



Fiscal 2011 Financial Results

May 10, 2012

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President and Chief Executive Officer*





Overview of FY2011 Results

FY2011 Results

Financial Results (Consolidated)



(Units: B yen)

	FY2011 Forecasts	FY2011 Results	Achieve- ment (%)	Fore- casting variance	FY2010 Results	Y on Y	
						Change (%)	Change
Sales	269.0	267.3	99.4	(1.7)	282.4	(5.3)	(15.1)
Operating income	46.0	47.0	102.2	1.0	46.9	0.2	0.1
Ordinary income	44.0	46.1	104.8	2.1	45.2	2.0	0.9
Net income	27.0	27.1	100.4	0.1	20.0	35.3	7.1

All numerical values are rounded to the nearest unit.

Due to change in the accounting periods, results of FY2010 include 15 months from Jan. 2010 to Mar. 2011 for the US subsidiaries.

(Units: yen)

Exchange rate (average)	FY2011 Forecast*	FY2011 Results	FY2010 Results	Y on Y
USD(\$)	78	79.06	86.73	7.67 yen appreciation
EUR(€)	108	109.00	115.60	6.60 yen appreciation

*: Revised in 3Q FY2011

FY2011 Results

Financial Position and Cash Flows (Consolidated)



(Units: B yen)

<Financial position>	3/31/2012	3/31/2011	Y on Y Change
Total assets	522.2	523.2	(1.0)
Net assets	347.2	328.1	19.1
Equity ratio (%)	65.9	62.7	3.2
Net assets per share (yen)	1,028	980	48

(Units: B yen)

<Cash flows>	FY2011 Results	FY2010 Results	Y on Y Change
Net cash provided by operating activities	54.7	56.5	(1.8)
Net cash provided by investing activities	(38.3)	(13.9)	(24.4)
Net cash provided by financing activities	(27.7)	(27.0)	(0.7)
Net increase (decrease)	(12.0)	13.0	(25.0)
Cash and cash equivalents at end of period	98.7	110.7	(12.0)

FY2011 Results

Breakdown of Sales (Consolidated)

(Units: B yen)



	FY2011 Forecasts	FY2011 Results	Achievement (%)	Forecasting Variance	FY2010 Results	Y on Y	
						Change (%)	Change
Prescription drugs	165.8	164.4	99.1	(1.4)	158.9	3.4	5.5
Crestor	36.6	35.7	97.6	(0.9)	29.0	23.4	6.7
Irbetan	9.7	8.9	92.0	(0.8)	7.3	22.9	1.6
Cymbalta	6.1	6.6	108.4	0.5	2.7	148.7	3.9
Total of 3 key products	52.4	51.3	97.8	(1.1)	38.9	31.9	12.4
OxyContin	9.9	8.9	89.5	(1.0)	9.6	(8.0)	(0.7)
Finibax	4.6	4.7	102.2	0.1	3.6	32.0	1.1
Differin	3.6	3.7	101.5	0.1	3.2	14.6	0.5
Pirespa	3.4	3.4	99.1	(0.0)	2.8	22.3	0.6
Rapiacta	1.4	1.4	97.3	(0.0)	0.3	386.2	1.1
Total of 8 strategic products	75.3	73.2	97.2	(2.1)	58.3	25.6	14.9
Flomox	20.9	20.7	99.2	(0.2)	21.9	(5.3)	(1.2)
Rinderon	9.5	9.2	97.1	(0.3)	9.5	(3.1)	(0.3)
Claritin	7.2	7.8	108.7	0.6	10.0	(21.6)	(2.2)
Flumarin	6.4	6.9	108.1	0.5	7.5	(7.9)	(0.6)
Export/Overseas subsidiaries	16.7	17.0	101.7	0.3	37.4	(54.6)	(20.4)
Shionogi Inc.	5.7	5.8	102.6	0.1	27.0	(78.4)	(21.2)
C&O	1.9	1.9	101.6	0.0	-	-	-
Doripenem	4.2	4.2	100.8	0.0	4.7	(9.5)	(0.5)
Contract manufacturing	7.8	7.6	97.5	(0.2)	5.4	40.5	2.2
OTC and quasi-drugs	4.9	5.0	102.5	0.1	5.2	(3.0)	(0.2)
Diagnostics	2.8	2.7	96.7	(0.1)	2.9	(5.3)	(0.2)
Royalty income	69.0	68.7	99.5	(0.3)	68.9	(0.4)	(0.2)
Crestor	65.8	64.7	98.4	(1.1)	64.2	0.8	0.5
Others	2.0	1.9	95.9	(0.1)	3.6	(47.3)	(1.7)
Total	269.0	267.3	99.4	(1.7)	282.4	(5.3)	(15.1)

