

S-O-N-G  
for you!

*1<sup>st</sup> Half and 2<sup>nd</sup> Quarter of Fiscal 2009*  
*Financial Results*

*November 5, 2009*

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*President and Representative Director*



**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.
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The background of the slide is a soft-focus photograph of a laboratory setting. In the foreground, several clear microcentrifuge tubes are arranged in a row, each containing a small amount of blue liquid. A pipette is positioned above the tubes, with its tip pointing towards one of them. The overall color palette is light blue and white, creating a clean and professional atmosphere.

*Overview of 1<sup>st</sup> Half and 2<sup>nd</sup> Quarter  
FY2009 Results*



## *Financial Results* *(Consolidated & Non-Consolidated)*

(Units: billion yen)

<b>&lt;Consolidated&gt;</b>	<b>1<sup>st</sup> Half FY2009 Forecast</b>	<b>1<sup>st</sup> Half FY2009 Result</b>	<b>Achievement (%)</b>	<b>1<sup>st</sup> Half FY2008 Result</b>	<b>Y on Y change (%)</b>	<b>Y on Y change</b>
Sales	<b>130.0</b>	<b>132.6</b>	<b>102.0</b>	<b>105.0</b>	<b>26.3</b>	<b>27.6</b>
Operating income	<b>17.0</b>	<b>17.8</b>	<b>104.9</b>	<b>18.4</b>	<b>(3.4)</b>	<b>(0.6)</b>
Ordinary income	<b>16.0</b>	<b>16.3</b>	<b>102.5</b>	<b>18.9</b>	<b>(13.6)</b>	<b>(2.6)</b>
Net income	<b>10.0</b>	<b>11.5</b>	<b>115.9</b>	<b>11.8</b>	<b>(2.1)</b>	<b>(0.3)</b>

<b>&lt;Non-consolidated&gt;</b>	<b>1<sup>st</sup> Half FY2009 Forecast</b>	<b>1<sup>st</sup> Half FY2009 Result</b>	<b>Achievement (%)</b>	<b>1<sup>st</sup> Half FY2008 Result</b>	<b>Y on Y change (%)</b>	<b>Y on Y change</b>
Sales	<b>106.5</b>	<b>108.3</b>	<b>101.8</b>	<b>100.0</b>	<b>8.3</b>	<b>8.3</b>
Operating income	<b>17.0</b>	<b>16.8</b>	<b>99.3</b>	<b>16.2</b>	<b>3.7</b>	<b>0.6</b>
Ordinary income	<b>17.0</b>	<b>16.8</b>	<b>99.0</b>	<b>17.9</b>	<b>(6.1)</b>	<b>(1.1)</b>
Net income	<b>10.5</b>	<b>11.6</b>	<b>111.4</b>	<b>11.4</b>	<b>2.1</b>	<b>0.2</b>



## *Financial Position and Cash Flows (Consolidated)*

(Units: billion yen)

<b>&lt;Financial position&gt;</b>	<b>As of Sep. 30 2009</b>	<b>As of Mar. 31 2009</b>	<b>Y on Y change</b>
Total assets	<b>524.4</b>	<b>501.8</b>	<b>22.6</b>
Net assets	<b>326.7</b>	<b>310.0</b>	<b>16.7</b>
Equity ratio (%)	<b>62.2</b>	<b>61.7</b>	<b>+ 0.5</b>
Net assets per share (yen)	<b>974</b>	<b>924</b>	<b>50</b>
<b>&lt;Cash flows&gt;</b>	<b>1<sup>st</sup> Half FY2009 Result</b>	<b>1<sup>st</sup> Half FY2008 Result</b>	<b>Y on Y change</b>
Net cash provided by operating activities	<b>20.6</b>	<b>18.3</b>	<b>2.3</b>
Net cash provided by (used in) investing activities	<b>(5.2)</b>	<b>8.7</b>	<b>(13.9)</b>
Net cash provided by (used in) financing activities	<b>8.0</b>	<b>(4.6)</b>	<b>12.6</b>
<b>Total</b>	<b>23.7</b>	<b>22.2</b>	<b>1.5</b>
Cash & cash equivalents at end of period	<b>75.3</b>	<b>89.8</b>	<b>-</b>



