S-O-N-G
for you!

1st Half of Fiscal 2014 Financial Results

October 30, 2014

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President and CEO

SHIONOGI

Overview of 1st Half FY2014 Financial Results

Summary of 1H FY2014

Sales on track

Operating income and ordinary income higher than 1H forecasts

- Ordinary income: higher than the levels achieved in the 1H of any prior fiscal year (third straight year)

Net income exceeded 1H forecast, excluding an allowance recorded as prior period income taxes

Accelerating global development of high-priority compounds through clear priorities and focused resourcing (S-297995, S-888711, S-649266, etc.)

Financial Results (Consolidated)

(Units: B yen)

	FY2014 forecasts	FY2014 1H forecasts*	FY2014 1H results	Achievement (%)	FY2013 1H results	Y on Y change (%)	Y on Y change
Sales	269.0	130.0	129.8	99.9	138.7	(6.4)	(8.9)
Operating income	45.0	18.5	22.7	122.8	27.9	(18.7)	(5.2)
Ordinary income	50.0	24.0	31.4	130.9	27.3	15.0	4.1
Net income	33.0	16.0	9.7	60.7	21.1	(53.9)	(11.4)
Net income	-	-	**23.5	-	21.1	-	-

- **Ordinary income level from Apr. to Sep. 2014 is higher than the levels achieved in the 1H of any prior fiscal year (third straight 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 1H results
USD ($) – JPY (¥)	100	103.01
EUR (€) – JPY (¥)	140	138.90
GBP (£) – JPY (¥)	165	172.73

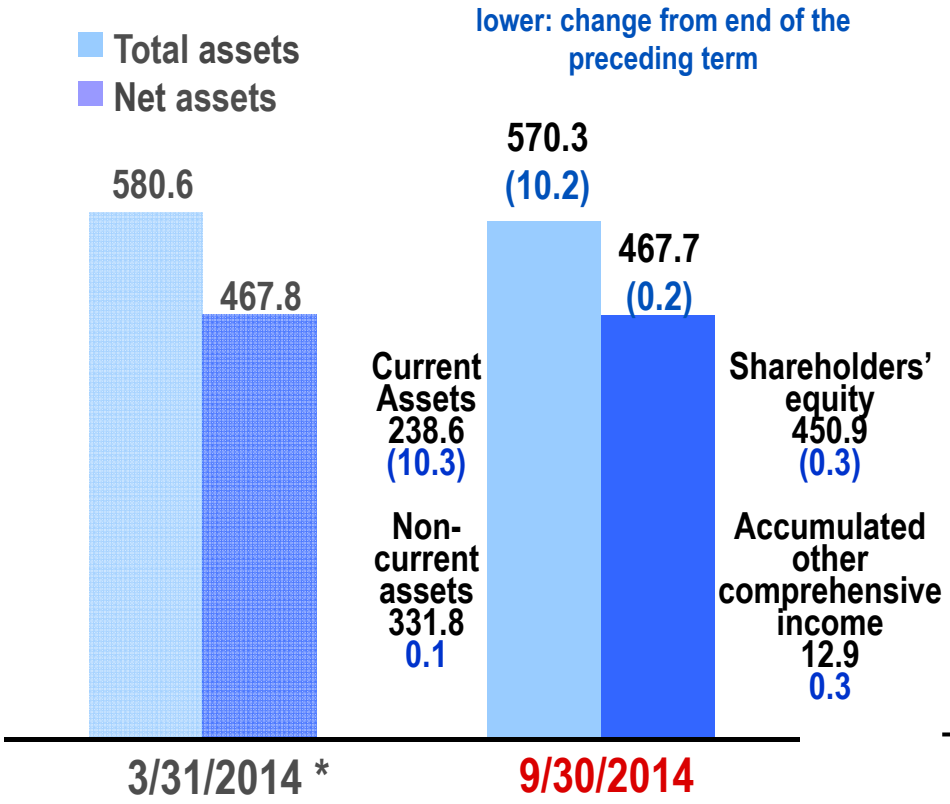
SHIONOGI

* The consolidated earnings forecasts announced on May 9, 2014 were written here, and the revisions to the forecasts were announced on Oct. 20, 2014
** Hypothetical net income excluding the additional allowance recorded as prior period income taxes

Financial Position and Cash Flow (Consolidated)

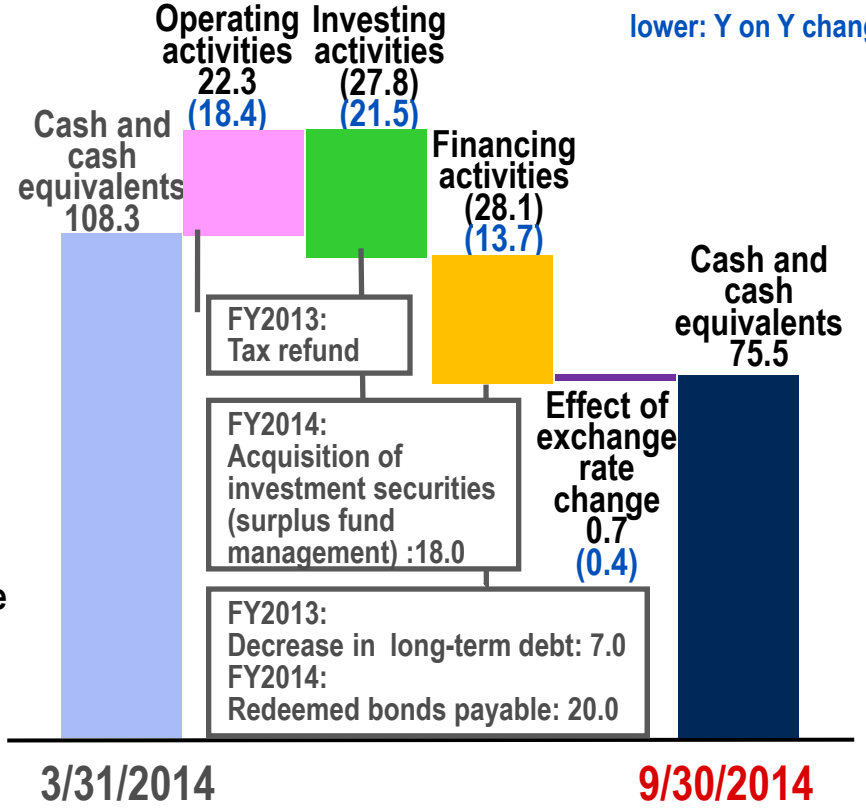
(Units: B yen)

Financial Position



	3/31/2014 *	9/30/2014
Equity ratio	79.9%	81.3%

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 Revenue (Consolidated)

(Units: B yen)