Due to change in the accounting periods, results of FY2010 include 15 months from Jan. 2010 to Mar. 2011 for the US subsidiaries. 4

FY2011 Results

Statements of Income (Consolidated)



(Units: B yen)

	FY2011 Forecasts	FY2011 Results	Achieve- ment (%)	Forecasting Variance	FY2010 Results	Y on Y	
						Change (%)	Change
Sales	269.0	267.3	99.4	(1.7)	282.4	(5.3)	(15.1)
[Royalty income]	69.0	68.7	99.5	(0.3)	68.9	(0.4)	(0.2)
Cost of sales	28.6 [38.5] 77.0	29.1 [39.1] 77.8	101.0	0.8	28.9 [38.3] 81.7	(4.9)	(3.9)
Gross profit	192.0	189.5	98.7	(2.5)	200.6	(5.5)	(11.1)
SG&A expenses	54.3 146.0	53.3 142.5	97.6	(3.5)	54.4 153.7	(7.3)	(11.2)
Selling & general expenses	89.0	88.9	99.9	(0.1)	102.8	(13.5)	(13.9)
R&D expenses	57.0	53.6	94.0	(3.4)	50.9	5.3	2.7
Operating income	17.1 46.0	17.6 47.0	102.2	1.0	16.6 46.9	0.2	0.1
Non-operating income and expenses	L2.0	L0.9	-	1.1	L1.7	-	-
Ordinary income	16.4 44.0	17.2 46.1	104.8	2.1	16.0 45.2	2.0	0.9
Extraordinary income and loss	L1.2	L4.6	-	(3.4)	L12.0	-	-
Income before income taxes	42.8	41.5	96.9	(1.3)	33.1	25.2	8.4
Total income taxes	15.8	14.4	91.1	(1.4)	13.1	9.8	1.3
Net income	27.0	27.1	100.4	0.1	20.0	35.3	7.1

Small numbers in red are percentages of sales, and numbers in red provided in parentheses are percentages of royalty excluded sales.

FY2011 Results

Financial Results of Shionogi Inc.



(Units: upper/million dollar, lower/billion yen)

	FY2011 Forecasts	FY2011 Results	FY2011				
			1 st Half Results	2 nd Half Forecasts	2 nd Half Results	3Q	4Q
Sales	73 5.7	74 5.8	(31) (2.4)	104 8.2	105 8.2	52 4.1	53 4.1
Cost of sales	28 2.2	29 2.3	15 1.2	13 0.9	14 1.1	6 0.4	8 0.7
SG&A expenses	192 14.9	191 15.1	85 6.7	106 8.1	106 8.4	50 3.9	56 4.5
Operating income	(146) (11.4)	(146) (11.5)	(131) (10.4)	(15) (0.9)	(15) (1.1)	(4) (0.2)	(11) (0.9)

<Results in 4Q and 2nd Half of FY2011>

- **Sales:** Met the target for two consecutive quarters - Slow Naprelan growth, but steady growth of Kapvay and Orapred. Fortamet preliminary injunction minimized generic impact. Some additional gain resulted from the sales of the Prenate trademark, Adrenaclick and Twinject.
- **Gross to net ratio:** Controlled as planned
- **Cost of sales and SG&A expenses:** Stable business operation reflecting continued focus on cost containment
- **Operating income:** On track for the 2nd half target

FY2011 Results

Accounting for Business Combination Associated with C&O



◆ Completed Accounting for Business Combination (Impact on Consolidated Statements of Income)

(Units: B yen)

	Fair Value	Amortization		Item
		FY2011 Results	FY2012 Forecasts	
Intangible assets	2.8	0.1	0.2	Selling expenses
Goodwill	8.1	0.2	0.4	Selling expenses

- Acquired the remaining 2.18% from minority shareholders (final stock owner ratio: 66%)
- Amortization is unchanged in FY2011 results and FY2012 forecasts

◆ Financial Results of C&O

(Units: B yen)

	FY2011 Forecasts	FY2011 Results	FY2011	
			Jul-Sep	Oct-Dec
Sales	1.9	1.9	0.9	1.0
Operating income	0.0	(0.1)	(0.0)	(0.1)

- Market growth of antibiotics is temporarily slowed as a result of the examination of the clinical use of antibiotics by medical institutions nationwide in August 2011.



◆ Domestic sales (prescription drugs)

- Further focus for 8 strategic products resulted in a sales increase of 25.6% y on y
- 6 of 8 strategic products adjusted the “Premium for promotion of new drug creation and resolution of unapproved drugs/indications”

◆ Crestor Royalty

- Steady growth of global sales by AZ. Slight increase of 0.8% y on y due to the effect of exchange rate and extensive discussion with AZ

◆ Shionogi Inc.

