



1st Half of Fiscal 2011 Financial Results

November 1, 2011

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President and Chief Executive Officer



Overview of 1st Half FY2011

Financial Results

1st Half FY2011 Results



Financial Results (Consolidated)

(Units: B yen)

	1 st Half FY2011 Forecasts	1 st Half FY2011 Results	Achievement (%)	1 st Half FY2010 Results	Y on Y Change (%)	Change
Sales	134.5	124.0	92.2	143.3	(13.5)	(19.3)
Operating income	24.5	18.2	74.4	19.2	(5.1)	(1.0)
Ordinary income	23.5	18.4	78.4	17.6	4.1	0.8
Net income	15.5	8.2	52.9	6.8	19.5	1.4

Due to change in the accounting periods, 1st half results of FY2010 include 9 months from Jan.1 to Sep.30 for the US subsidiaries.

(Units: yen)

Exchange rate (average)	Forecasts	1 st Half FY2011 Results
USD(\$)	80	79.74
EUR(€)	115	113.72



Financial Position (Consolidated)

(Units: B yen)

	Sep. 30, 2011	Mar. 31, 2011	Change
Total assets	512.9	523.2	(10.3)
Net assets	324.7	328.0	(3.3)
Equity ratio (%)	62.6	62.7	(0.1)

◆ Acquisition of C&O Pharmaceutical Technology (Holdings) Limited

- Acquired majority of C&O as of the end of September, making it a subsidiary of Shionogi (General offer was ended on October 12, 2011)
- At present, the difference between the acquisition price and C&O's net assets will be accounted for as goodwill
- However, detailed evaluation of intangible assets and definition of purchase price allocation may alter the balance sheet treatment



Cash Flows (Consolidated)

(Units: B yen)

	1 st Half FY2011	1 st Half FY2010	Change
Net cash provided by operating activities	23.3	30.9	(7.6)
Net cash provided by investing activities	(25.3)	(16.3)	(9.0)
Net cash provided by financing activities	(13.8)	(13.1)	(0.7)
Net increase (decrease)	(16.7)	(0.9)	(15.8)
Cash and cash equivalents at end of period	93.9	96.7	—

◆ Net cash used in investing activities

- Product acquisition from Victory Pharma, Inc.: 9.4 billion yen
- Acquisition of shares in C&O: 10.5 billion yen (as of the end of September, 2011)

1st Half FY2011 Results



Sales by Segments (Consolidated)

(Units: B yen)

	1 st Half FY2011 Forecasts	1 st Half FY2011 Results	Achievement (%)	1 st Half FY2010 Results	Y on Y Change (%)	Y on Y Change
Prescription drugs	80.4	78.7	98.0	75.1	4.8	3.6
Crestor	17.6	17.2	97.7	13.7	25.7	3.5
Irbetan	4.8	4.3	88.7	3.3	29.0	1.0
Cymbalta	2.5	2.8	113.5	0.9	219.6	1.9
Total of 3 strategic products	24.9	24.3	97.5	17.9	35.9	6.4
OxyContin	5.1	4.5	88.3	4.8	(6.1)	(0.3)
Finibax	2.0	2.2	109.8	1.8	21.9	0.4
Differin	1.9	1.7	89.6	1.5	16.7	0.2
Pirespa	1.6	1.6	101.5	1.3	29.4	0.3
Rapiacta	0.1	0	7.2	0	-	0
Total of 8 strategic products	35.6	34.3	96.4	27.2	26.3	7.1
Flomox	9.0	9.8	109.3	10.1	(2.8)	(0.3)
Rinderon	4.5	4.8	107.7	5.0	(3.8)	(0.2)
Claritin	3.5	3.2	90.4	3.1	3.1	0.1
Flumarin	3.3	3.5	106.0	3.9	(10.2)	(0.4)
Export/Overseas subsidiaries	12.3	2.0	17.0	26.0	(92.0)	(24.0)
Shionogi Inc.	7.2	(2.4)	-	21.0	-	(23.4)
Doripenem	1.9	1.9	97.7	2.5	(25.3)	(0.6)
Contract manufacturing	3.1	3.7	122.5	1.8	108.0	1.9
OTC and quasi-drugs	2.5	2.7	108.0	2.8	(4.9)	(0.1)
Diagnostics	1.2	1.3	112.7	1.5	(7.7)	(0.2)
Royalty income	34.0	34.3	101.0	34.8	(1.6)	(0.5)
Crestor	32.0	32.3	101.0	32.8	(1.4)	(0.5)
Others	1.0	0.9	95.0	1.2	(19.5)	(0.3)
Total	134.5	124.0	92.2	143.3	(13.5)	(19.3)

Due to change in the accounting periods, 1st half results of FY2010 include 9 months from Jan.1 to Sep.30 for the US subsidiaries.

1st Half FY2011 Results



Statements of Income (Consolidated)

(Units: B yen)

	1 st Half FY2011 Forecasts	1 st Half FY2011 Results	Achievement (%)	1 st Half FY2010 Forecasts	Y on Y Change (%)	Y on Y Change
Sales	134.5	124.0	92.2	143.3	(13.5)	(19.3)
[Royalty income]	[34.0]	[34.3]	[101.0]	[34.8]	[(1.6)]	[(0.5)]
	27.5 [36.8]	30.3 [41.8]		27.2 [36.0]		
Cost of sales	37.0	37.5	101.4	39.0	(3.9)	(1.5)
Gross profit	97.5	86.4	88.7	104.3	(17.1)	(17.9)
SG&A expenses	54.3 73.0	55.0 68.2	93.5	59.3 85.0	(19.8)	(16.8)
Selling & general expenses	45.0	42.5	94.5	56.9	(25.4)	(14.4)
R&D expenses	28.0	25.7	91.8	28.0	(8.5)	(2.3)
Operating income	18.2 24.5	14.7 18.2	74.4	13.4 19.2	(5.1)	(1.0)
Extraordinary income and loss	—	L3.8	—	L6.1	—	—

Due to change in the accounting periods, 1st half results of FY2010 include 9 months from Jan.1 to Sep.30 for the US subsidiaries.