## Sales by Segment (Consolidated)

(Units: billion yen)	1 <sup>st</sup> Half FY2009 Forecast	1 <sup>st</sup> Half FY2009 Result	Achievement (%)	1 <sup>st</sup> Half FY2008 Result	Y on Y change (%)	Y on Y change
<b>Prescription drugs</b>	<b>74.3</b>	<b>74.7</b>	<b>100.5</b>	<b>74.3</b>	<b>0.6</b>	<b>0.4</b>
Crestor	10.5	11.5	109.8	8.3	38.2	3.2
Flomox	11.0	11.3	102.8	12.1	(6.8)	(0.8)
Rinderon	5.0	5.1	102.7	5.2	(0.5)	(0.1)
Flumarin	4.5	4.7	104.4	5.5	(13.9)	(0.8)
OxyContin	4.2	4.2	100.5	4.0	6.2	0.2
Claritin	3.5	3.4	97.9	3.3	4.3	0.1
Vancomycin	3.4	3.4	101.2	4.6	(25.3)	(1.2)
Imunace	1.8	2.6	142.6	3.6	(28.6)	(1.0)
Finibax	1.9	1.8	92.3	1.3	30.2	0.5
Irbetan	1.4	1.2	87.2	1.0	26.4	0.2
Differin	1.4	1.0	72.7	-	-	1.0
Pirespa	0.8	0.6	75.6	-	-	0.6
Avelox	0.8	0.5	65.2	0.7	(20.8)	(0.2)
<b>Export/Overseas operating</b>	<b>23.4</b>	<b>23.9</b>	<b>102.1</b>	<b>4.1</b>	<b>482.1</b>	<b>19.8</b>
Sciele Pharma, Inc.	18.1	18.3	101.5	-	-	18.3
Doripenem	2.5	2.9	116.3	1.1	175.0	1.8
<b>Contract manufacturing</b>	<b>2.8</b>	<b>3.4</b>	<b>122.7</b>	<b>3.0</b>	<b>13.2</b>	<b>0.4</b>
<b>OTC and quasi-drugs</b>	<b>2.6</b>	<b>3.0</b>	<b>113.7</b>	<b>2.8</b>	<b>4.0</b>	<b>0.2</b>
<b>Diagnostics</b>	<b>1.6</b>	<b>1.6</b>	<b>97.6</b>	<b>1.7</b>	<b>(8.0)</b>	<b>(0.1)</b>
<b>Royalty income</b>	<b>23.4</b>	<b>24.0</b>	<b>102.6</b>	<b>17.8</b>	<b>35.0</b>	<b>6.2</b>
Crestor	22.0	22.5	102.5	16.6	36.1	5.9
<b>Real estate &amp; others</b>	<b>1.9</b>	<b>2.1</b>	<b>110.4</b>	<b>1.3</b>	<b>57.5</b>	<b>0.8</b>
<b>Total</b>	<b>130.0</b>	<b>132.6</b>	<b>102.0</b>	<b>105.0</b>	<b>26.3</b>	<b>27.6</b>



## Statements of Operating Income (Consolidated)

(Units: billion yen)	1st Half FY2009 Forecast	1st Half FY2009 Result	Achievement (%)	1st Half FY2008 Result	Y on Y change (%)	Y on Y change
Sales	130.0	132.6	102.0	105.0	26.3	27.6
[Royalty]	[23.4]	[24.0]	[102.6]	[17.8]	[35.0]	[6.2]
	28.1 [34.2]	27.8 [33.9]		31.4 [37.8]		
Cost of sales	36.5	36.8	101.0	32.9	11.8	3.9
Gross profit	93.5	95.7	102.4	72.0	32.9	23.7
	58.8	58.8		51.0		
SG&A expenses	76.5	77.9	101.9	53.6	45.4	24.3
Selling & general expenses	48.5	50.0	103.1	32.8	52.4	17.2
R&D expenses	28.0	27.9	99.7	20.7	34.3	7.2
	13.1	13.4		17.6		
Operating income	17.0	17.8	104.9	18.4	(3.4)	(0.6)



***FY2009 Financial Forecast***





# *Financial Forecast*

## *(Consolidated & Non-Consolidated)*

(Units: billion yen)

### <Consolidated>

	<b>FY2009 Forecast</b>	<b>FY2008 Result</b>	<b>Y on Y change (%)</b>	<b>Y on Y change</b>
Sales	<b>280.0</b>	<b>227.5</b>	<b>23.1</b>	<b>52.5</b>
Operating income	<b>60.0</b>	<b>32.0</b>	<b>87.4</b>	<b>28.0</b>
Ordinary income	<b>58.0</b>	<b>32.0</b>	<b>81.2</b>	<b>26.0</b>
Net income	<b>35.0</b>	<b>15.6</b>	<b>123.5</b>	<b>19.4</b>