	FY2014		Achievement (%)	FY2013 1H results	Y on Y	
	1H forecasts	1H results			change (%)	change
Prescription drugs	80.5	77.0	95.6	80.9	(4.9)	(3.9)
Total of 3 key products	34.5	34.0	98.7	32.5	4.8	1.5
Total of 8 strategic products	47.3	45.7	96.6	44.4	2.9	1.3
Overseas subsidiaries/export	15.0	14.6	97.0	15.4	(5.2)	(0.8)
Shionogi Inc.	7.9	7.4	93.9	9.5	(22.1)	(2.1)
Osphena®	2.5	1.7	67.5	a) 0.1	-	1.6
C&O	3.4	3.3	96.4	2.9	12.8	0.4
Contract manufacturing	4.8	6.1	126.4	5.0	21.1	1.1
OTC and quasi-drugs	2.4	2.5	102.2	2.3	5.7	0.2
Royalty income	26.0	28.3	108.9	33.4	(15.3)	(5.1)
Crestor®	24.2	24.4	100.8	31.2	(21.8)	(6.8)
Others	1.3	1.5	115.1	1.7	(12.9)	(0.2)
Total	**130.0**	**129.8**	**99.9**	**138.7**	**(6.4)**	**(8.9)**

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

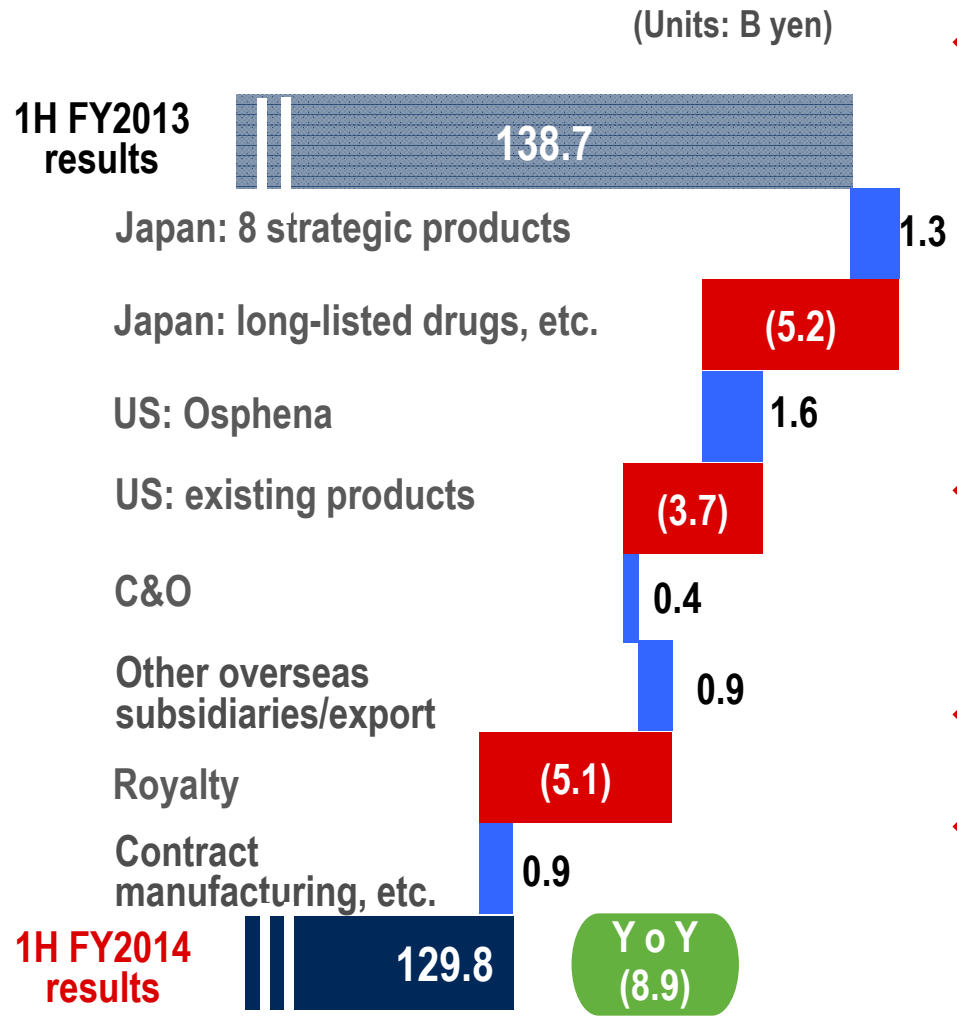
a) Osphena revenue recognition of 1H FY2013 was based on the number of prescriptions

Japan: Sales of 8 Strategic Products

(Units: B yen)

	FY2014		Achievement (%)	FY2013 1H results	Y on Y	
	1H forecasts	1H results			change (%)	change
Prescription drugs	80.5	77.0	95.6	80.9	(4.9)	(3.9)
Crestor	21.0	21.1	100.2	20.6	2.3	0.5
Irbetan franchise	7.3	7.5	103.1	6.7	13.0	0.8
Cymbalta	6.2	5.5	88.2	5.2	4.2	0.3
Total of 3 key products	34.5	34.0	98.7	32.5	4.8	1.5
OxyContin franchise	5.5	5.3	96.0	5.4	(1.7)	(0.1)
Finibax	2.3	1.9	84.0	2.3	(14.8)	(0.4)
Differin	2.1	1.8	85.5	1.9	(5.4)	(0.1)
Pirespa	2.7	2.6	96.6	2.4	10.8	0.2
Rapiacta	0.2	0.1	25.3	0.1	(33.6)	(0.0)
Total of 8 strategic products	47.3	45.7	96.6	44.4	2.9	1.3
[percent of sales]	58.8%	59.4%		54.9%		

Change in Sales vs. Previous Year



- **Japanese domestic business**
  - Negative impact of NHI drug price revisions averaged approx. 2%
    - Expanded sales of Crestor and Irbetan franchise despite lower NHI drug prices
    - Decreased contribution of long-listed drugs due to NHI drug price revisions and generic penetration
- **Shionogi Inc. (existing products)**
  - Divestiture of PSD502 in 2Q FY2014
  - Sales of FY2013 included Naprelan® and divestitures of pediatric products around (4.5)
- **C&O**
  - Expanded sales of *Amolin*
- **Royalty income**
  - Reduced royalty rate of Crestor due to the new agreement with AstraZeneca (6.8)
  - Increased other royalties
- **Other businesses on track**

