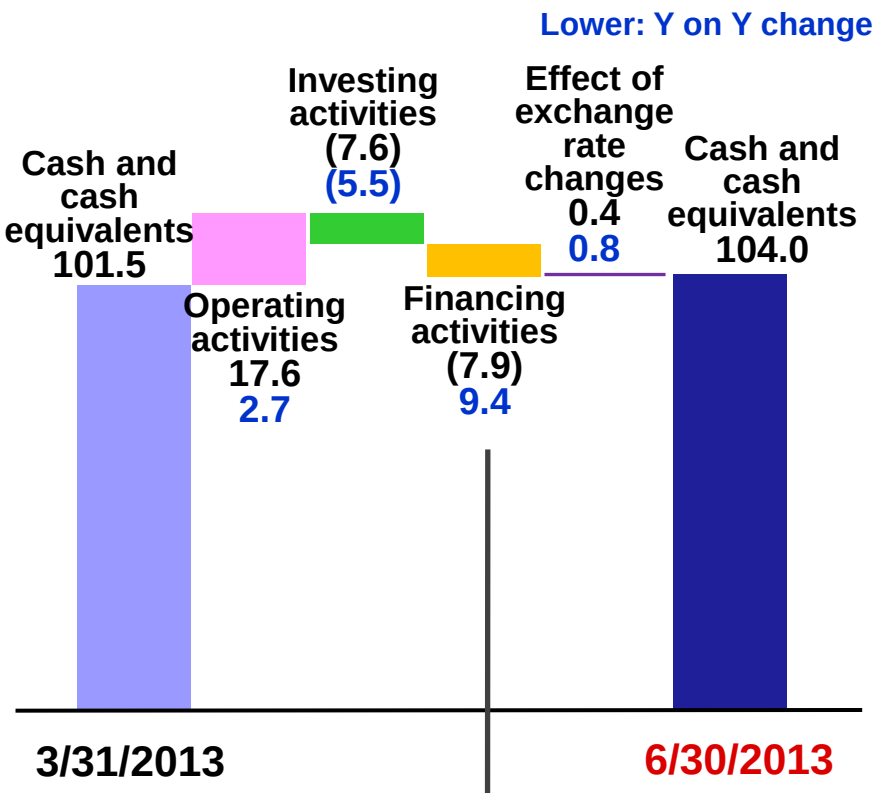
(Units: B yen)

Financial Position



	3/31/2013	6/30/2013
Equity ratio	73.1%	73.7%

Cash Flow



FY2012:
Redemption of debenture: 10.0

Breakdown of Sales (Consolidated)

(Units: B yen)

	FY2013		Progress vs. forecasts (%)	FY2012 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Prescription drugs	83.1	40.4	48.7	39.7	1.9	0.7
Total of 3 key products	32.5	15.5	47.6	13.1	18.4	2.4
Total of 8 strategic products	45.0	21.6	48.0	18.9	14.4	2.7
Overseas subsidiaries/export	14.4	8.4	58.0	* 7.4	13.3	1.0
Shionogi Inc.	9.0	5.4	59.6	3.5	53.0	1.9
Osphena™	0.8	-	-	-	-	-
C&O	2.9	1.3	44.3	1.5	(14.2)	(0.2)
Contract manufacturing	5.2	2.4	45.7	2.3	1.4	0.1
OTC and quasi-drugs	2.7	1.0	36.9	1.3	(25.2)	(0.3)
Diagnostics	0.6	0.4	74.3	0.6	(22.6)	(0.2)
Royalty income	31.0	14.0	45.3	16.0	(12.5)	(2.0)
Crestor	29.5	13.1	44.4	14.7	(10.9)	(1.6)
Others	1.0	0.6	60.8	0.5	33.2	0.1
Total	138.0	67.3	48.7	67.8	(0.8)	(0.5)