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



Difference between Forecasts and Results

Extraordinary income and loss: L3.8 B yen

● Extraordinary income:	+ 0.6
➤ Sales of idle real estate and investment securities	0.5
➤ Gain on sales of investment securities	0.1
● Extraordinary loss:	(4.5)
➤ Impairment loss	(1.5)
➤ Loss on penalty	(1.1)
➤ Impact of the Great Eastern Japan Earthquake	(1.0)
➤ Business structure improvement expenses	(0.5)
➤ Loss on valuation of investment securities	(0.1)
	(FYI: 1Q) (2.7)

Note: As the described numerical value is cut, the total value might not agree with the sum of individual numerical values.



Financial Results of Shionogi Inc.

(Units: upper/M dollar, lower/B yen)

	FY2011						FY2010
	1 st Half						1 st Half Results
	Forecasts	Results	1Q	2Q			
			Results	Results	Additional Allowance	Before Allowance	
Sales	91 7.2	(31) (2.4)	31 2.5	(62) (5.0)	117 9.3	54 4.2	235 21.0
Cost of sales	14 1.1	15 1.2	6 0.5	8 0.7	-	8 0.7	56 5.0
SG&A expenses	97 7.7	85 6.7	43 3.5	42 3.2	-	42 3.2	214 19.1
Operating income	(20) (1.6)	(131) (10.4)	(17) (1.4)	(113) (9.0)	-	3 0.2	(35) (3.2)

<Results in 2Q FY2011>

- **Sales:** Sales before the deduction of the additional allowance was close to the prior forecast. The products from Victory Pharma contributed as planned. Prenate, however, was below forecast due to supply interruptions
- **SG&A expenses:** Stabilized by continued focus on cost containment
- **Operating income:** Results before deduction of additional allowances exceeded the forecast slightly
- **Additional allowance:** Reflects revised allowances for returns (\$72M) and rebates (\$45M)

US Operations ((Calculation Process for Return Allowance)



Traditional Method

$$\left(\begin{array}{l} \text{Stocks in circulation} \\ \text{Data from major wholesalers} \\ \text{Assumed stocks in pharmacies} \end{array} \right) \times \begin{array}{l} \text{Average return ratio} \\ \text{based on past record} \\ \text{of major products} \end{array} = \text{Allowance for sales returns}$$

Revised Method

Lot-by-lot analysis of product-by-product return history and current stocks at major wholesalers and pharmacies (estimated)

Projected returns by product, by lot, by quarter (illustrated)

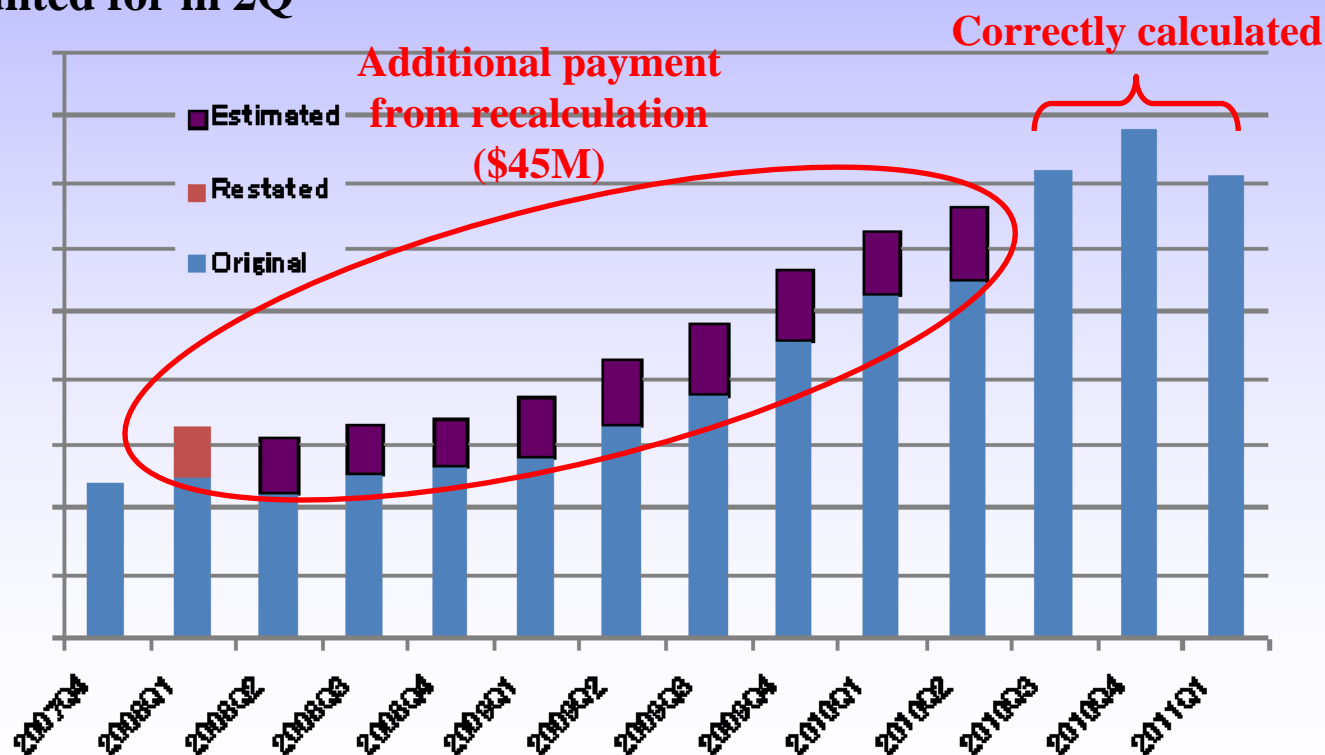
	2011 3Q	2011 4Q	2012 1Q	2012 2Q	2012 3Q	2012 4Q	2013 1Q	2013 2Q	2013 3Q	2013 4Q	2014 1Q	2014 2Q	2014 3Q	2014 4Q	Sales returns (Return ratio)
Lot. A															\$XXM (a%)
Lot. B															\$XXM (b%)
Lot. C															\$XXM (c%)
Lot. D															\$XXM (d%)
:															
Lot. Z															\$XXM (z%)

Example shows extensive variability that may be seen in product returns Total: \$72M

US Operations (Determination of Medicaid Rebates)



- For drugs covered by Medicaid, Medicaid rebates are calculated and paid based on a method specified by authorities
- Based on internal audit, our calculations were found to be potentially incorrect. Recent quarters were correctly calculated, but retrospective recalculation of past quarters was believed to potentially be required. Investigation and verification were undertaken and cumulative insufficient payments for prior quarters were accounted for in 2Q





Review of 1st Half FY2011

◆ Japanese domestic sales (prescription drugs)

- Sales of 3 strategic products or 8 strategic drugs increased 36% or 26% y on y, respectively
- Delay of progress in SG&A expenses as a result of the Great Eastern Japan Earthquake

◆ Crestor royalty

- Growth based on robust expansion of global sales in spite of yen appreciation

◆ R&D

- Completion in Bioequivalence study of Ospemifene
- Progression of development of S-555739 (Ph2b in Japan, Ph1 in the US)

◆ Overseas operations (Shionogi Inc.)