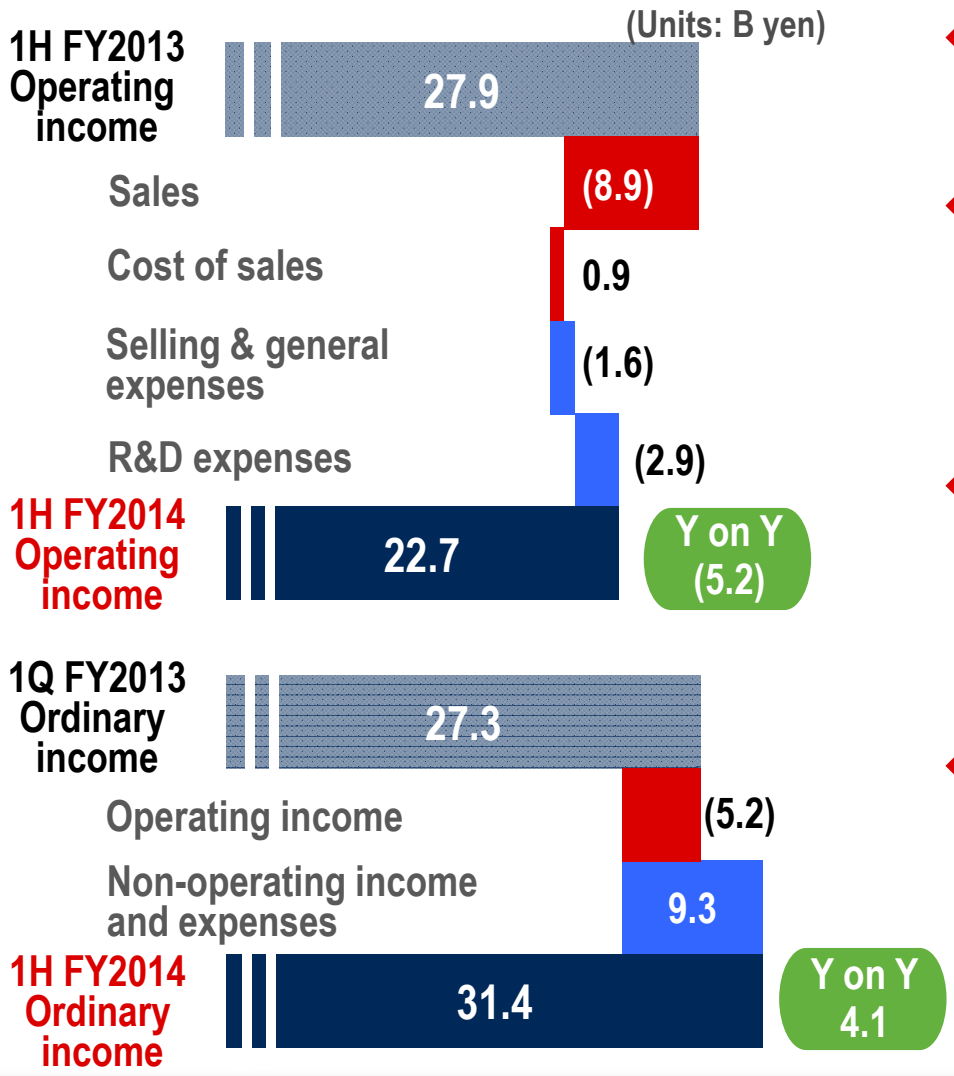
Statements of Income (Consolidated)

(Units: B yen)

	FY2014		vs. forecasts		FY2013 1H results	Y on Y	
	1H forecasts	1H results	Achieve-ment (%)	difference		Change (%)	change
Sales	130.0	129.8	99.9	(0.2)	138.7	(6.4)	(8.9)
[Royalty income]	26.0	28.3	108.9	2.3	33.4	(15.3)	(5.1)
Cost of sales	29.2 [36.5] 38.0	29.4 [37.6] 38.1	100.4	0.1	26.9 [35.4] 37.2	2.4	0.9
Gross profit	92.0	91.7	99.7	(0.3)	101.5	(9.6)	(9.8)
SG&A expenses	56.5 73.5	53.1 69.0	93.8	(4.5)	53.0 73.5	(6.2)	(4.5)
Selling & general expenses	46.5	45.8	98.4	(0.7)	47.4	(3.5)	(1.6)
R&D expenses	27.0	23.2	85.9	(3.8)	26.1	(11.1)	(2.9)
Operating income	14.2 18.5	17.5 22.7	122.8	4.2	20.1 27.9	(18.7)	(5.2)
[Excluding royalty income]	(7.5)	(5.6)	-	1.9	(5.5)	-	(0.1)
Non-operating income and expenses	P5.5	P8.7	158.1	3.2	L0.6	-	9.3
Ordinary income	18.5 24.0	24.2 31.4	130.9	7.4	19.7 27.3	15.0	4.1
Extraordinary income and loss	-	P0.2	-	0.2	P4.3	-	(4.1)
Income before income taxes and minority interests	24.0	31.7	131.9	7.7	31.6	0.1	0.1
Total income taxes, etc.	8.0	22.0	274.4	14.0	10.5	108.4	11.5
Net income	16.0	9.7	60.7	(6.3)	21.1	(53.9)	(11.4)

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, etc.
- **Selling & general expenses**
  - Optimized costs in all group companies
    - Japan: Preferential investment in high-priority products and activities
    - Shionogi Inc.: Continued investment in Osphena
- **R&D expenses**
  - More focused investment in high-priority development programs
  - Reduced expenses by co-development with NovaQuest
- **Non-operating income and tax**
  - Increased dividends from ViiV
  - Accounted for increase in value of foreign-currency assets due to the weak yen
  - Reduced interest cost by repayment of debt

Co-development with NovaQuest

Purpose of the co-development agreement

- To attain our financial targets for a fiscal year 2020, Shionogi must accelerate progress of its development projects, which are its future growth drivers
- Shionogi has declared fiscal year 2014 to be the year that it overcomes the Crestor hill, focusing on our core competencies, and establishing our platform for moving forward into a genuine growth phase
- As a one-time-only event, Shionogi entered into a Co-development agreement with NovaQuest, reducing its R&D expenses through use of external funding while sharing development risk with NovaQuest

Outline

- Shionogi will receive a maximum of $85M funding from NovaQuest ($50M in the fiscal year 2014) for the development of S-297995 and other compounds
- Shionogi will make success payments to NovaQuest based on the achievement of contractually-defined development milestones
- Shionogi has no obligation to pay any milestones to NovaQuest if development fails

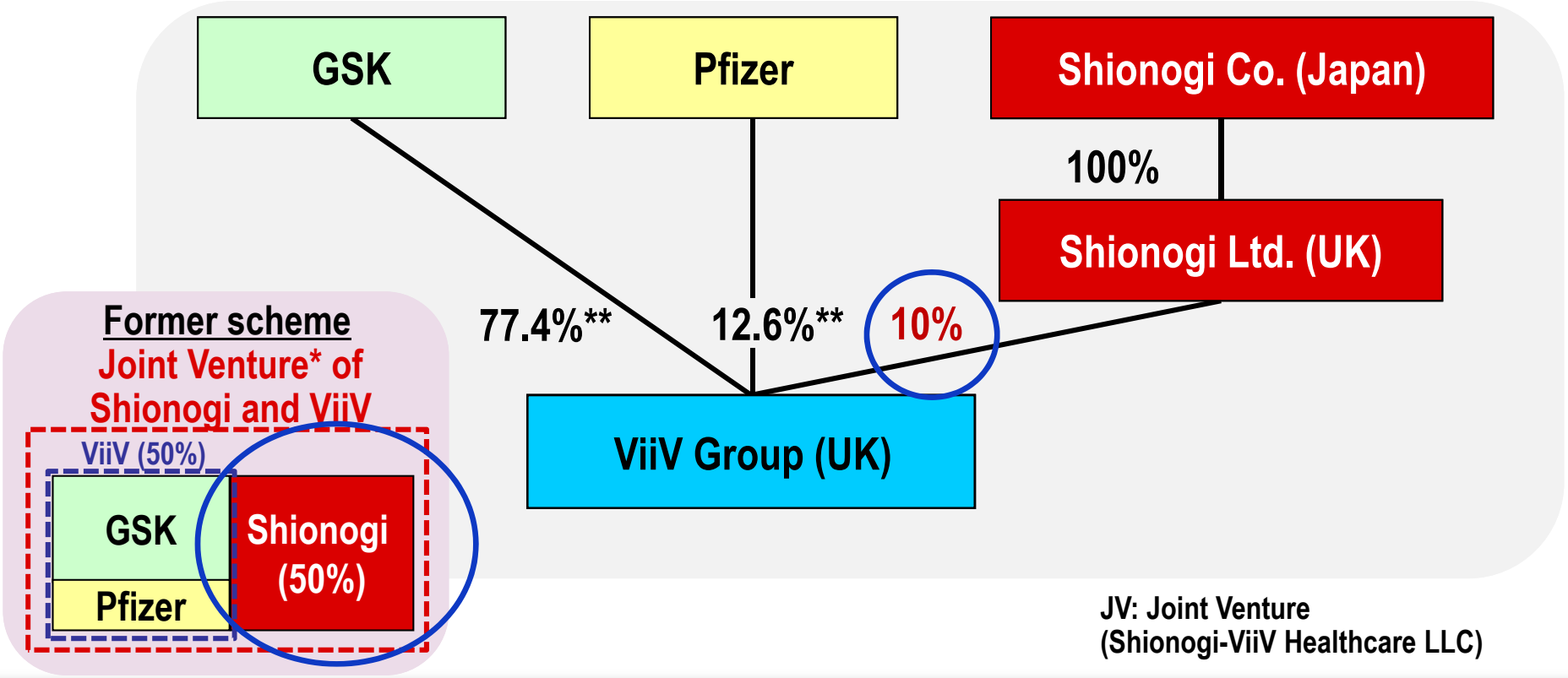
Accelerate the development of key global/domestic pipeline programs