- Solved the quality issues reported in FY2010, establishing steady supply chain management
- Focused marketing resources on key promoted products, mainly Napreelan and Kapvay, controlled deductions, and reviewed product portfolio to increase profitability
- Identified future exposure and recognized additional allowances for returns and rebates in the 1st half of FY2011, and adopting more conservative accounting procedures

⇒ Stable business operation in the 2nd half

◆ C&O

- Acquired capital in C&O, and fully committed to the business operation by the appointment of 4 management representatives to the board of directors (3 of them are in China)



FY2012 Financial Forecasts

FY2012 Forecasts

Financial Forecasts (Consolidated)



(Units: B yen)

	FY2012 Forecasts		FY2011 Results	Y on Y	
	Full Year	1 st Half		Change (%)	Change
Sales	289.0	138.0	267.3	8.1	21.7
Operating income	56.0	24.5	47.0	19.1	9.0
Ordinary income	54.0	23.5	46.1	17.2	7.9
Net income	32.0	14.0	27.1	18.1	4.9

The depreciation method of tangible fixed asset will be changed from declining-balance method mainly now we use to straight-line method in FY2012. FY2012 forecasts are calculated based on this change.

FY2012 Forecasts

Forecasts of Sales Breakdown (Consolidated)



(Units: B yen)

	FY2012 Forecasts		FY2011 Results	Y on Y	
	Full year	1 st Half		Change (%)	Change
Prescription drugs	168.6	79.5	164.4	2.6	4.2
Crestor	37.0	18.0	35.7	3.6	1.3
Irbetan	10.0	4.8	8.9	12.0	1.1
Cymbalta	13.8	5.9	6.6	108.7	7.2
Total of 3 key products	60.8	28.7	51.3	18.6	9.5
OxyContin	9.7	4.8	8.9	9.4	0.8
Finibax	6.1	3.0	4.7	29.7	1.4
Differin	4.5	2.1	3.7	23.1	0.8
Pirespa	3.9	1.8	3.4	15.7	0.5
Rapiacta	2.5	0.0	1.4	83.6	1.1
Total of 8 strategic products	87.5	40.4	73.2	19.5	14.3
Export/Overseas subsidiaries	29.7	14.6	17.0	74.9	12.7
Shionogi Inc.	15.5	7.0	5.8	165.0	9.7
C&O	5.6	2.9	1.9	190.1	3.7
Doripenem	3.4	1.8	4.2	(19.7)	(0.8)
Contract manufacturing	10.1	4.7	7.6	32.9	2.5
OTC and quasi-drugs	5.1	2.7	5.0	1.5	0.1
Diagnostics	2.4	1.0	2.7	(11.4)	(0.3)
Royalty income	71.2	34.5	68.7	3.7	2.5
Crestor	68.0	32.7	64.7	5.0	3.3
Others	1.9	1.0	1.9	(1.0)	(0.0)
Total	289.0	138.0	267.3	8.1	21.7



FY2012 Forecasts

Statements of Operating Income (Consolidated)



(Units: B yen)

	FY2012 Forecasts		FY2011 Results	Y on Y	
	Full Year	1 st Half		Change (%)	Change
Sales	289.0	138.3	267.3	8.1	21.7
[Royalty income]	71.2	34.5	68.7	3.7	2.5
Cost of sales	28.5 [37.8] 82.4	29.0 [38.6] 40.0	29.1 [39.1] 77.8	6.0	4.6
Gross profit	206.6	98.0	189.5	9.0	17.1
SG&A expenses	52.1 150.6	53.3 73.5	53.3 142.5	5.7	8.1
Selling & general expenses	94.0	47.0	88.9	5.7	5.1
R&D expenses	56.6	26.5	53.6	5.6	3.0
Operating income	19.4 56.0	17.8 24.5	17.6 47.0	19.1	9.0

Small numbers in red are percentages of sales, and numbers in red provided in parentheses are percentages of royalty excluded sales.



◆ **Preliminary injunction (PI) proceedings**

- **January 2009:**
Shionogi sued Lupin in the US District Court against the ANDA filing of Fortamet
- **September 2011:**
Lupin started selling the generic version of Fortamet at-risk in the US
- **December 2011:**
The US District Court granted Shionogi's motion for a PI against Lupin
(The PI prevents Lupin from further importing and selling Generic Fortamet before the district court renders a decision in the on-going litigation relating to two US patents covering Fortamet)
- **February 2012:**
The CAFC remanded the decision, and then US District Court again granted the PI
Shionogi provided CAFC with briefing as per CAFC's request.
- **April 2012:**
Lupin appealed to CAFC, and CAFC has granted Lupin's request to stay the PI
⇒ Lupin is able to resume sales of its product (Patent suit is still on trial)

◆ **Impact on Fortamet sales in FY2011 and FY2012**

- **Sales and profit for the 2nd half of FY2011:**
Net sales: \$14M Gross margin: \$12M
- **Estimated downside impact on sales in FY2012 is projected from the results in the 2nd half of FY2011 [1st half results included additional deductions]**

CAFC: Court of Appeals for the Federal Circuit, typical hears all appeals from any of the US district courts where the original action included a complaint arising under the patent laws.