- Accounting allowances for product returns and Medicaid rebates
- Without inclusion of these accounting allowances, the financial results in 2Q almost reached the original forecast



Review of US Operations (Events and Improvement Efforts)

	FY2010		FY2011	
	3Q	4Q	1Q	2Q
Deteriorating factors in business	Generic competition Wholesaler's stock buydown High level of rebates and chargebacks		Generic competition Revising allowances	
Returns	■Returns due to quality issues		■Unexpected returns from past sales ■Conducted analysis to assess best return ratio calculation	■Revised calculation process for return allowances ■Accounted for past sales
Medicaid rebates	■Suspected re-calculation may be required	■Accounted allowances for 3Q and 4Q with proper calculation ■Started to investigate and verify to determine proper calculation	■Used corrected approach from 1Q forward	■Booked insufficient payment from 2008/1Q to 2010/2Q
Trial cards	■Excessive provision of trial cards (e.g. for Prenate)		■Eliminated old excessive programs ■Establish firm controls on current programs	

Review of US Operations (for Business Structure Improvement and Future Growth)

	FY2008-2009	FY2010	FY2011	After FY2013
	Operation as “Specialty pharma” business model	Transition to “Pure pharma” model	Stabilize business performance	Regrowth by new drugs
Event	<ul style="list-style-type: none"> ■ Acquisition of Sciele Pharma ■ Acquisition of Addrenex by Sciele 	<ul style="list-style-type: none"> ■ Deterioration in business ■ Establishment of Shionogi Inc. ■ Reduce the workforce 	<ul style="list-style-type: none"> ■ Complete integration from Atlanta to NJ ■ Establishment of new management team 	
Product		<ul style="list-style-type: none"> ■ Shut down of the Primary Care unit ■ Quality issues ■ Dispatch experts on CMC from Japan ■ Improving management of wholesalers 	<ul style="list-style-type: none"> ■ Acquisition of products from Victory 	<ul style="list-style-type: none"> ■ Ospemifene ■ S-349572 ■ S-297995 etc.

- ◆ Because of decreasing sales of former Sciele products, performance became unstable in transition to a new model focused on “Shionogi-brand products”.
- ◆ Business stability is improving substantially, due to factors including integration of offices, improved focus and skill of commercial organization, careful management of wholesalers, trial cards and rebate programs, and better financial management

FY2011 Financial Forecasts

FY2011 Forecasts



Revision of FY2011 Financial Forecasts (Consolidated)

(Units: B yen)

	FY2011							FY2010	Y on Y Change (%)
	Full Year			1 st Half	2 nd Half			Results	
	Original Forecasts	Revised Forecasts	Change from Original	Results	Original Forecasts	Revised Forecasts	Change from Original		
Sales	286.0	269.0	(17.0)	124.0	151.5	145.0	(6.5)	282.3	(4.7)
Operating income	58.0	46.0	(12.0)	18.2	33.5	27.7	(5.7)	46.8	(1.9)
Ordinary income	56.0	44.0	(12.0)	18.4	32.5	25.5	(6.9)	45.1	(2.6)
Net income	37.0	27.0	(10.0)	8.2	21.5	18.7	(2.7)	20.0	34.8

Due to change in the accounting periods, results in FY2010 include 15 months for the U.S. subsidiaries.

FY2011 Forecasts



Revision of FY2011 Forecasts (Sales by Segments/Consolidated)

(Units: B yen)

	FY2011							FY2010	Y on Y
	Full Year			1st Half	2nd Half			Results	Change (%)
	Original	Revised	Change	Results	Original	Revised	Change		
Prescription drugs	167.5	165.8	(1.7)	78.7	87.1	87.1	–	158.9	4.4
Crestor	37.0	36.6	(0.4)	17.2	19.4	19.4	–	29.0	26.4
Irbetan	10.5	9.7	(0.8)	4.3	5.7	5.4	(0.3)	7.3	33.5
Cymbalta	5.5	6.1	0.6	2.8	3.0	3.3	0.3	2.7	129.4
Total of 3 strategic products	53.0	52.4	(0.6)	24.3	28.1	28.1	–	38.9	34.8
OxyContin	10.5	9.9	(0.6)	4.5	5.4	5.4	–	9.6	2.8
Finibax	4.2	4.6	0.4	2.2	2.2	2.4	0.2	3.6	29.1
Differin	4.1	3.6	(0.5)	1.7	2.2	1.9	(0.3)	3.2	12.9
Pirespa	3.4	3.4	-	1.6	1.8	1.8	–	2.8	23.4
Rapiacta	1.5	1.4	(0.1)	0	1.4	1.4	–	0.3	399.8
Total of 8 strategic products	76.7	75.3	(1.4)	34.3	41.1	41.0	(0.1)	58.3	29.2
Flomox	19.0	20.9	1.9	9.8	10.0	11.1	1.1	21.9	(4.5)
Rinderon	9.2	9.5	0.3	4.8	4.7	4.7	–	9.5	(0.2)
Claritin	7.5	7.2	(0.3)	3.2	4.0	4.0	–	10.0	(27.9)
Flumarin	6.2	6.4	0.2	3.5	2.9	2.9	–	7.5	(14.9)
Export/Overseas subsidiaries	31.9	15.3	(16.6)	2.0	19.6	13.3	(6.3)	37.4	(59.3)
Shionogi Inc.	20.8	5.7	(15.1)	(2.4)	13.6	8.2	(5.4)	27.0	(78.6)
Doripenem	5.0	4.8	(0.2)	1.9	3.1	2.9	(0.2)	4.7	2.7
Contract manufacturing	6.8	7.8	1.0	3.7	3.7	4.1	0.4	5.4	44.2
OTC and quasi-drugs	5.1	5.3	0.2	2.7	2.6	2.6	–	5.2	2.4
Diagnostics	2.7	2.8	0.1	1.3	1.5	1.5	–	2.9	(2.1)
Royalty income	70.0	70.0	-	34.3	36.0	35.7	(0.3)	68.9	1.6
Crestor	67.0	67.3	0.3	32.3	35.0	35.0	–	64.2	4.8
Others	2.0	2.0	-	0.9	1.0	1.1	0.1	3.6	(45.3)
Total	286.0	269.0	(17.0)	124.0	151.5	145.0	(6.5)	282.3	(4.7)