NovaQuest: Formed in 2000 and spun out from Quintiles in 2010, NovaQuest Capital (NovaQuest) has a principal focus of funding late-stage clinical compounds and commercial phase biopharmaceutical products.

Tax Reassessment Notice from the Osaka Regional Taxation Bureau

New arrangement with ViiV Healthcare Ltd. (announced on Oct. 29, 2012)

- In the process of revising the agreement covering the anti-HIV drugs*, Shionogi transferred its JV equity as an investment-in-kind in its UK-based subsidiary Shionogi Ltd.
- Then Shionogi became a 10% shareholder of ViiV by the transaction of JV right



JV: Joint Venture
(Shionogi-ViiV Healthcare LLC)

* Dolutegravir (Tivicay®), S/GSK1265744, etc. including their combination drugs
** GSK increased from 76.5% to 77.4%, Pfizer decreased from 13.5% to 12.6%, effective on Oct. 1, 2013

Tax Reassessment Notice from the Osaka Regional Taxation Bureau

The outline of this incident

- Shionogi had discussed this investment-in-kind with the Osaka Regional Taxation Bureau prior to implementation thereof and the Taxation Bureau confirmed that it would be considered as a tax-qualified investment
- The Taxation Bureau has sent a tax reassessment notification to Shionogi, taking the new position that this investment-in-kind could not be authorized as a tax-qualified investment, without providing any clear or convincing rationale for this new position
- Reassessed tax liabilities were approx. 40.5 billion yen, and, as a result of this reassessment, it was estimated that Shionogi would be required to pay a total of approx. 1.3 billion yen in additional taxes, including local taxes

Impact on the business performance

- Approx. 1.3 billion yen, including additional back-taxes, were recorded in 1H FY2014 as prior period income taxes
- Also, approx. 12.5 billion yen was recorded in 1H FY2014 as prior period income taxes due to a shortage in the loss carried forward amount from the year-end FY2013

Future action

- Shionogi is preparing to take necessary steps, such as filing a motion for complaint, against the tax reassessment decision

FY2014 Financial Forecasts

Actions in 1H FY2014

Began FY2014 with ordinary income forecast of 50 B yen

Establish a stable foundation for our mid- to long-term growth by clear priorities and focused resourcing in the first year of SGS2020

◆ Overcome the "Crestor Hill" as soon as possible

- Promote clear priorities and focused resourcing, appropriate cost allocation and reduction of cost of goods throughout the Shionogi group
- Focus sales resources on the domestic and US markets; i.e. those with the highest growth potential
- Accelerate R&D activities through clear priorities and focused resourcing

Achievements and Changes in Business Environment

Achievement in 1H FY2014: Ordinary income was higher than in 1H of any prior fiscal year

- Achieved tight cost control and focused cost allocation throughout all of the Shionogi group
- Royalty income exceeded the original forecasts by 2.3 B yen
- Increased dividend from ViiV Healthcare and increased value of assets in foreign currency generated by a drop in the yen

Changes in business environment

- Robust expansion of Tivicay franchise
- More difficult situation than expected in the domestic market
  - Effects of NHI drug price reductions
  - Lower than expected sales of long-listed drugs due to the promotion of generic drug use by the government and a competitive market

Challenges Detected in 1H FY2014

Identified challenges

- **Cost-effectiveness analysis throughout our business operations**
  - Achieved good cost control and focused resource allocation; however,
  - Need more analysis for maximally effective resource allocation
- **Strengthen the domestic business**
  - Growth in strategic products could not fully cover the unexpected sales decrease in long-listed products
    - Need more effective responses to changes in the domestic market
    - Need to drive Cymbalta growth in the pain/CNS area more intensively
- **Sales growth rate of Osphena in the US**
  - Reach a broader range of physicians with interest in treating dyspareunia
  - Increase effectiveness of our communications to physicians and patients

Key Actions for 2H FY2014

Undertake activities for our longer-term growth after FY2015 while meeting our revised ordinary income target in FY2014

- **Continued improvement of business operations**
  - Follow the PDCA cycle throughout the Shionogi group to check the results of our activities and investments while building a business structure capable of sustainably generating a good return on investment
- **Strategic resource allocation in the domestic and US businesses, and construction of a business base capable of realizing the full value of our mid- to long-term product portfolio**
- **Accelerating the development and launch of our late-stage pipeline products through investment of increased royalty income in FY2014 into R&D activities**

Revision of FY2014 Financial Forecasts (Consolidated)

(Units: B yen)

	FY2014							FY2013 results	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	Original	revised	change		
Sales	269.0	273.5	4.5	129.8	139.0	143.7	4.7	289.7	(5.6)
Operating income	45.0	49.5	4.5	22.7	26.5	26.8	0.3	61.9	(20.0)
Ordinary income	50.0	58.0	8.0	31.4	26.0	26.6	0.6	62.2	(6.8)
Net income	33.0	30.0	(3.0)	9.7	17.0	20.3	3.3	40.6	(26.1)

Exchange rate (average)	FY2014 forecasts (original)	FY2014 forecasts (revised)	change
USD($) – JPY(¥)	100	105	5
EUR(€) – JPY(¥)	140	140	-
GBP(£) – JPY(¥)	165	170	5

Revision of Sales by Segments (Consolidated)

(Units: B yen)