FY2012 Forecasts

Forecasts of Shionogi Inc.



(Units: upper/million dollar, **lower/billion yen**)

	FY2012 Forecasts		FY2011 Results	Y on Y		FY2011 2nd Half Results
	Full Year	1st Half		Change (%)	Change	
Sales	194 15.5	87 7.0	74 5.8	161.9	120 9.7	105 8.2
Cost of sales	21 1.6	10 0.8	29 2.3	(28.3)	(8) (0.7)	14 1.1
SG&A expenses	211 16.9	107 8.5	191 15.1	10.4	20 1.8	106 8.4
Operating income	(38) (3.0)	(30) (2.4)	(146) (11.5)	-	108 8.5	(15) (1.1)

Assumed exchange rates: 79.06 yen (FY2011) and 80 yen (FY2012) to the dollar, Y on Y change (%) calculated in US\$.
Yen of Y on Y change includes the difference of exchange rate mentioned above.

◆ **In consideration of the changed circumstance relating to Fortamet, Shionogi Inc. will achieve the FY2012 forecast through the following actions**

- Partially offset the impact of generic Fortamet re-launch through the growth of promoted products (Naprelan and Kapvay) and the launch of authorized generic
- Continue to review product portfolio to focus on the most profitable products
- Continue stable business operations in FY2012 by maintaining focus on deduction control and cost containment

FY2012 forecasts above do not include the costs for pre-launch activities of Ospemifene.

FY2012 Forecasts

Forecasts of C&O



(Units: B yen)

	FY2012 Forecasts		FY2011 Results
	Full year	1 st Half	
Sales	5.6	2.9	1.9
Operating income	0.5	0.3	(0.1)

Results of FY2011 include 6 months from Jul. to Dec. 2011.

◆ Market trend of antibiotics in China

- Impact on antibiotics of the examination continues, but the prescriptions are showing a trend toward recovery

◆ Strengthening of C&O business

- Assign Shionogi Japan employees to key positions to strengthen the management
- Promote cooperation amongst all divisions of Shionogi
- Implement action plan to maximize the market share of Flumarin

Shareholder Return

Dividend Forecasts



	Dividends per Share			Payout ratio
	Half-year	Year-end	Annual	
	Yen	Yen	Yen	
FY2009	18.00	18.00	36.00	31.2%
FY2010	20.00	20.00	40.00	66.9%
FY2011	20.00	(Forecast) 20.00	(Forecast) 40.00	49.4%
FY2012	(Forecast) 20.00	(Forecast) 20.00	(Forecast) 40.00	41.9%