### <Non-consolidated>

	<b>FY2009 Forecast</b>	<b>FY2008 Result</b>	<b>Y on Y change (%)</b>	<b>Y on Y change</b>
Sales	<b>225.5</b>	<b>206.7</b>	<b>9.1</b>	<b>18.8</b>
Operating income	<b>51.5</b>	<b>36.2</b>	<b>42.1</b>	<b>15.3</b>
Ordinary income	<b>51.5</b>	<b>37.9</b>	<b>35.8</b>	<b>13.6</b>
Net income	<b>32.0</b>	<b>23.8</b>	<b>34.1</b>	<b>8.2</b>

## Sales by Segment (Consolidated)

(Units: billion yen)	FY2009 Forecast	FY2008 Result	Y on Y change (%)	Y on Y change
<b>Prescription drugs</b>	<b>155.5</b>	<b>153.2</b>	<b>1.5</b>	<b>2.3</b>
Crestor	23.0	17.7	30.0	5.3
Flomox	24.0	27.3	(12.1)	(3.3)
Rinderon	9.5	9.6	(1.0)	(0.1)
Flumarin	9.0	10.1	(10.9)	(1.1)
OxyContin	8.8	7.7	14.4	1.1
Claritin	9.7	9.6	0.5	0.1
Vancomycin	6.5	8.1	(20.1)	(1.6)
Imunace	4.6	6.1	(24.6)	(1.5)
Finibax	4.0	2.9	37.5	1.1
Irbetan	3.5	1.2	197.0	2.3
Differin	2.8	1.2	138.6	1.6
Pirespa	1.7	0.2	949.6	1.5
Avelox	1.3	1.5	(16.0)	(0.2)
<b>Export/Overseas operating</b>	<b>54.3</b>	<b>18.6</b>	<b>191.6</b>	<b>35.7</b>
Sciele Pharma, Inc.	43.0	9.2	366.8	33.8
Doripenem	5.0	3.5	41.9	1.5
<b>Contract manufacturing</b>	<b>6.4</b>	<b>5.7</b>	<b>11.0</b>	<b>0.7</b>
<b>OTC and quasi-drugs</b>	<b>5.0</b>	<b>5.2</b>	<b>(4.2)</b>	<b>(0.2)</b>
<b>Diagnostics</b>	<b>3.0</b>	<b>3.3</b>	<b>(9.6)</b>	<b>(0.3)</b>
<b>Royalty income</b>	<b>52.0</b>	<b>36.8</b>	<b>41.0</b>	<b>15.2</b>
Crestor	49.5	34.3	44.3	15.2
<b>Real estate &amp; others</b>	<b>3.8</b>	<b>4.4</b>	<b>(14.2)</b>	<b>(0.6)</b>
<b>Total</b>	<b>280.0</b>	<b>227.5</b>	<b>23.1</b>	<b>52.5</b>