Due to change in the accounting periods, results in FY2010 include 15 months for the U.S. subsidiaries.

FY2011 Forecasts



Revision of FY2011 Forecasts of Shionogi Inc.

(Units: upper/M dollar, lower/B yen)

	FY2011							FY2010
	Full Year			1 st Half	2 nd Half			Results
	Original	Revised	Change	Results	Original	Revised	Change	
Sales	260 20.8	73 5.7	(187) (15.1)	(31) (2.4)	169 13.6	104 8.2	(65) (5.4)	312 27.0
Cost of sales	43 3.4	28 2.2	(15) (1.2)	15 1.2	29 2.3	13 0.9	(16) (1.4)	79 6.8
SG&A expenses	217 17.4	192 14.9	(25) (2.5)	85 (6.7)	120 9.7	106 8.1	(14) (1.6)	312 27.0
Operating income	0 0	(146) (11.4)	(146) (11.4)	(131) (10.4)	20 1.6	(15) (0.9)	(35) (2.5)	(80) (6.9)

<Forecasts for 2nd Half FY2011>

Due to change in the accounting periods, results in FY2010 include 15 months for the U.S. subsidiaries.

- **Sales:** The average sales per quarter in the revised projection for the 2nd half, is similar to the 2Q sales result obtained before allowances
Positive factors: improvements in quality issues, promotional performance for Naprelan and Kapvay, launch of authorized generic strategy
Challenges: Entry of generic version of Fortamet, consequences of interruption of Prenate supply
- **Deductions:** Improved due to changes in commercialization strategy (e.g. Kapvay and Ulesfia) and more stable and reliable projections going forward
- **SG&A expenses:** Ongoing cost containment efforts from present level

FY2011 Forecasts



Revision of FY2011 Financial Forecasts (Statements of Income: Consolidated)

(Units: B yen)

	FY2011						FY2010	Y on Y Change (%)
	Full Year			1st Half	2nd Half		Results	
	Original	Revised	Change	Results	Original	Revised		
Sales	286.0	269.0	(17.0)	124.0	151.5	145.0	282.3	(4.7)
[Royalty income]	[70.0]	[70.0]	-	[34.3]	[36.0]	[35.6]	[68.9]	[1.6]
Cost of sales	27.6 [36.6] 79.0	28.6 [38.7] 77.0	(2.0)	30.3 [41.8] 37.5	27.7 [36.4] 42.0	27.2 [36.1] 39.4	28.9 [38.3] 81.7	(5.8)
Gross profit	207.0	192.0	(15.0)	86.4	109.5	105.5	200.6	(4.3)
SG&A expenses	52.1 149.0	54.3 146.0	(3.0)	55.0 68.2	50.2 76.0	53.6 77.7	54.4 153.7	(5.0)
Selling & general expenses	92.0	89.0	(3.0)	42.5	47.0	46.4	102.8	(13.4)
R&D expenses	57.0	57.0	-	25.7	29.0	31.2	50.9	11.9
Operating income	20.3 58.0	17.1 46.0	(12.0)	14.7 18.2	22.1 33.5	19.1 27.7	16.6 46.8	(1.9)

Small numbers in red are percentages of sales, and numbers in red provided in parentheses are percentages of royalty excluded sales.
Due to change in the accounting periods, results in FY2010 include 15 months for the U.S. subsidiaries.

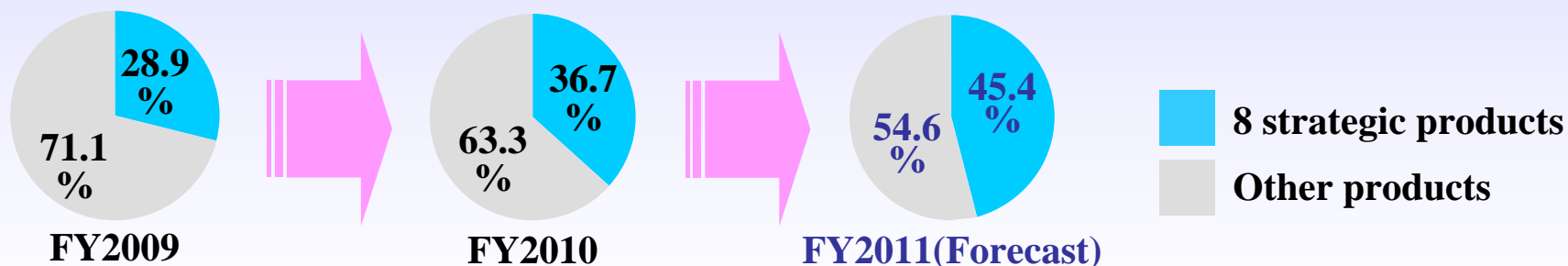
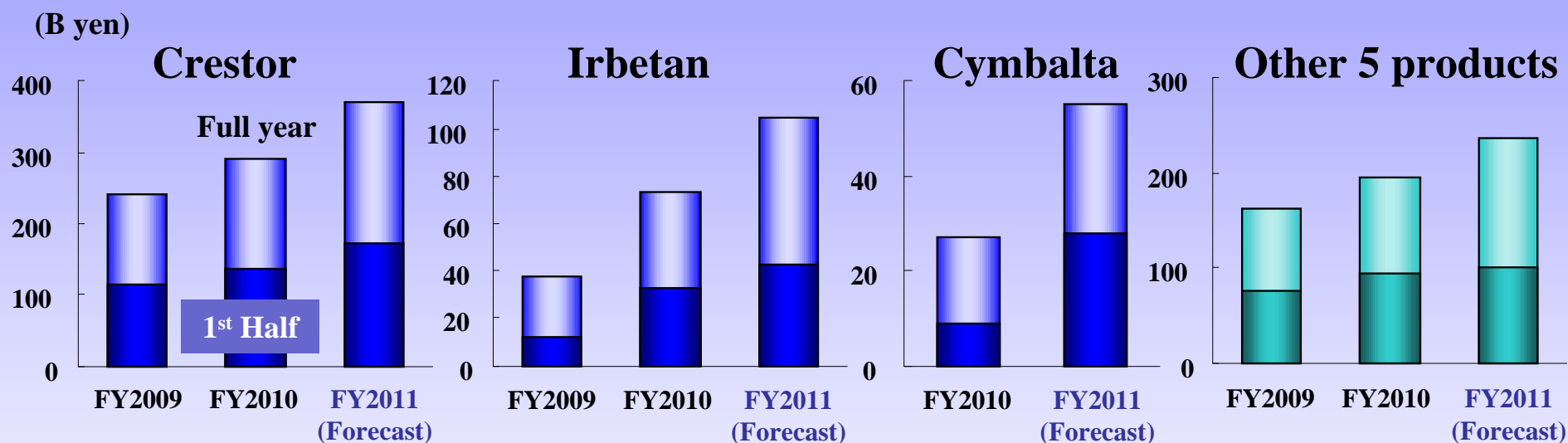
*Direction to Achievement of
the 3rd Mid-Term Business Plan*