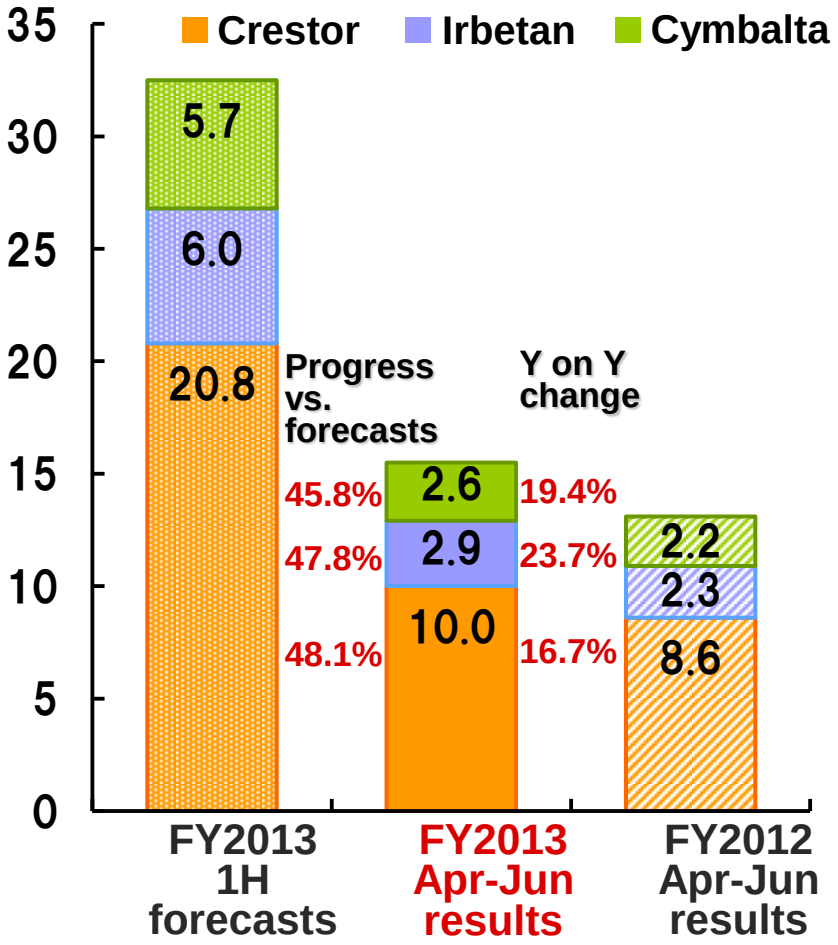
Eight strategic products: Crestor, Irbetan, Cymbalta (3 key products), and OxyContin, Finibax, Differin, Pirespa, Rapiacta

* Taiwan Shionogi has changed its accounting period since Jan 2012, and FY2012 Apr-Jun results include 6 months from Jan 2012 to Jun 2012.

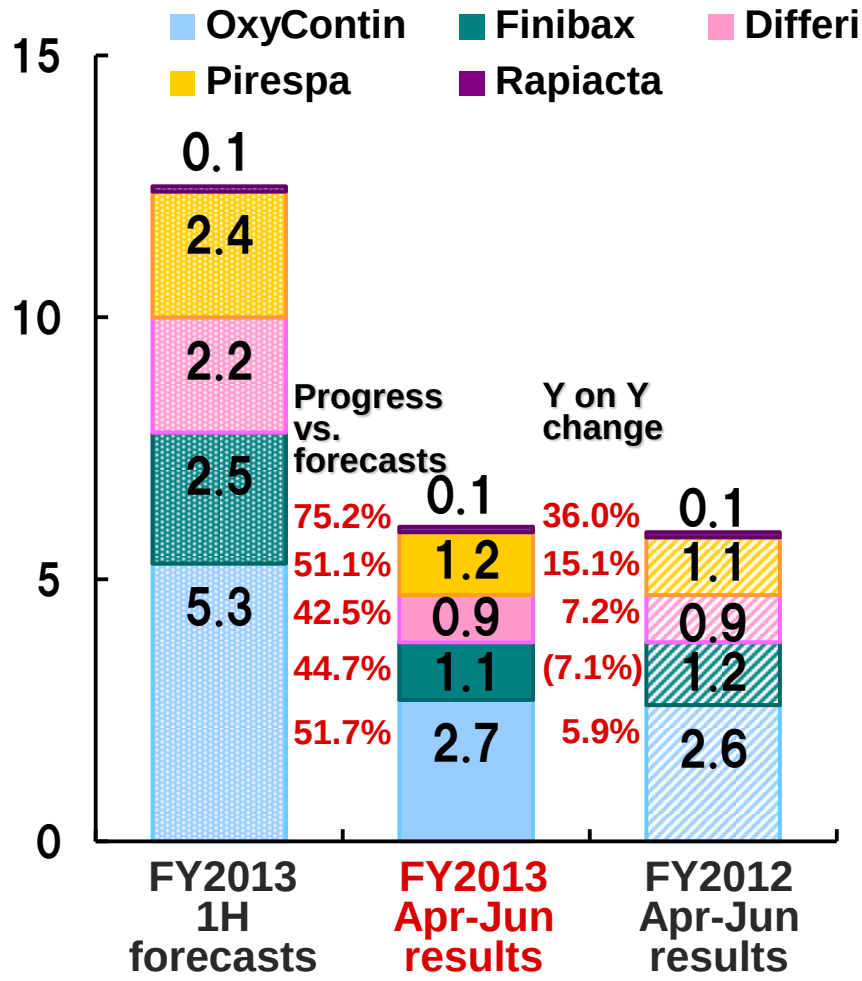
Domestic: Sales of 8 Strategic Products (Apr-Jun)