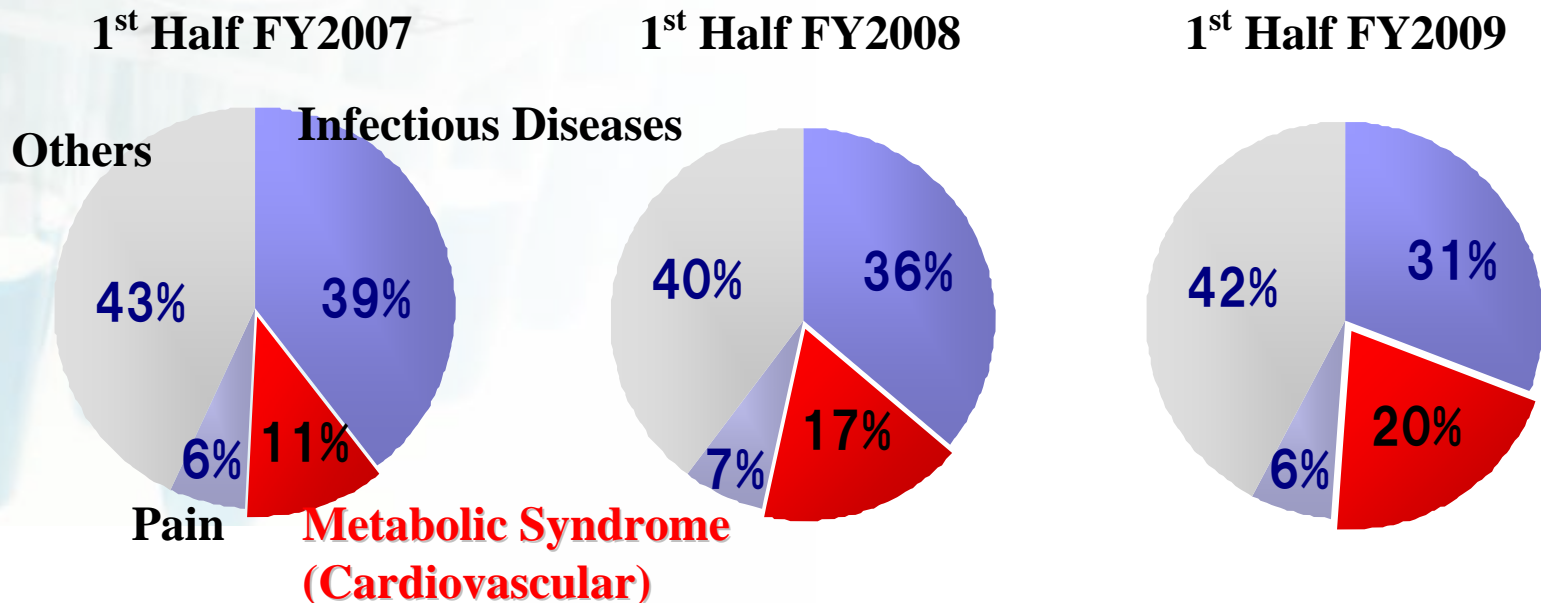
## Operating Income (Consolidated)

(Units: billion yen)	FY2009 Forecast	FY2008 Result	Y on Y change (%)	Y on Y change
Sales	280.0	227.5	23.1	52.5
[Royalty]	[52.0]	[36.8]	[41.0]	[15.2]
	26.4	31.2		
	[32.5]	[37.2]		
Cost of sales	74.0	70.9	4.3	3.1
Gross profit	206.0	156.5	31.6	49.5
	52.1	54.7		
SG&A expenses	146.0	124.5	17.2	21.5
Selling & general expenses	96.0	71.7	33.8	24.3
R&D expenses	50.0	52.8	(5.3)	(2.8)
	21.4	14.1		
Operating income	60.0	32.0	87.4	28.0

# Progress Situation of Strengthening Domestic Sales and Marketing

- Steadily expand business performance by building well-balanced sales mix (shift from acute diseases to chronic diseases)
  - **Smooth expansion of cardiovascular area**

## 1<sup>st</sup> Half Sales Trend from 2007 to 2009 by Therapeutic Areas (Prescription Drugs)



# Toward Continuous Growth of Domestic Sales by Expanding Newly-launched Products

- Consistent growth through the sales expansion of **new products launched during the 2nd Mid-Term Business Plan**

➤ Expansion based on the evidence of large-scale clinical trials

- Enhance segmental approach

➤ HP, GP and dispensing pharmacies

**New Products Sales Proportion in Prescription Drugs**

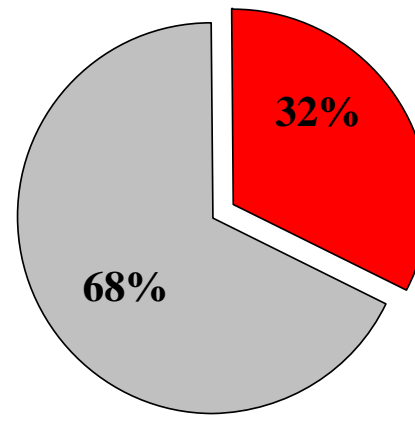
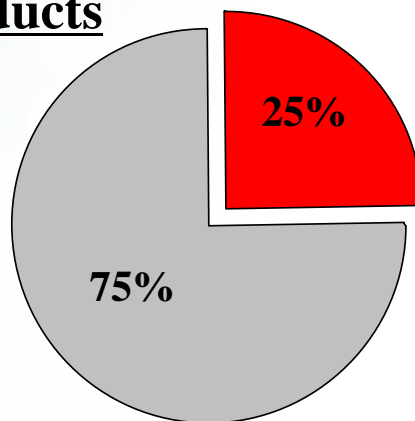
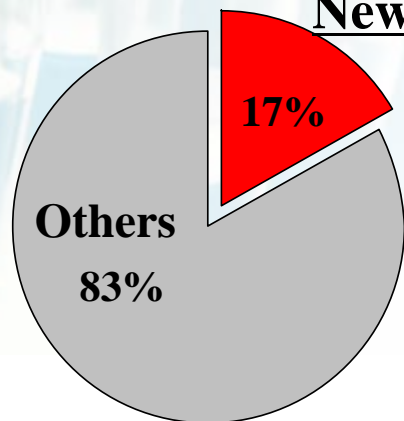
Sales proportion (%)	1 <sup>st</sup> Half FY2007	1 <sup>st</sup> Half FY2008	1 <sup>st</sup> Half FY2009
Crestor	6%	11%	15%
Claritin	4%	4%	5%
OxyContin	4%	5%	6%
Finibax	2%	2%	2%
Irbe tan	0%	1%	2%
Differin	0%	0%	1%
Pirespa	0%	0%	1%
Avelox	1%	1%	1%
Cetrotide	0.1%	0.3%	0.1%
<b>New product total</b>	<b>17%</b>	<b>25%</b>	<b>32%</b>
Others	83%	75%	68%
<b>Prescription drugs</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