	FY2014							FY2013 results	Y on Y change (%)
	full year			1H	2H				
	original	revised	change	results	original	revised	change		
Prescription drugs	167.0	163.5	(3.5)	77.0	86.5	86.5	-	168.3	(2.8)
Crestor	42.5	42.6	0.1	21.1	21.5	21.5	-	41.1	3.7
Irbetan franchise	15.9	16.5	0.6	7.5	8.6	9.0	0.4	13.9	19.0
Cymbalta	13.6	12.9	(0.7)	5.5	7.4	7.4	-	11.4	13.2
Total of 3 key products	72.0	72.0	-	34.0	37.5	38.0	0.5	66.3	8.5
OxyContin franchise	10.7	10.7	-	5.3	5.2	5.4	0.2	10.6	0.7
Finibax	4.6	4.2	(0.4)	1.9	2.3	2.3	-	4.7	(10.5)
Differin	4.6	4.4	(0.2)	1.8	2.5	2.6	0.1	4.4	0.1
Pirespa	5.6	5.5	(0.1)	2.6	2.9	2.9	-	4.8	14.4
Rapiacta	2.5	2.5	-	0.1	2.3	2.4	0.1	2.0	23.3
Total of 8 strategic products	100.0	99.3	(0.7)	45.7	52.7	53.6	0.9	92.9	6.9
Overseas subsidiaries/export	31.3	31.3	-	14.6	16.3	16.7	0.4	34.0	(8.0)
Shionogi Inc.	17.7	17.7	-	7.4	9.8	10.3	0.5	21.4	(17.2)
Osphena	7.0	7.0	-	1.7	4.5	5.3	0.8	1.1	536.6
C&O	7.5	7.5	-	3.3	4.1	4.2	0.1	5.9	27.7
Contract manufacturing	11.4	11.4	-	6.1	6.6	5.3	(1.3)	8.4	36.1
OTC and quasi-drugs	4.6	4.6	-	2.5	2.2	2.1	(0.1)	4.5	1.9
Royalty income	52.0	60.0	8.0	28.3	26.0	31.7	5.7	70.7	(15.1)
Crestor	47.5	49.0	1.5	24.4	23.3	24.6	1.3	65.7	(25.4)
Others	2.7	2.7	-	1.5	1.4	1.2	(0.2)	3.8	(29.2)
Total	269.0	273.5	4.5	129.8	139.0	143.7	4.7	289.7	(5.6)

FY2014 Financial Forecasts

Revision of Statement of Income (Consolidated)

(Units: B yen)

	FY2014 full year original	FY2014 full year revised	FY2014 full year change	FY2014 1H results	FY2014 2H original	FY2014 2H revised	FY2014 2H change	FY2013 results	Y on Y change (%)
Sales	269.0	273.5	4.5	129.8	139.0	143.7	4.7	289.7	(5.6)
【Royalty income】	52.0	60.0	8.0	28.3	26.0	31.7	5.7	70.7	(15.1)
Cost of sales	29.4 [36.4] 79.0	28.7 [36.8] 78.5	(0.5)	29.4 [37.6] 38.1	29.5 [36.3] 41.0	28.1 [36.0] 40.4	(0.6)	26.9 [35.6] 78.0	0.7
Gross profit	190.0	195.0	5.0	91.7	98.0	103.3	5.3	211.7	(7.9)
SG&A expenses	53.9 145.0	53.2 145.5	0.5	53.1 69.0	51.4 71.5	53.3 76.5	5.0	51.7 149.8	(2.9)
Selling & general expenses	93.0	93.5	0.5	45.8	46.5	47.7	1.2	96.2	(2.9)
R&D expenses	52.0	52.0	-	23.2	25.0	28.8	3.8	53.6	(3.0)
Operating income	16.7 45.0	18.1 49.5	4.5	17.5 22.7	19.1 26.5	18.6 26.8	0.3	21.4 61.9	(20.0)
【Excluding royalty income】	(7.0)	(10.5)	(3.5)	(5.6)	0.5	(4.9)	(5.4)	(8.8)	-
Non-operating income and expenses	P5.0	P8.5	3.5	P8.7	L0.5	L0.2	0.3	P0.4	-
Ordinary income	18.6 50.0	21.2 58.0	8.0	24.2 31.4	18.7 26.0	18.5 26.6	0.6	21.5 62.2	(6.8)

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

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

Japanese Domestic Sales Driving Shionogi's Growth

◆ Construction a business base suited to a changing Japanese market

- Reorganized the domestic commercial business structure
  - Divided the Pharmaceutical Promotion Department into four individual regional departments, allowing a tighter focus on the specific sales and marketing needs of each region
  - Established "the Pharmaceutical Promotion Department - Tokyo Hospitals" to focus on KOLs and to coordinate sales and marketing efforts for Tokyo Hospitals in collaboration with the Product Marketing Department and the Global Development Division

◆ Supporting future growth drivers in the mid- to long-term product portfolio

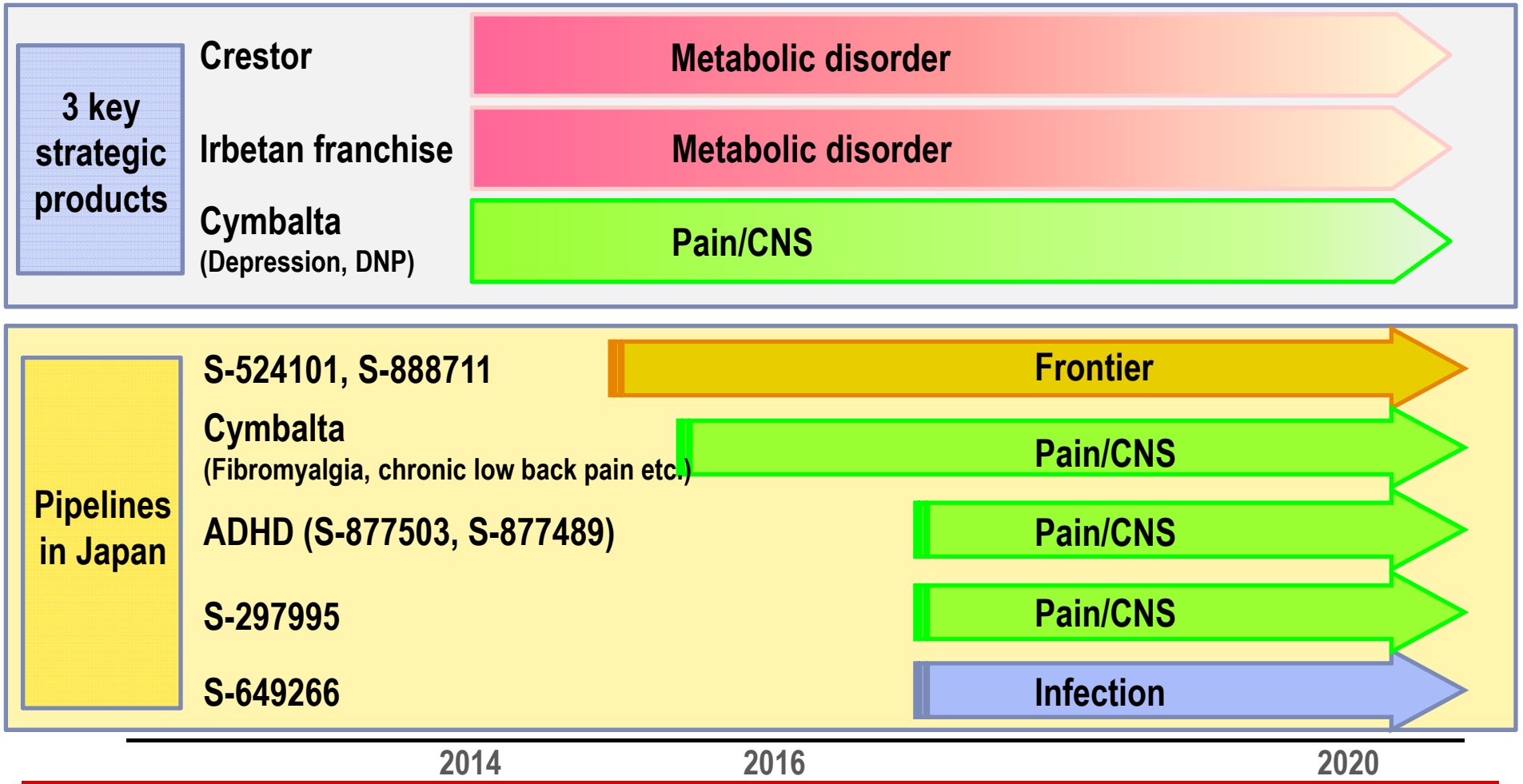
- Further focus on 3 key strategic products
  - Continue to strengthen the patient-focused info-service "TRINITY"
  - Expand the sales capability in the Pain/CNS areas by focusing resources on Cymbalta, which has further growth potential
- Enhance presence in dermatology through the combined portfolio of Differin and GlashVista®