(Units: B yen)

◆ 3 Key Products



◆ 5 Strategic Products



Statements of Income (Consolidated)

(Units: B yen)

	FY2013		Progress vs. forecasts (%)	FY2012 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			change (%)	change
Sales	138.0	67.3	48.7	67.8	(0.8)	(0.5)
[Royalty income]	31.0	14.0	45.3	16.0	(12.5)	(2.0)
Cost of sales	28.3 (36.4) 39.0	27.3 (34.5) 18.4	47.1	30.3 (39.7) 20.6	(10.8)	(2.2)
Gross profit	99.0	48.9	49.4	47.2	3.5	1.7
SG&A expenses	54.3 75.0	54.6 36.8	49.0	51.4 34.9	5.4	1.9
Selling & general expenses	48.0	23.6	49.2	23.1	2.2	0.5
R&D expenses	27.0	13.1	48.6	11.8	11.6	1.3
Operating income	17.4 24.0	18.1 12.2	50.7	18.2 12.4	(1.7)	(0.2)

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

Overseas Business (Shionogi Inc.)

- **Divestiture and exclusive licensing of pediatric products**
  - Three pediatric products including Kapvay™
  - Decrease of SG&A and amortization costs related to the products ⇒ Focus resources on Osphena™ and Naprelan®
- **Launch of Osphena™**
  - Started full-scale promotion since June 3, 2013
  - Promotional activities are on track, including the investment in Osphena™
  - Enhancing awareness of Osphena™ centered on OB-GYN physicians, and NRx/TRx are increasing
- **Doripenem marketing rights returned from Janssen***
  - Janssen has returned its rights to doripenem to Shionogi at the end of June 2013
  - Shionogi now has global rights for doripenem
  - Shionogi Inc. now distributes DORIBAX® in the US

* Janssen Pharmaceuticals, Inc.

Pipeline

Accomplishments in 1st Quarter FY2013

- **Osphena™: Launched in the US**
  - Indication: Moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy (VVA), due to menopause
  - Started full-scale promotion in June 2013
- **Metreleptin: NHI price listing and launch in Japan**
  - NHI price listing: May 24, 2013 (Launch: July 25, 2013)
  - Indication: Lipodystrophy (orphan drug)
  - Product name: METRELEPTIN for subcutaneous injection 11.25 mg 'SHIONOGI'
- **S-474474: Approved in Japan**
  - Approval: June 28, 2013
  - Indication: Hypertension
  - Product name: IRTRA® Combination Tablets LD/HD
  - Combination of ARB IRBETAN® and diuretic trichlormethiazide FLUITRAN®
  - Expanding our product lineup for anti-hypertension with AIMIX® Combination tablets LD/HD, combination of irbesartan and calcium antagonist amlodipine besilate