Direction to Achievement of the 3rd Mid-Term Business Plan



Current Situation in Domestic Sales (focus on 8 strategic products)

◆ Sales trend and proportion in domestic sales



- Continuous growth compared with FY2010
- Robust sales expansion of 8 strategic products

Direction to Achievement of the 3rd Mid-Term Business Plan

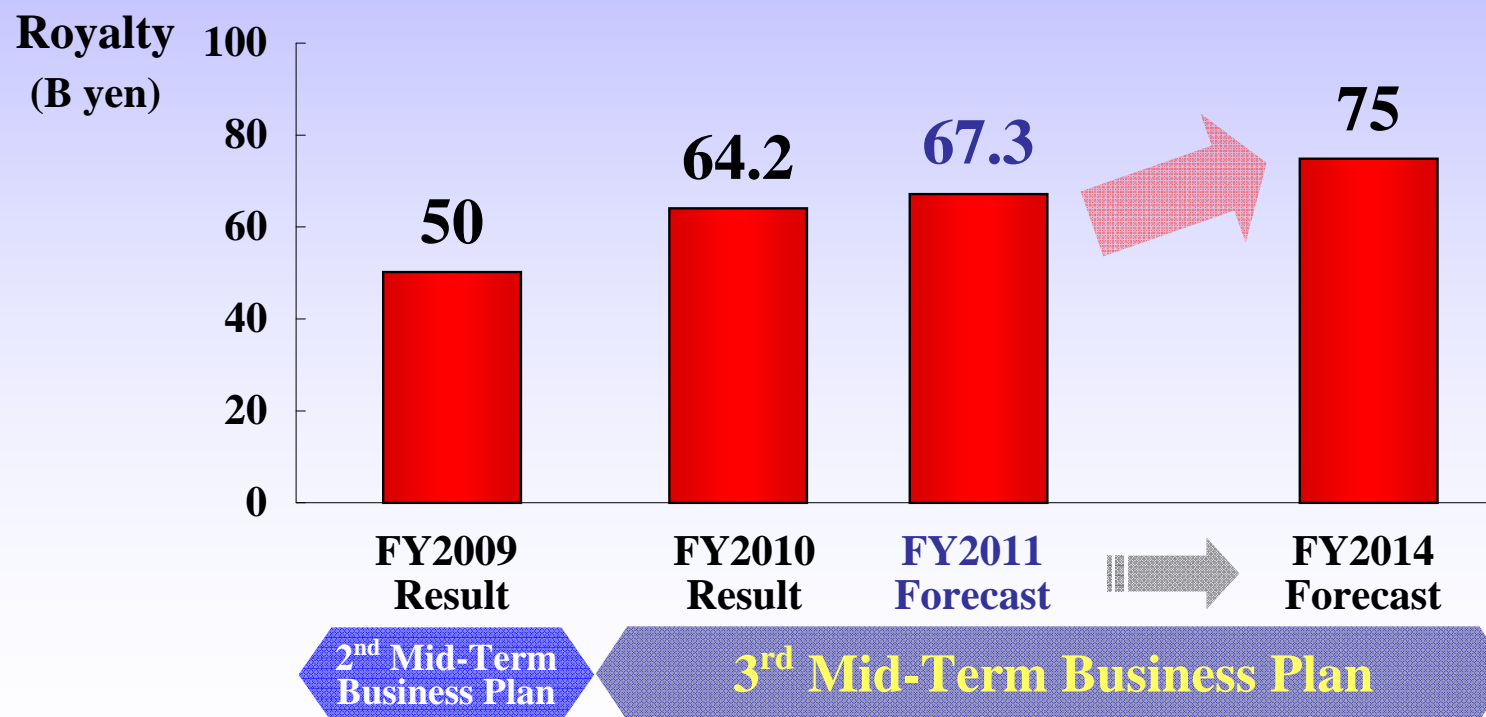


Crestor Royalty

◆ Steady growth of global sales by AstraZeneca

- Nine months results (Jan.-Sep.) : \$4.9B (increased of 18% y on y)

Year	2006	2007	2008	2009	2010	2011(Jan.-Sep.)
Global sales (\$B)	2.0	2.8	3.6	4.5	5.7	4.9





Acquisition of C&O Pharmaceutical Technology (Holdings) Limited

◆ **Completion of a general offer**

- **Completion date: October 12, 2011**
- **Proportion of shareholding after the offer**
 - **Shionogi: 63.82%, Sumitomo Corp. : 29%, Mr. Gao Bin: 5%**