Building a business base capable of supporting the continuous growth of strategic products into the mid- to long-term

TRINITY: A diabetic patient-focused activities implemented across therapeutic areas aiming for enhancing our information provision

Key Actions in 2H FY2014

Product Portfolio That Contribute for Further Growth in Domestic Sales



Advancing promising new drugs to prepare for the future expiration of patents on 3 key strategic products

ADHD: Attention deficit hyperactivity disorder
DNP: Diabetic neuropathic pain

Strengthen the US Business

◆ Strengthen commercial approach to drive Osphena's growth

- Broadening the physician audience and updating key messages
  - ➢ Focus more attention on addressing dyspareunia as a part of the overall wellness of post-menopausal women
  - ➢ Communicate to an expanded HCP audience (e.g. PCPs involved in other aspects of post-menopausal wellness, but who do not currently focus on dyspareunia)
- Provide stronger support for patients throughout their treatment journey
  - ➢ Increase their awareness of Osphena as a non-estrogen product and of its brand name through effective communications including DTC
- 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

Revitalization of US operation to target profitability after FY2015

PCPs: Primary Care Physicians
DTC: Direct to consumer

Further Focus on Cost Control

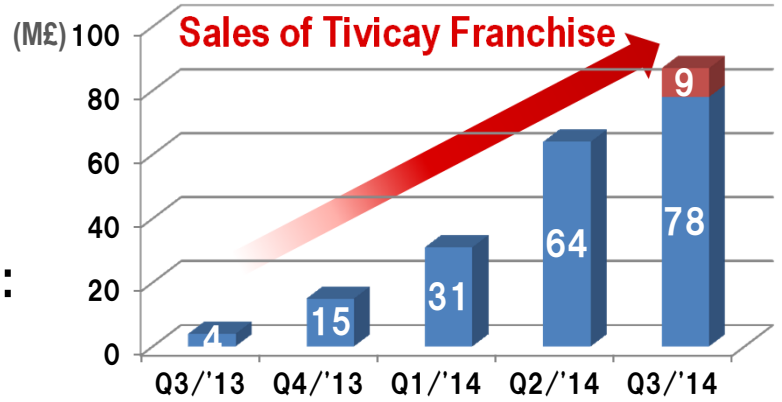
- **Cost of sales**
  - Maintain current emphasis on cost reduction and inventory adjustment
- **Selling & general expenses**
  - Continue to focus on high-priority products and activities with the targeted resource allocation
  - Invest in building the business base to support mid- to long-term growth
- **R&D expenses**
  - Utilize the additional royalty income to accelerate the development of high-priority compounds
  - Create further opportunities for development by partnering and out-licensing
    - Accelerating R&D activities while controlling R&D expenses (e.g. the collaboration with NovaQuest

Achieving financial targets while sustaining investment for future growth via strategic cost management throughout the Shionogi group

Realizing the Potential of the HIV Franchise with ViiV Healthcare

◆ Tivicay® franchise shows strong growth globally

- Global sales (Jan.-Sep., 2014): £182M (US$304M)
  - ➢ Tivicay: £173M (US$289M)
  - ➢ Triumeq®: £9M (US$15M)
- Sales in Japan (Tivicay, Apr.-Sep., 2014): £8M (US$14M)



◆ Ongoing efforts to maximize HIV franchise by ViiV Healthcare

- Triumeq® (dolutegravir/abacavir/lamivudine single-pill regimen)
  - ➢ Approval: Aug. 2014 (US), Sep. 2014 (EU)
- ViiV and Janssen have entered into an agreement for the development and commercialization of a single pill combining dolutegravir and Janssen's NNRTI rilpivirine in Jun. 2014
  - ➢ Phase III studies will be initiated in 1Q 2015 (calendar)
- S/GSK1265744LAP with rilpivirine (LATTE II study)
  - ➢ Phase II study (progressed into the maintenance phase)

LAP: Long acting parenteral formulation

Parallel Actions to Drive Mid- to Long-Term Growth

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

Dividend Forecasts

	Dividends per Share		
	half-year	year-end	annual
	Yen	Yen (forecast)	Yen (forecast)
FY2014	24 . 00	24 . 00	48 . 00
FY2013	22 . 00	24 . 00	46 . 00

Research & Development

Clear Priorities and Focused Resourcing on Medical Needs

Focusing Targets in FY2014

High-priority compounds in Japan

- Cymbalta (Fibromyalgia): NDA submission (Jun. 2014),
  (Chronic low back pain): plan to submit NDA in FY2014 (NDA submission in preparation)
- S-888711 (Thrombocytopenia): plan to submit NDA in FY2014 (NDA submission in preparation)
- 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

Focus on global compounds

- S-297995 (Alleviation of opioid-induced adverse effects): Ongoing global Phase III
  - Modification of global Phase III study package agreed with FDA
- S-888711: Plan to initiate global clinical trials after discussion with EMA and FDA
- S-649266 (Infection): Global Phase II initiation

Clear priorities and focused resourcing in development

- Out-licensed acute coronary syndrome biologic program to MedImmune, LLC

S-297995 (Naldemedine): Phase III Update

- **Impact of Anesthetic and Analgesic Drug Products Advisory Committee on peripheral μ-opioid receptor antagonists**
  - FDA approved Movantik™ and Relistor® s.c. in Sep. 2014
  - FDA did not require a large CV outcomes randomized trial for the NDA
- **Discussed our Phase III plan for S-297995 with FDA**
  - Agreed on a revised Phase III package
- **COMPOSE Program (7 studies)**
  - Recruitment proceeding on target globally
  - Confirmatory study (COMPOSE 1): Plan to code break at the end of FY2014
- **Plan to submit NDA in 1Q FY2016 in US and Japan**