High-priority Compounds in 1st Quarter FY2013

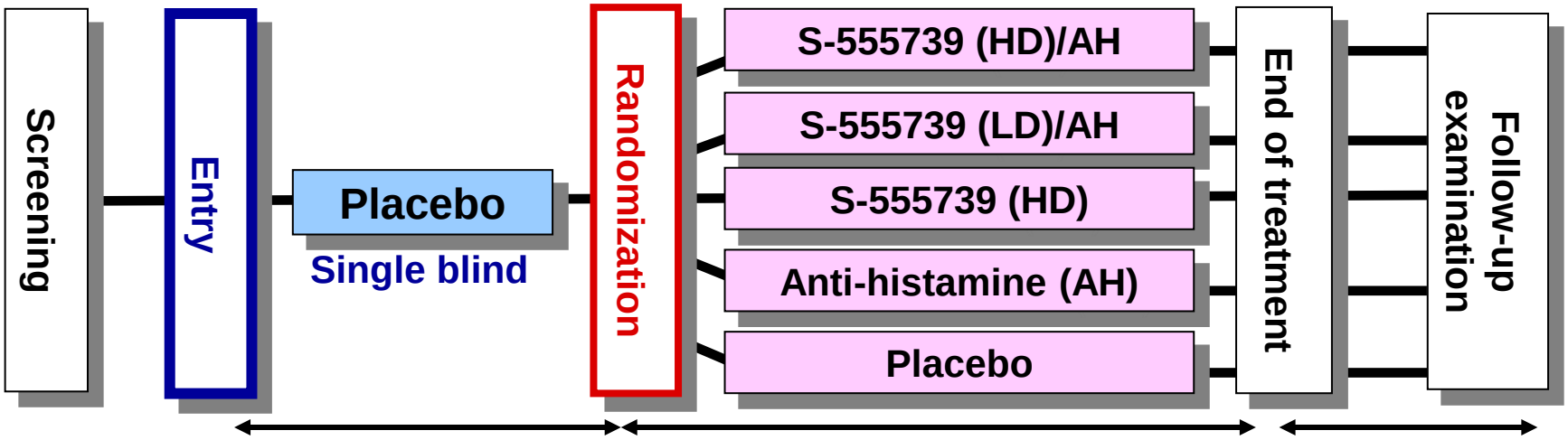
- S-297995: Initiated Global Phase III
- S-555739: Initiated Japanese Phase III for allergic rhinitis
- S-888711: Japanese Phase III in preparation
- S-556971: Suspended initiation of Japanese Phase III, and will assess formulation
- S-2367: Suspended the development of S-2367, and switched to a follow-up compound

S-297995 (Naldemedine): Global Phase III Program

◆ Condition: Opioid Induced Constipation

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-555739: Phase III Study in Japan - Flash Results



- **Conducted in seasonal allergic rhinitis patients in Spring 2013**
  - Statistically significant difference between S-555739/AH and AH were not observed in the total nasal symptom score (primary endpoint) but were observed in the total of nasal and ocular symptom scores
  - One of the main explanations for these results is that the drastic reduction in pollen levels after patient entry with resultant large improvement in scores in all treatment groups.
  - A planned Phase III study in Fall 2013 will be conducted in perennial allergic rhinitis, where allergen exposure is more stable

S-888711 (Lusutrombopag): Phase IIb Study in Japan - Flash Results

Synopsis

- To evaluate the efficacy, safety, and pharmacokinetics after 7-day multiple dose administration, and to define the optimal dose of S-888711
- Doses: 2.0, 3.0, 4.0 mg and placebo QD, PO
- Endpoints
  - Platelet count and the frequency of platelet transfusions
  - Adverse events and side effects