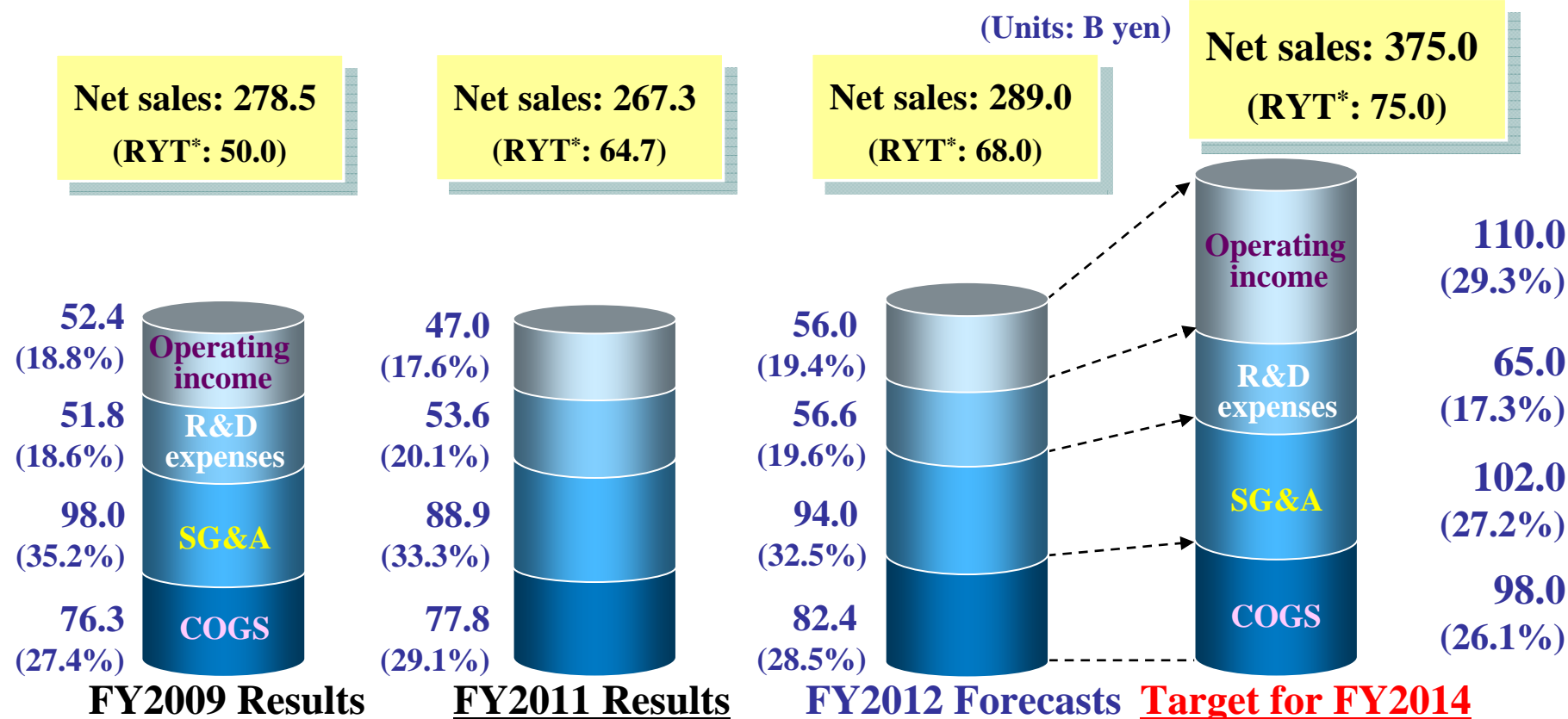
- **FY2011 forecast: 40 yen as planned**
- **FY2012 forecast: 40 yen**
- **Sustain the consolidated payout ratio of 35% based on the 3rd Med-Term Business Plan and return the profit to shareholders in case the financial result exceeds FY2012 forecast**



Progress Toward Achievement of the 3rd Mid-Term Business Plan

Progress toward Achievement of the 3rd Mid-Term Business Plan

Two-year-progress toward the FY2014 Target



To achieve the 3rd Mid-Term Business Plan and invest in R&D for future growth

- Consolidated net sales: 100 B yen up (exclude royalty)
- SG&A expenses: 6% reduction on a net sales basis
- COGS: 3% reduction on a net sales basis

(): % of net sales,
*: Royalty of Crestor

Domestic Sales (prescription drugs)



- Reorganized Human Health Care Division in January 2012 to further focus on newly launched products, increasing of hospital market share and enhancing the productivity per sales representatives (MRs), and strengthen the support for MRs and achieve sales growth through focus on the 8 strategic products
 1. Speed up communication between the head office and field
 2. Strengthen the strategic planning function
 3. Enhance the education and training systems for MRs
 - Return to our basic focus on providing doctors with detailed information about drug in a timely fashion based on Shionogi Policy to adapt to environmental changes due to the enforcement of Transparent Guidelines
- ⇒ Increase the trust of patients, their families and healthcare providers through the above activities, and enhance Shionogi's presence

<Key points to achieve the FY2012 targets>

- Continue sales growth by further focusing on the 8 strategic products to diminish the negative impact of the NHI price revision
- Strengthen strategic planning and implementation based on 3R (Right Targeting, Right Message and Right Frequency) to support MRs



- **Improving manufacturing cost**
 - **Review of suppliers of raw materials and outsourcing process with a global perspective**
 - **Reconsider the timing of capital investments, and review repair and maintenance fees**
 - **Rethink about outsourcing of the products manufactured by Shionogi**
- **Reviewing company-wide costs**
 - **Clarify ongoing costs, and comprehensively review them from the standpoint of cost control**

<Key points to achieve the FY2012 targets>

- **Cost of sales**
 - **Cover the rise in COGS rate on domestic prescription drugs due to NHI price revision with the improvement of manufacturing costs, except for the change of depreciation method and the temporary events that occurred in FY2011**
- **SG&A expenses**
 - **Increased costs for pre-launch activity of Ospemifene and newly consolidated C&O, but review the other costs to keep the total flat y on y in absolute consolidated terms**