S-649266: Acceleration of Global Development

Results of non-clinical and Phase I studies

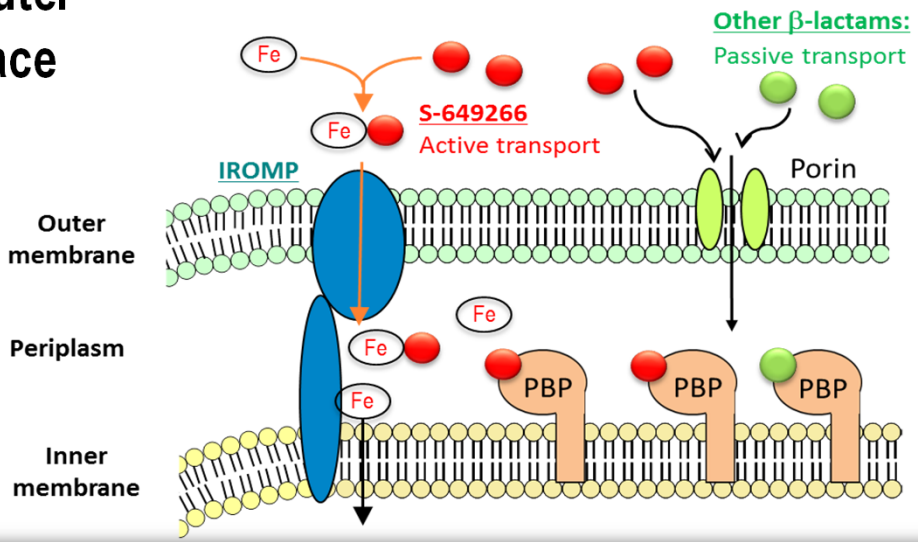
- Potent antibacterial activity against multidrug-resistant bacteria
- Highly stable against serine or metallo-β-lactamases
- Demonstrated safety and tolerability in healthy volunteers in single and multiple dose studies

Mechanism: "Trojan Horse"

- Unique structural features to bind free iron as a siderophore
- Actively transported through the outer membrane into the periplasmic space and disrupts cell wall synthesis

Development schedule

- Stage: Global Phase II
- Plan to start Phase III in FY2015



IROMP: Iron regulated outer membrane proteins
PBP: Penicillin Binding protein

S-649266: Potent Antibacterial Activity Against Multidrug-resistant Bacteria

◆ *In vitro* antibacterial activity of S-649266 against clinical isolates of β-lactamase-producing gram-negative bacteria

Phenotype. Genotype (number of isolates)	Test Compound (MIC：μg/mL)							
	S-649266		Meropenem		Cefepime		Piperacillin/ Tazobactam	
	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}	MIC_{50}	MIC_{90}
Carbapenemase producers(193)	0.25	4	≧32	≧32	≧64	≧64	N.D.	>256
KPC producers(47)	≦0.063	0.5	8	≧32	32	≧64	>256	>256
NDM-1 producers (50)	1	4	≧32	≧32	≧64	≧64	N.D.	N.D.
VIM producers (28)	0.25	4	16	≧32	≧64	≧64	256	>256
Metallo beta-lactamase producing *Pseudomonae aeruginosa*(33)	0.5	4	≧32	>32	>64	>64	128	>256
Multidrug-resistant *Pseudomonas aeruginosa*(30)	0.25	1	16	>32	32	>64	256	>256
Multidrug-resistant *Acinetobacter baumannii*(30)	0.25	4	≧32	>32	64	>64	>256	>256

Expect antibacterial activity against multidrug-resistant P. aeruginosa and multidrug-resistant A. baumannii, which are problematic in clinical settings

DATA: IDWeek 2014, Poster No. 252 (Partial modification)
MIC: Minimum inhibitory concentration N.D.: Not determined

Cymbalta (duloxetine): Life Cycle Management in Japan

- **Serotonin and noradrenaline reuptake inhibitor**
  - Inhibitory effect on descending pain

- **In-licensed from Eli Lilly (US)**

- **Global indications (approved as of April in 2014)**

Major depression	105 countries
Diabetic neuropathic pain	100 countries
Generalized anxiety disorder	88 countries
Fibromyalgia	35 countries
Abdominal pressure - induced incontinence	49 countries
Chronic skeletal muscle pain, chronic low back pain and osteoarthritis	31 countries

Cymbalta (duloxetine): Life Cycle Management in Japan

- **Cymbalta® capsules 20mg, 30mg**
  - Once-daily, oral dose
- **Approved indications in Japan: Co-promotion with Eli Lilly Japan**
  - Depression, depressive condition: Launched in April 2010
  - Diabetic neuropathic pain: Approval for Additional Indication in February 2012
- **Development for additional indications: Joint development and co-promotion with Eli Lilly Japan**
  - Fibromyalgia: Submitted NDA (development for new indications with high medical need, requested by Review Committee*)
  - Chronic low back pain: Completed Phase III, NDA submission in preparation
  - Osteoarthritis: Initiated Phase III study

* 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.

Maximizing R&D Value through Alliance

- Biologic research program
  - Global license agreement signed in Sep. 2014 that MedImmune, LLC in-licenses Shionogi's novel preclinical biologic program for the treatment of acute coronary syndrome by raising HDL levels
  - Expect to maximize this program's value through MedImmune's proven capabilities in biologics research combined with AstraZeneca's commercial capabilities in marketing cardiovascular therapies

- PSD502
  - Completed the out-license of all rights to PSD502 to Plethora Solutions PLC