◆ **Significance for a general offer**

- **Expansion of global business foothold following the US**
 - **Establishment of sales and development platform in China which has significant pharmaceutical market**
- **Synergy effects from the consistency of therapeutic area**
 - **Prompt launch and sales expansion of our products such as Flumarin and other antibiotics in Chinese market through C&O**
- **Business deployment by the collaboration**
 - **Stable operation and sustainable growth by collaboration with Sumitomo Corp. and Mr. Gao Bin, an Executive Director of C&O**

Contribute to achievement of the 3rd Mid-Term Business Plan and subsequent growth of Shionogi group



◆ Domestic sales

- Continuous concentration on 8 strategic products

◆ Crestor royalty

- Sustainable growth in the world allow us to invest in growth strategy

◆ Overseas operations

- Expand the sales of “Shionogi-brand products” by prompt development and launch of global pipelines
- Enter the Chinese business with C&O, and expand the sales and profit based on the launch of our products

◆ R&D

- Achieve steady development toward the launch from FY2013 onward by the appropriate prioritization on pipeline such as Go/No-Go decision

Steady progress for the “Real Growth”
→ Toward the financial target for FY2014



Dividend Forecast

	Dividends per Share		
	Half-year	Year-end	Annual
	Yen	Yen (Forecast)	Yen (Forecast)
FY2011	20 . 00	20 . 00	40 . 00
FY2010	20 . 00	20 . 00	40 . 00

- **FY2011 forecast: 40 yen as planned**

Pipeline



Change of Phases (since August 2011)

◆ Change of Phases

- **Finibax[®] (Carbapenem antibiotic, Injection): Bacterial infection**
 - Pediatric infection: NDA filing in Japan
- **Ospemifene (Selective Estrogen Receptor Modulator; SERM, Oral): Post-menopausal vulvar and vaginal atrophy**
 - Completed BE and NDA filing in preparation in the US
- **S-555739 (PGD2 receptor antagonist, Oral): Allergic rhinitis**
 - Started Phase I in the US
 - Started Phase IIb in Japan
- **S-288310 (Cancer peptide vaccine, injection): Bladder cancer**
 - Started Phase I/II in Asia
- **S-524101 (Sublingual tablet of house-dust mite allergen extracts for immunotherapy): Allergic rhinitis caused by house-dust mite allergen**
 - Phase II in preparation in Japan

Finibax[®]: Additional Dosage for Pediatric Infection

◆ **NDA in August 5, 2011**

- **Pediatric infections (additional new dosage regimen)**
- **Purulent meningitis (additional new indication)**

◆ **Results of pediatric clinical study**

- **Efficacy**
 - **Efficacy against general infectious diseases: 96.8% (92/95)**
 - **Confirmed efficacy against purulent meningitis**
- **Safety**
 - **Side effect: 28.0% (30/107)**
 - **No side effect in central nervous system (e.g. twitching which can occur upon carbapenem administration)**
 - **No serious adverse events or severe side effects reported**

Finibax[®]: Results of Clinical Study in Pediatrics

◆ Clinical efficacy

Diseases	CR	PR	MR	NC	Total	Efficacy rate
General infectious diseases	69	23	3	0	95	96.8%
Respiratory tract infections	47	9	2	0	58	96.6%
Urinary-tract infections	8	4	0	0	12	100.0%
Tympanitis	4	4	0	0	8	100.0%
Septicemia, others*	10	6	1	0	17	94.1%
Purulent meningitis**	2	4	0	0	6	100.0%

General infectious diseases: 20mg/kg x 1, 2 or 3 times/day; Purulent meningitis: 30mg or 40mg/kg x 1, 3 times/day

*: septicemia (5), lymph vessel/lymph pneumonia (2), pharynx/pharyngitis (4), adenoiditis (1), circummandibular cellulitis phlegmon (5)

** : including combination therapy based on guideline



Ospemifene: NDA in Preparation in the US *(Post-menopausal Vulvar and Vaginal Atrophy: VVA)*

VVA: Vulvar and vaginal atrophy

◆ Market and profile

- Large potential market (more than half of women aged 60 or older are suffering from VVA*)
- About 3.6M VVA patients are seeking treatment in the US, and 70-80% of them are undertreated
- Pivotal Phase III study successfully met all co-primary endpoints, and the results show a statistically significant difference from placebo.
- Offers a new treatment with VVA patients as first-in-class oral SERM

◆ Result of BE

- Completed the bioequivalence study with the commercial product

◆ Schedule

- NDA filing in the US expected in the 1st half of FY2012
- Under consideration for global development in Japan and EU

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



Ospemifene: Results of Pivotal Phase III study: Placebo-Controlled Study 15-50310

Co-primary endpoints (Change from baseline to week 12)	Ospemifene 60mg N = 276 (Comparison to placebo)
Increase in superficial cells from vaginal smear	P<0.001
Decrease in parabasal cells from vaginal smear	P<0.001
Decrease in vaginal pH	P<0.001
Improvement in most bothersome moderate to severe symptom assessed on a 0-3 scale (as recommended by FDA)	Dyspareunia: p<0.05 Dryness: p<0.05

- 2nd placebo-controlled study 15–50821 successfully met 4 co-primary endpoints. The results show statistically significant difference from placebo in increase in superficial cells from vaginal smear, decrease in parabasal cells from vaginal smear, decrease in vaginal pH and improvement in dyspareunia.