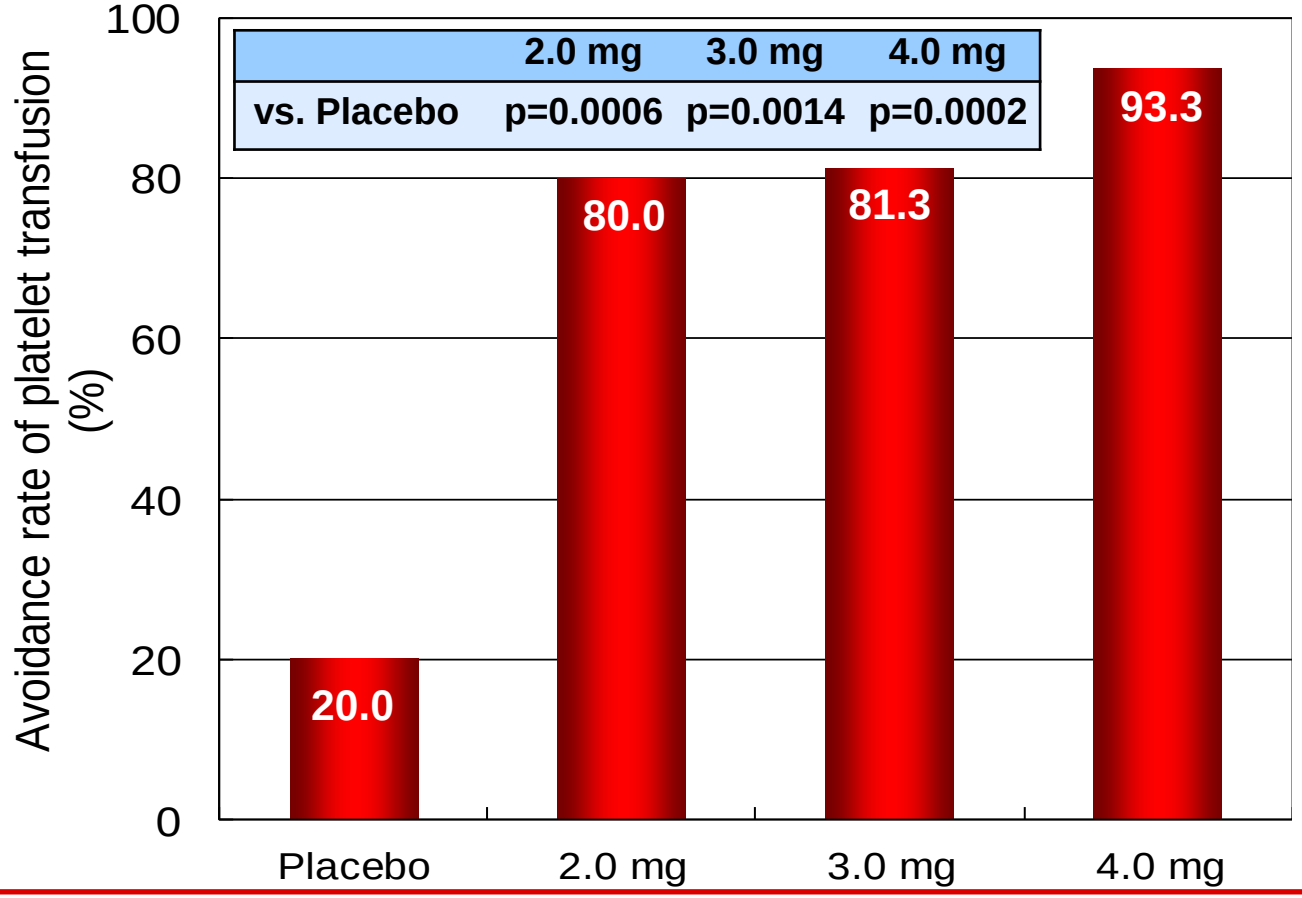
Results

- The rate of avoidance of platelet transfusion was equal to or greater than 80% in the S-888711 groups, significantly higher than in the placebo group ($p<0.01$).
- Dose-proportional adverse events or side effects were not observed.
- Four thrombotic events, in four patients, were observed upon proactive CT/MRI assessment of portal vein system; they were all transient. As each event may have resulted from the invasive procedures, further investigation of the risk is needed.

Upcoming events

- Initiate Phase III confirmatory study in FY2013

S-888711: Primary Endpoint: Avoidance Rate of Platelet Transfusion



S-888711 can be a new alternative to platelet transfusion before elective invasive procedures

Progress of Late-phase Compounds

S-556971

- Phase IIb study in patient with dyslipidemia in Japan was conducted
- In the primary efficacy endpoint, every dosage was superior to placebo
- develop its formulation to maximize the efficacy

S-2367 (Velneperit)