Progress toward Achievement of the 3rd Mid-Term Business Plan

Overseas Business Operations



- **Shionogi Inc.:** Increase sales and profit by launching new products starting in FY2013 and continuing proactive business development activities while maintaining stable business operations
- **C&O:** Expand presence in the China market by promoting judicious use and differentiation of our main products (antibiotics), and expanding the sales within the context of the current government restrictions on antibiotic use
- **Taiwan Shionogi:** Utilize as a foothold to promote judicious use of antibiotics in Asian markets next to Japan
- **Shionogi-ViiV:** Establish the best scheme to maximize profit of S-349572, and secure its position as the best-in-class integrase inhibitor in the HIV market

<Key points to achieve the FY2012 targets>

- **Shionogi Inc.**
 - Focus marketing resources on key promoted products, mainly Naprelan and Kapvay to increase sales and strengthen countermeasures against generics
 - Maintain stable business operations to establish a strong business base for growth from FY2013
 - Focus on the pre-launch activities of Ospemifene
- **C&O**
 - Communicate the merit of the combination of Flumarin and Amolin to expand sales and profit
 - Launch Edaravone to complement the China business
 - Strengthen the R&D and cGMP activities

Progress toward Achievement of the 3rd Mid-Term Business Plan *R&D*



- Implement the basic strategies of the 3rd mid-term business plan - Strategy 2 “Investments in the new growth drivers” and Strategy 3 “Therapeutic areas to be focused on”
 - Vigorously advance the global pipeline, S-349572 (dolutegravir), Ospemifene, S-297995, S-555739, and cancer peptide vaccine
 - Complement future growth drivers after Crestor cliff by in-licensing
 - Deal with unmet medical needs in priority areas flexibly and pursue innovative early research in new therapeutic areas

<Key points to achieve the FY2012 forecasts>

- NDA filed for Ospemifene, and NDA filing for S-349572 as planned
- Speed up global development by the full-scale operation of EU development foothold in UK
- Maximize the development asset value with appropriate prioritization



◆ **Crestor Royalty**

- Steady growth of global sales based on strong clinical evidence such as “total lipid control” and “the statin that promotes efficient plaque regression”
- Only one promoted branded statin after the launch of generic Lipitor
- Impact of Lipitor generics in the US market is limited so far

◆ **Others**

- Efficient balance sheet
 - Continued review of the efficiency of asset utilization, and consideration of the potential sale of assets
- Strengthen tax strategy in accordance with our globalization
 - Manage the balance of profit and cost with the global business footholds



Pipeline



Core Global Development Products		
S-349572 (dolutegravir)*	HIV infection	Global: NDA filing
Ospemifene	Post-menopausal vaginal atrophy	US: NDA filing (filed in April 2012)
S-297995	Alleviation of opioid-induced adverse effects	US/Japan: Phase IIb LPO, key-opening Meeting with each regulatory agency
S-555739	Allergic rhinitis	Japan: Phase IIb LPO, key-opening US: Phase IIa FPI
S-888711	Thrombocytopenia	Japan: Phase IIb initiation
S-707106	Type 2 Diabetes	Go/No-go decision
S-288310	Bladder cancer	Japan: Go/No-go decision based on Phase I/II results
S-488410	Esophageal cancer	Japan: Go/No-go decision based on Phase I/II results
S-488210	Head and neck squamous cell carcinoma	EU: Phase I/II FPI
S-646240	Age-related macular degeneration	Japan: Phase IIa FPI
S-265744 LAP*	HIV infection	US: Phase I completion, Phase II initiation
S-649266	Bacterial infections	Japan: Phase I completion US: Phase I initiation

LPO: Last patient out, FPI: First patient in, LAP: Long-acting parenteral formulation

* Developed by Shionogi-ViiV Healthcare LLC

Dolutegravir (Integrase inhibitor, Oral): HIV infection

◆ **Initial data from Phase III study**

- **SPRING-2 study design**

- 822 treatment-naïve patients with HIV-1
- Dolutegravir 50mg (once-daily) vs. Raltegravir (RAL) 400mg (twice-daily), randomized (double-blind)
- Primary objective: antiviral activity of dolutegravir compared to RAL over 48-weeks
- Secondary objective: antiviral activity of dolutegravir compared to RAL at 96-weeks, to compare the tolerability, long-term safety and antiviral and immunologic activity of dolutegravir to RAL and to evaluate viral resistance in study participants experiencing virological failure

- **Show non-inferiority of antiviral activity of dolutegravir**

- Ratio of virological suppression (<50 copies/mL)
dolutegravir: 88% vs. RAL: 85%

- **The tolerability and rates of adverse events leading to withdrawal of dolutegravir were similar to those of RAL.**

Progressing other Phase III studies as planned ⇒ NDA/MAA in FY2012



Ospemifene (SERM, Oral): Vulvar and vaginal atrophy (VVA)

◆ **Status**

- **NDA filing in the US in April 2012**

◆ **Market**

- **Large potential market (60% of women aged 60 or older, about over 30 million women, are suffering from VVA*)**
- **About 3.6M of VVA patients are treated in the US**
- **70-80% of VVA patients are not treated**
- **Provide a new treatment option for VVA patients as the first-in-class oral product for this indication**
- **Under consideration for global development in Japan and EU**

Ospemifene will be the first NCE to be launched by Shionogi Inc. and a key driver for the future growth of Shionogi Inc.