S-555739: Progress toward Late Stage (Allergic Rhinitis)

◆ Mechanism

- PGD2 receptor antagonist

◆ Characteristic

- More potent receptor antagonist activity
- Mono-therapy shows suppressive effects against symptoms of allergic rhinitis. Combination therapy with antihistamine shows remarkable suppressive effects against various symptoms of allergic rhinitis.
- Good tolerability
- Suggest possibility of novel oral treatment in allergic rhinitis competitive against nasal corticosteroid

◆ Marketability

- Predicted total number of allergic rhinitis patients in Japan, the US and EU is about 6.4M



S-555739: Completed Clinical Studies

◆ Japan

- Phase I (single dose and multiple dose)
- POC (perennial allergic rhinitis)
- Additional Phase IIa (seasonal allergic rhinitis)

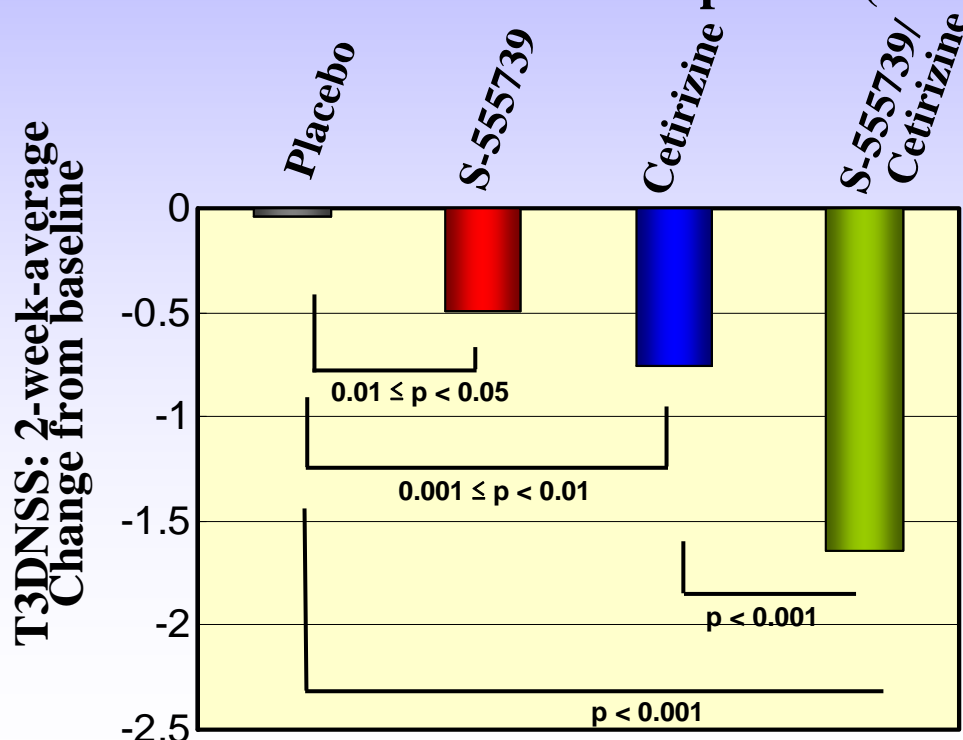
◆ Overseas

- Phase I in EU (multiple dose)
- POM in EU

- No adverse events or observations that could lead to significant safety concerns
- Blood levels achieve steady state 5 to 7 days after multiple dose administration

S-555739: Results of Phase IIa in Japan

- Conducted in spring 2011
- Patients with seasonal allergic rhinitis (Japanese cedar pollinosis)
- Group: S-555739, placebo, Cetirizine (CTZ), S-555739/CTZ combination
- Entered patient number: Target 450 \Rightarrow Actual 470
- Primary endpoint: Total day-time nasal symptom scores (T3DNSS) during first 2 weeks of treatment period (nasal congestion, sneezing, rhinorrhea)



- S-555739 improved T3DNSS compared with placebo, and showed no significance over CTZ
- S-555739/CTZ combination showed significant improvement in T3DNSS compared with each of S-555739 and CTZ
- Remarkable efficacy by combination were shown in other allergic rhinitis symptoms as well



S-555739:

Summary of Clinical Studies and Future Plans

◆ Summary of additional Phase IIa study conducted in Japan

- Efficacy of S-555739 against allergic rhinitis symptoms was proved, and it did not differ from efficacy of existing oral anti-allergy drugs
- Combination therapy of S-555739 with antihistamine showed remarkable suppressive effects against symptoms in allergic rhinitis, which could not be obtained by existing oral anti-allergy drugs
- Demonstrated good safety

◆ Global development to be activated

- Japan: Start Phase IIb (dose-exploring study)
- US: Start drug-drug interaction study, to move to Phase II study in autumn 2012

Pipeline



Growth Drivers to Achieve the 3rd Mid-Term Business Plan, Surmount “the Crestor Cliff,” and Realize Steady Medium-to-long-term Growth