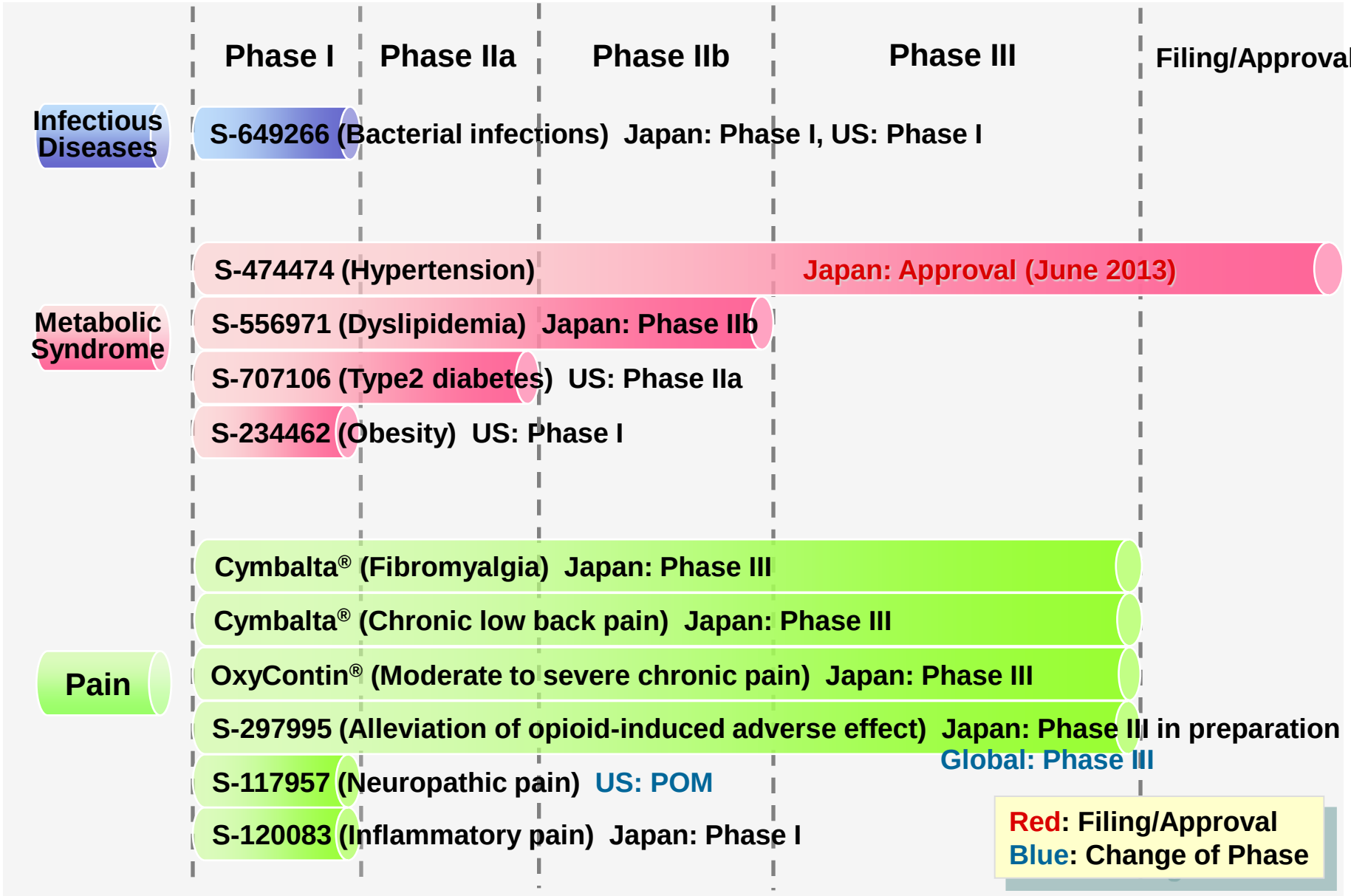
- Phase IIb study in patients with obesity with diabetes was conducted
- The development of S-2367 in Japan was suspended as result of the balance of interference in HbA1C and the efficacy
- Focus on the development of follow-up compound

Change of Phase (since May 2013)

Code No. (Generic name) 【Product name】	Category (Administration)	Indication	Change of Phase
S-474474 【IRTRA® 】	Angiotensin receptor antagonist/diuretic combination (Oral)	Hypertension	Japan: NDA submission (Jul. 2012) ⇒Approval (Jun. 2013)
S-297995 (Naldemedine)	Peripheral opioid receptor antagonist (Oral)	Alleviation of opioid-induced adverse effect	Global: Phase III in preparation ⇒Phase III
S-117957	Analgesic agent for neuropathic pain (Oral)	Neuropathic pain	USA: Phase I ⇒POM
S-888711 (Lusutrombopag)	Small molecule TPO mimetic (Oral)	Thrombocytopenia	Japan: Phase IIb ⇒Phase III in preparation
S-414114	NF-κB decoy oligodeoxynucleotide (Topical)	Atopic dermatitis	Japan: Phase I in preparation ⇒Phase I