SERM: Selective estrogen receptor modulator, NCE: New Chemical Entity

*: Bachmann, et al, The Journal of North American Menopause Society Vol.17,480,2011



S-297995 (Peripheral opioid receptor antagonist, Oral):
Relief of opioid-induced gastrointestinal symptoms such as nausea, vomiting and constipation

◆ **Current status and future plan**

- Phase IIb studies for opioid-induced constipation in the US and Japan
- Last patient out, key-opening and meeting with each regulatory agency in FY2012

S-555739 (PGD2 receptor antagonist, Oral): Allergic rhinitis

◆ **Current status and future plan**

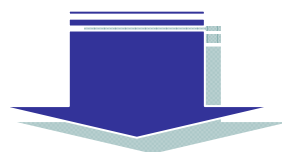
- Phase IIb in Japan
- Last patient out, key-opening in FY2012
- Phase I completed, Phase IIa in preparation in the US

Globally develop in-house compounds in Phase III study



◆ **Encompass worldwide right to peptide vaccines for all indications**

- **Entered into exclusive licensing agreement with OncoTherapy Science to develop and market cancer peptide vaccines**
- **Previous agreement (dated February 2009)**
 - **In-licensed specific peptides related to five different types of oncoantigens, and has been developing therapeutic vaccines for the treatment of cancers, including bladder cancer and esophageal cancer (S-288310, S-488410 and S-488210)**



Expected to be effective for other kinds of cancer therapy

- **New agreement (dated March 2012)**
 - **Not only several cancer therapies but also all indications for specific peptides**
 - **Encompass worldwide rights to peptide vaccines discovered by OTS, for all indications, to develop, manufacture and market peptide vaccines**



◆ **Approved**

- **Cymbalta®: Diabetic peripheral neuropathic pain**
 - Japan: Approved in February 2012

◆ **Change of Phases**

- **Ospemifene (Selective Estrogen Receptor Modulator, Oral):
Post-menopausal vaginal atrophy**
 - NDA filing in the US in April 2012
- **S-474474 (Irbesartan/trichlormethiazide combination, Oral):
Hypertension**
 - NDA filing in preparation in Japan
- **S-2367 (Neuropeptide Y Y5 receptor antagonist, Oral): Obesity**
 - Started Phase IIb in Japan
- **S-555739 (Prostaglandin D2 receptor antagonist, Oral):
Allergic rhinitis**
 - Phase IIa in preparation in the US
- **S-488210 (Cancer peptide vaccine, Injection):
Head and neck squamous cell carcinoma**
 - Started Phase I/II in EU



◆ **Newly added**

- **S-649266*** (Cephem antibiotic, Injection): Bacterial infections
 - Started Phase I in Japan
- **S-646240** (Peptide vaccine of age-related macular degeneration, Injection): Age-related Macular Degeneration
 - Started Phase IIa in Japan
- **S-877489**** (CNS stimulant, Oral): ADHD
 - Started Phase I in the US (for development in Japan)
- **S-877503**** (Non-CNS stimulant, Oral): ADHD
 - Started Phase I in Japan