Appendix
- Pipeline -

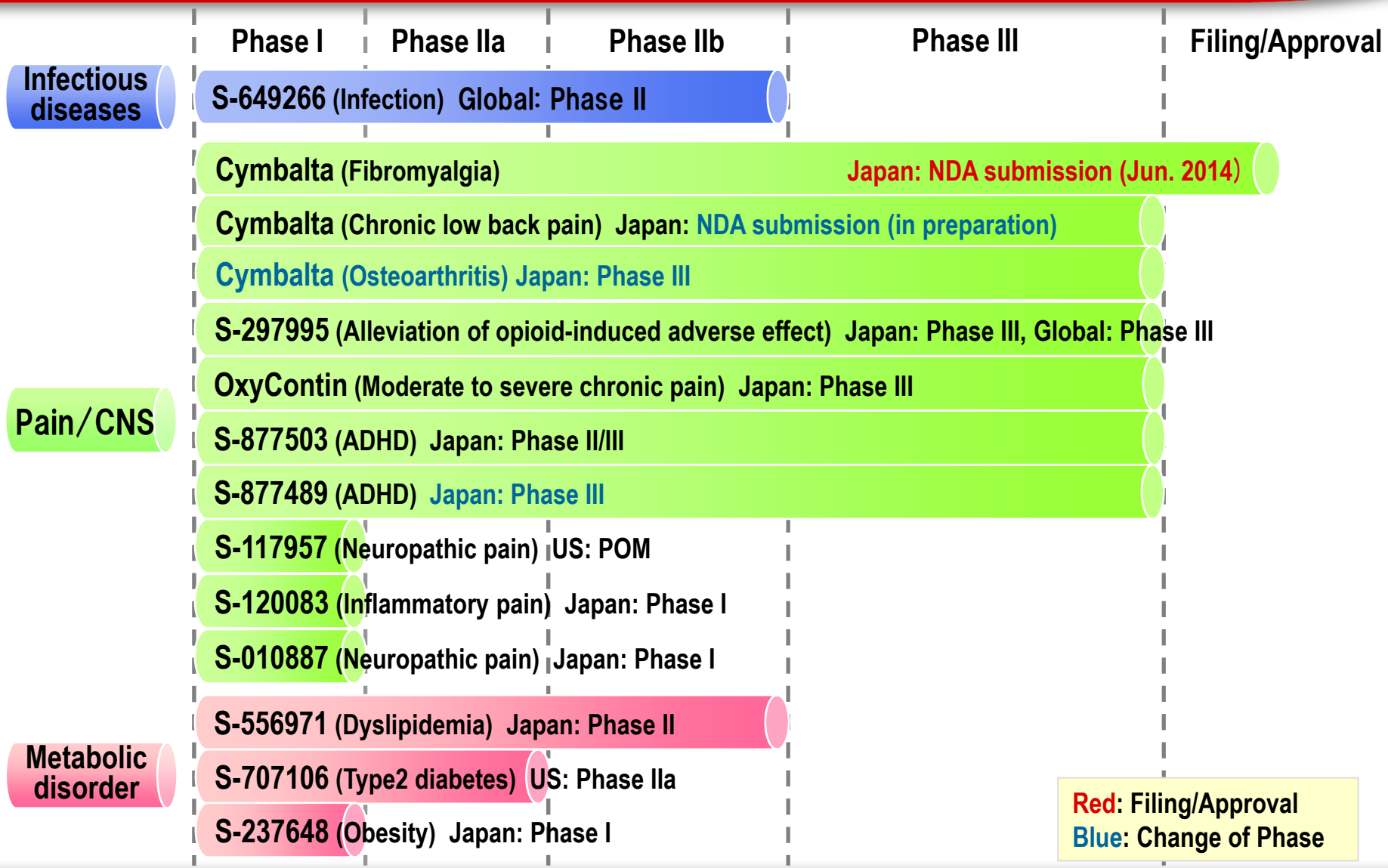
Pipeline

Change of Phase (since August 2014)

Code No. [Product/generic name]	Category (Administration)	Indication	Change of Phase
LY248686 Duloxetine hydrochloride [Cymbalta®]	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Chronic low back pain	Japan: Phase III ⇒Japan: NDA submission (in preparation)
LY248686 Duloxetine hydrochloride [Cymbalta®]	SNRI (Serotonin & noradrenaline reuptake inhibitor) (Oral)	Osteoarthritis	Japan: Phase III
S-877489 [Lisdexamfetamine]	DA and NE reuptake inhibitor /Releaser of DA, NE (Oral)	ADHD	Japan: Phase II ⇒Japan: Phase III
S-888711 [Lusutrombopag]	Small molecule TPO receptor agonist (Oral)	Thrombocytopenia	Japan: Phase III ⇒Japan: NDA submission (in preparation)
Dolutegravir/ abacavir/ lamivudine	Integrase inhibitor / Nucleoside reverse transcriptase inhibitor (Oral)	HIV infection	USA, Europe: NDA submission (Oct 2013) ⇒USA: Approval (Aug 2014), Europe: Approval (Sep 2014)

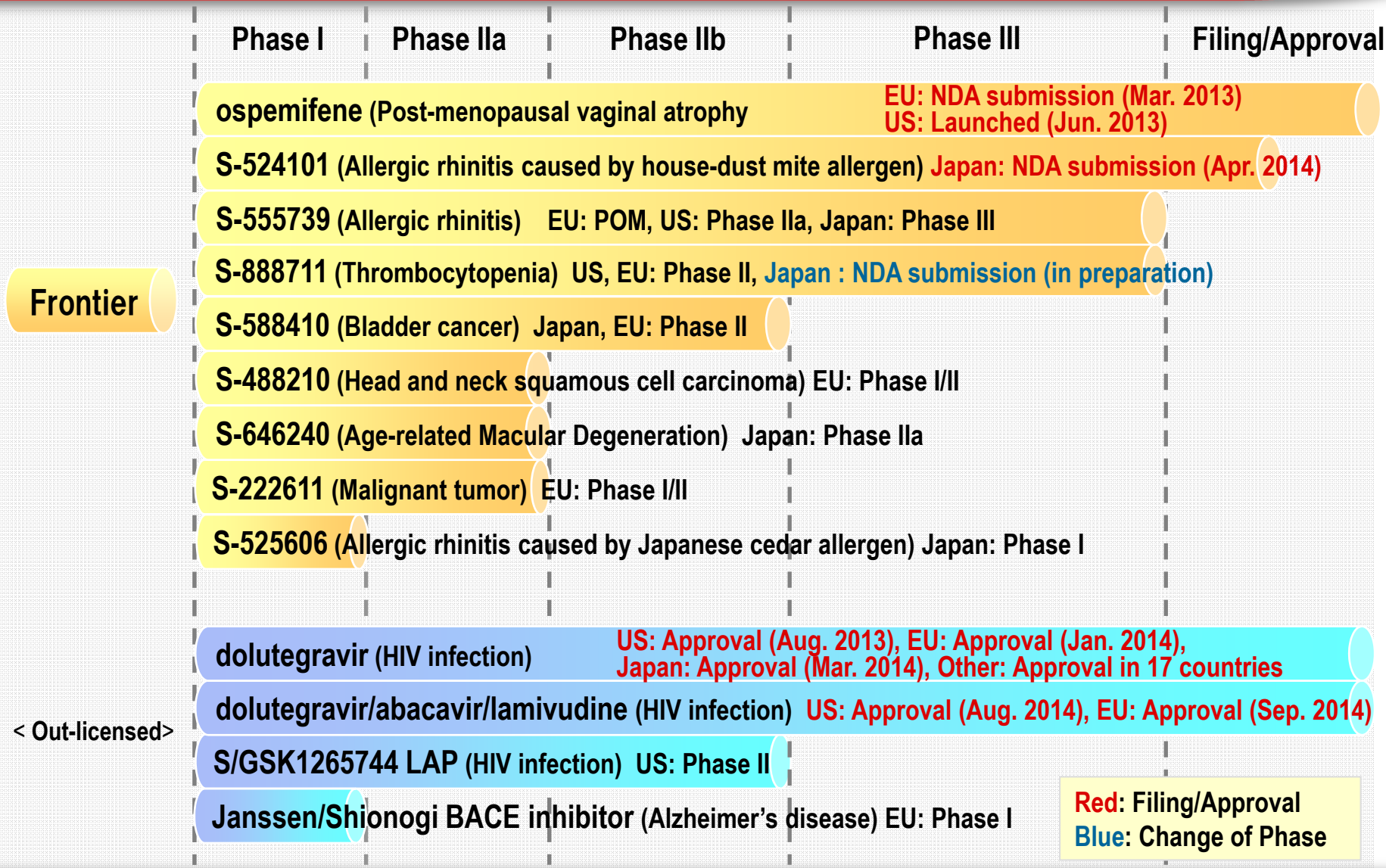
ADHD: Attention deficit hyperactivity disorder

Pipeline (as of October 2014)



ADHD: Attention deficit hyperactivity disorder POM: Proof of mechanism

Pipeline (as of October 2014)



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