S-349572(Dolutegravir)
Ospemifene
S-297995
S-555739

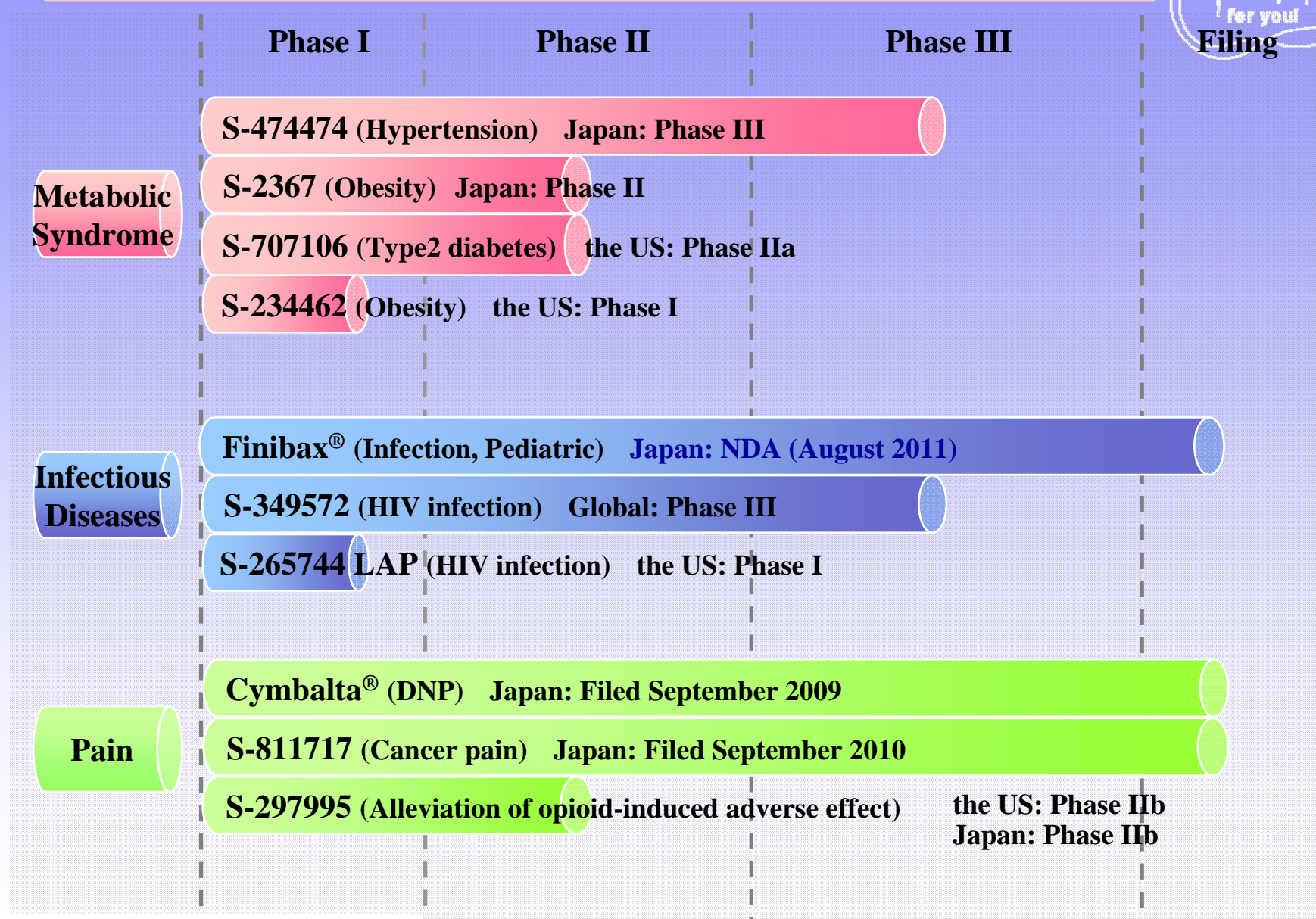
S-707106
S-888711
S-2367

S-265744 LAP
S-222611
S-288310
S-488410
S-524101
**Peptide vaccines for
ophthalmic disease**

DCS
NF-kB decoy oligo

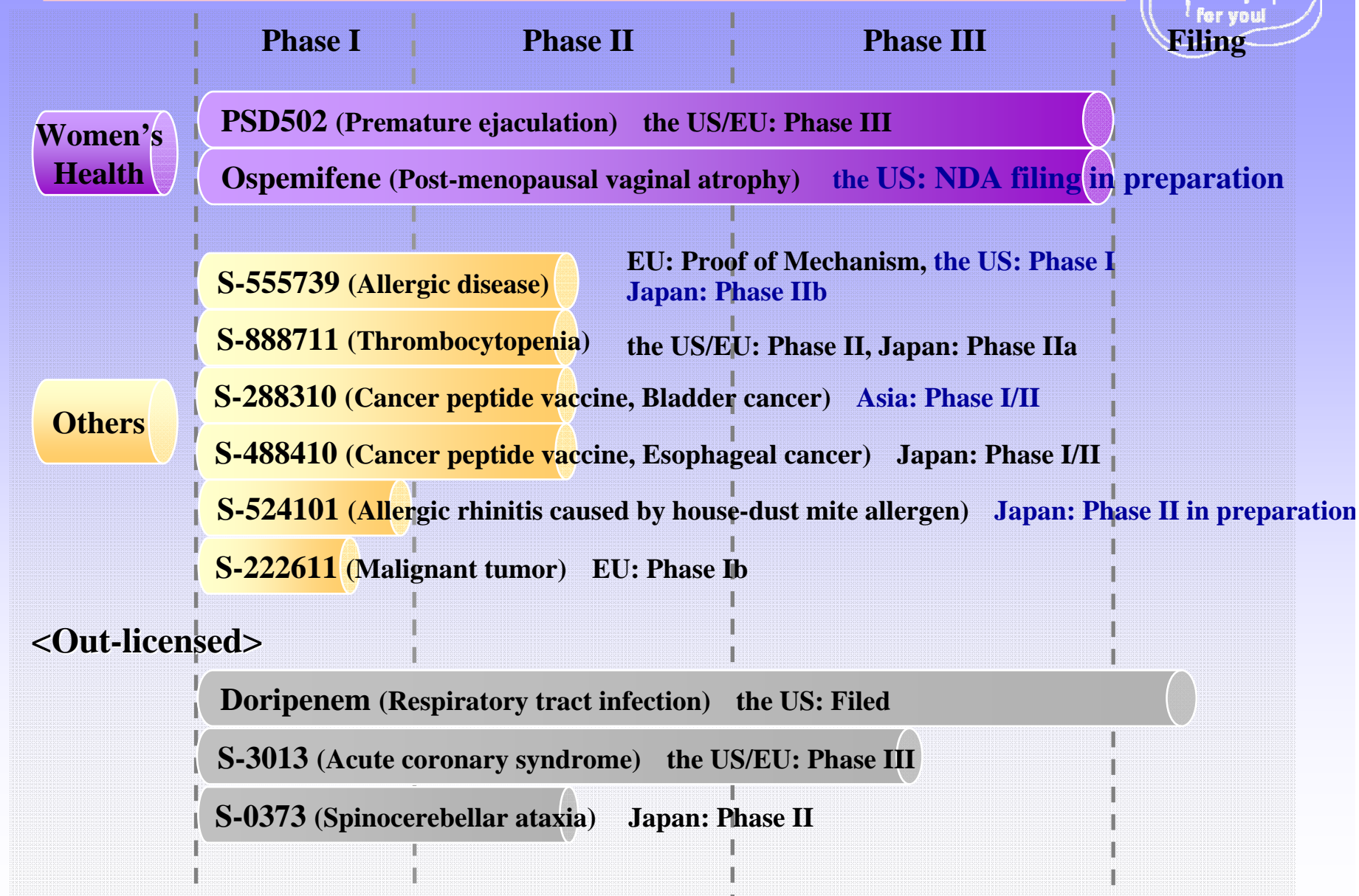
- *Securing paths to growth in Asia, the US and EU*
- *Constructing a strategic pipeline that incorporates in-licensed products*

Pipeline (as of October 2011)



LAP: Long acting parenteral formulation, DNP: Diabetic neuropathic pain

Pipeline (as of October 2011)





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.

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