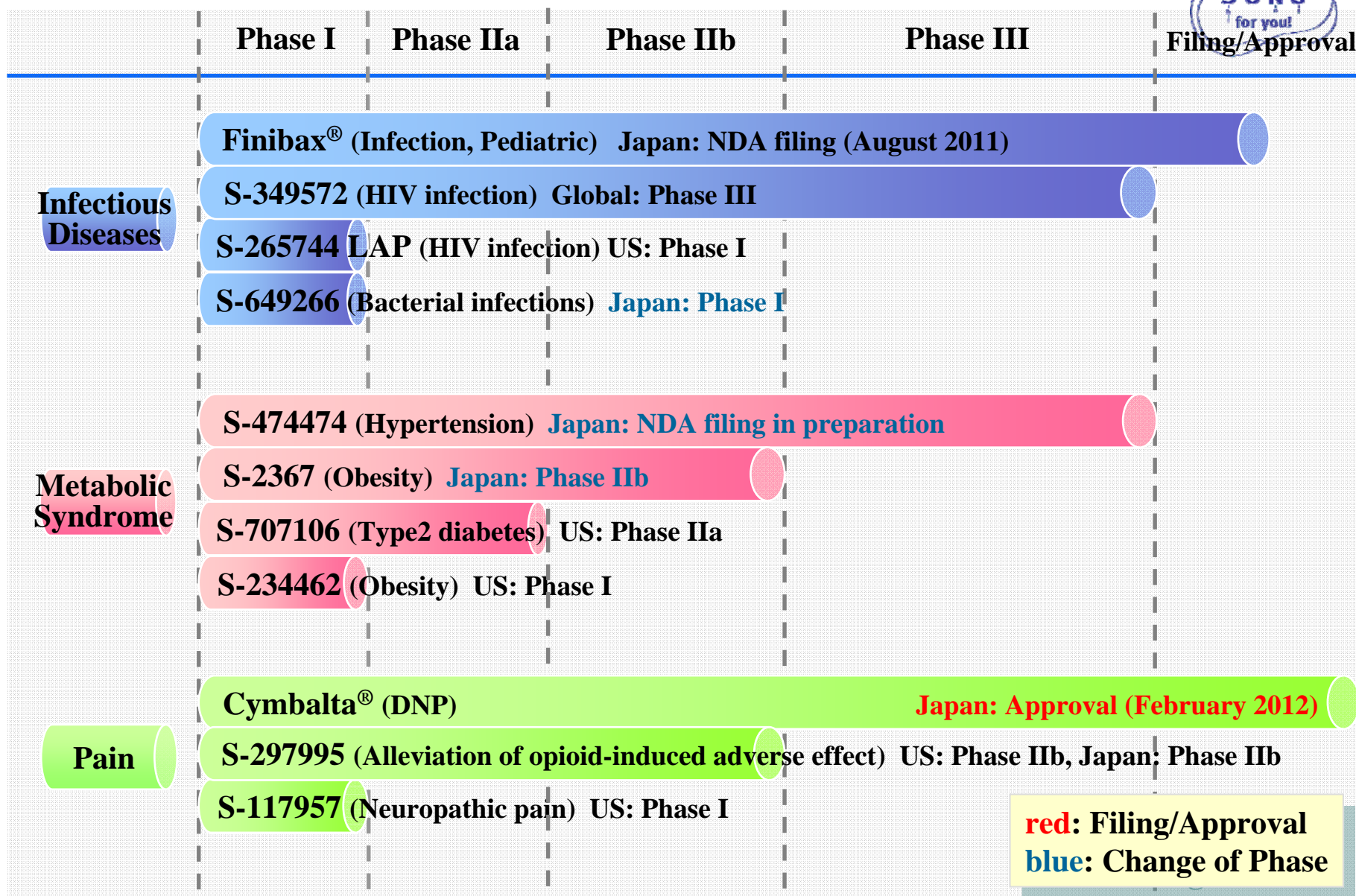
* : Collaboration with GSK

** : Collaboration with Shire

◆ **Discontinued development**

- **S-3013** (Secretory PLA2 inhibitor, Oral): Acute coronary syndromes
 - Licensed to Anthera

Pipeline (as of May 2012)



Pipeline (as of May 2012)



	Phase I	Phase IIa	Phase IIb	Phase III	Filing/Approval
Peptide Vaccine	S-288310 (Cancer peptide vaccine, Bladder cancer) Asia: Phase I/II				
	S-488410 (Cancer peptide vaccine, Esophageal cancer) Japan: Phase I/II				
	S-488210 (Cancer peptide vaccine, Head and neck squamous cell carcinoma)				EU: Phase I/II
	S-646240 (Age-related Macular Degeneration)				Japan: Phase IIa
Others	Ospemifene (Post-menopausal vaginal atrophy)				US: NDA filing (April 2012)
	PSD502 (Premature ejaculation)				US/EU: Phase III
	S-555739 (Allergic rhinitis)		EU: Proof of Mechanism, US: Phase IIa in preparation, Japan: Phase IIb		
	S-888711 (Thrombocytopenia)				US/EU: Phase II, Japan: Phase IIa
	S-524101 (Allergic rhinitis caused by house-dust mite allergen)				Japan: Phase II in preparation
	S-222611 (Malignant tumor)				EU: Phase Ib
	S-877489 (ADHD)				US: Phase I
	S-877503 (ADHD)				Japan: Phase I
<Out-licensed>	Doripenem (Respiratory tract infection)				US: Filed
	S-0373 (Spinocerebellar ataxia)				Japan: Phase II

red: Filing/Approval
blue: Change of Phase

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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