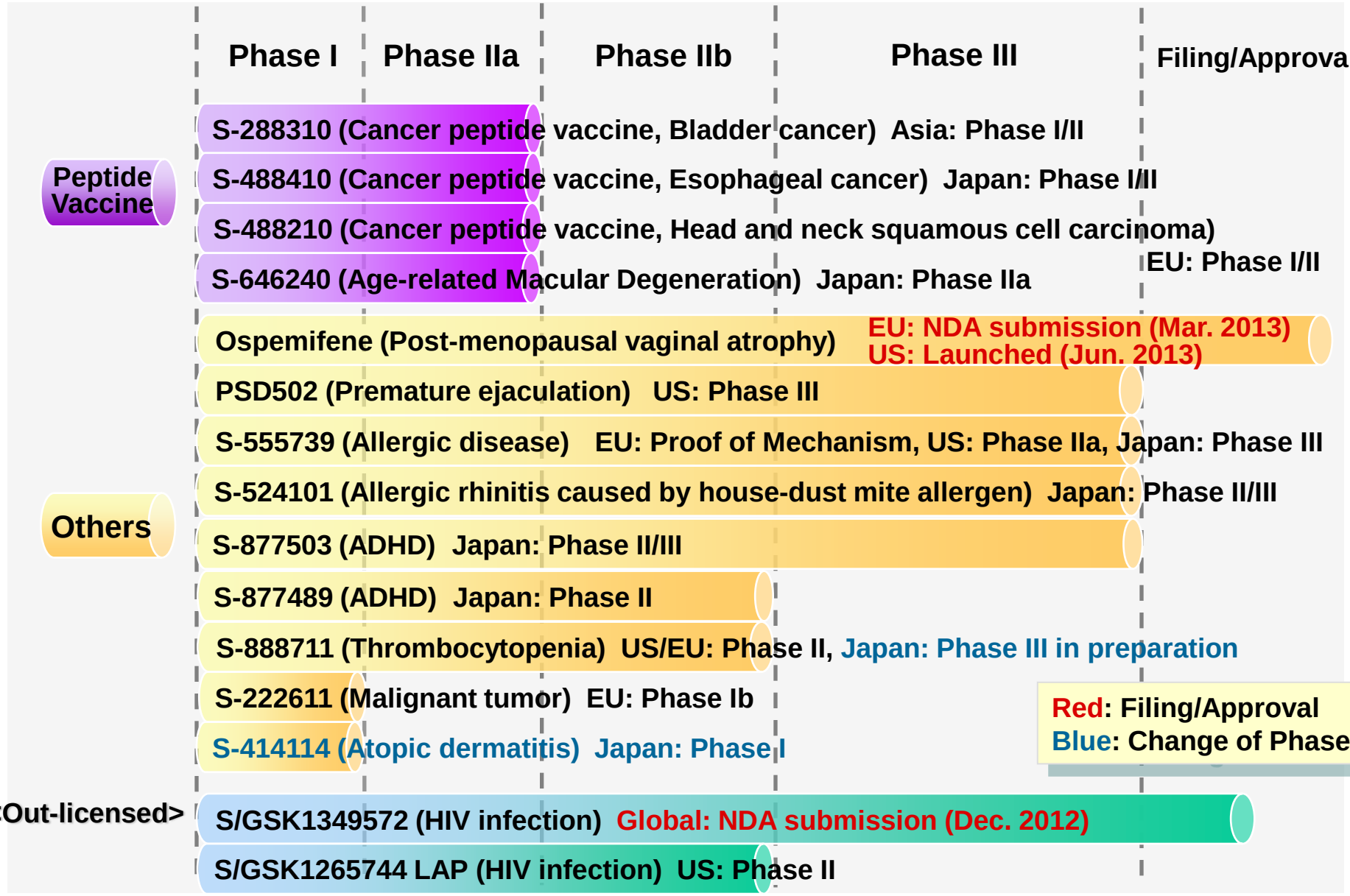
POM: Proof of mechanism
TPO: Thrombopoietin

Pipeline (as of August 2013)



POM: Proof of mechanism

Pipeline (as of August 2013)



ADHD: Attention deficit hyperactivity disorder
LAP: Long acting parenteral formulation

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