1<sup>st</sup> Half FY2007

1<sup>st</sup> Half FY2008

1<sup>st</sup> Half FY2009

New products





# Sciele's Results

(Units: million dollar)

(Units: billion yen)

	1 <sup>st</sup> Half FY2009 (Jan. - June)	FY2009
Sales	192	458
Operating Income	24	119

	1 <sup>st</sup> Half FY2009 (Jan. - June)	FY2009
	18.3	43.0
	2.2	11.2

(Units: million dollar)

Therapeutic Areas	Executing Aggressive Strategy for Achievement of Annual Plan	1 <sup>st</sup> Half FY2009 (Jan. - June)	FY2009
Cardiovascular	Further sales expansion of Nitrolingual Pumpspray (NLPS; Angina) and maintain Sular sales.	58	140
Diabetes	Continue growth of Fenoglide through more aggressive, strategic marketing to offset PrandiMet launch below expectations.	55	116
Women's Health	Expand sales of Prenate Family (Prenatal vitamin) with Prenate DHA as the primary growth driver.	39	99
Pediatrics	After launch of Ulesfia (Head lice) was delayed, it is achieving continued market share growth; growth due to seasonality of certain pediatric products.	40	103
<b>Total</b>	Some issues, like wholesaler reductions and delayed product launches, impacted 1H09. Achieve full year forecast mainly by new product launches as well as price increases to drive 2H09 revenues.	<b>192</b>	<b>458</b>



*Dividend Forecast*

	Dividends per Share		
	Half-year	Year-end	Annual
	Yen	Yen	Yen
		(Forecast)	(Forecast)
<b>FY2009</b>	<b>18 . 00</b>	<b>18 . 00</b>	<b>36 . 00</b>
<b>FY2008</b>	<b>14 . 00</b>	<b>14 . 00</b>	<b>28 . 00</b>



*Pipeline*



## *Change of Phases in Clinical Studies*

- **LY248686 (Duloxetine) (SNRI, Diabetic neuropathic pain)**
  - Japan: NDA filing September 2009
- **S-021812 (Peramivir) (Neuraminidase inhibitor, Influenza infection)**
  - Japan: NDA filing for adult October 2009
  - Pediatric Phase III study initiated in Japan
- **S-2367 (NPY Y5 receptor antagonist, Obesity)**
  - Phase IIa study initiated in Japan
- **S-888711 (Small molecule TPO mimetic (oral), thrombocytopenia)**
  - In preparation for Phase II study in the U.S. (to be initiated by the end of 2009)
- **S-222611 (Her2/EGFR dual inhibitor, Malignant tumor)**
  - In preparation for Phase Ib study in Europe (to be initiated by the end of 2009)
- **S-288310 (Peptide cancer vaccine, Bladder cancer)**
  - Phase I/II study initiated in Japan
- **S-234462 (NPY Y5 receptor antagonist, Obesity)**
  - In preparation for Phase I study in the U.S. (to be initiated by the end of 2009)

*NDA: New Drug Application, SNRI: Serotonin noradrenalin reuptake inhibitor,  
NPY: Neuropeptide Y, TPO: Thrombopoietin,  
Her2/EGFR: Human epidermal growth factor receptor type2/ Epidermal growth factor receptor*

## *Emergency Use Authorization (EUA) of Peramivir in the USA*

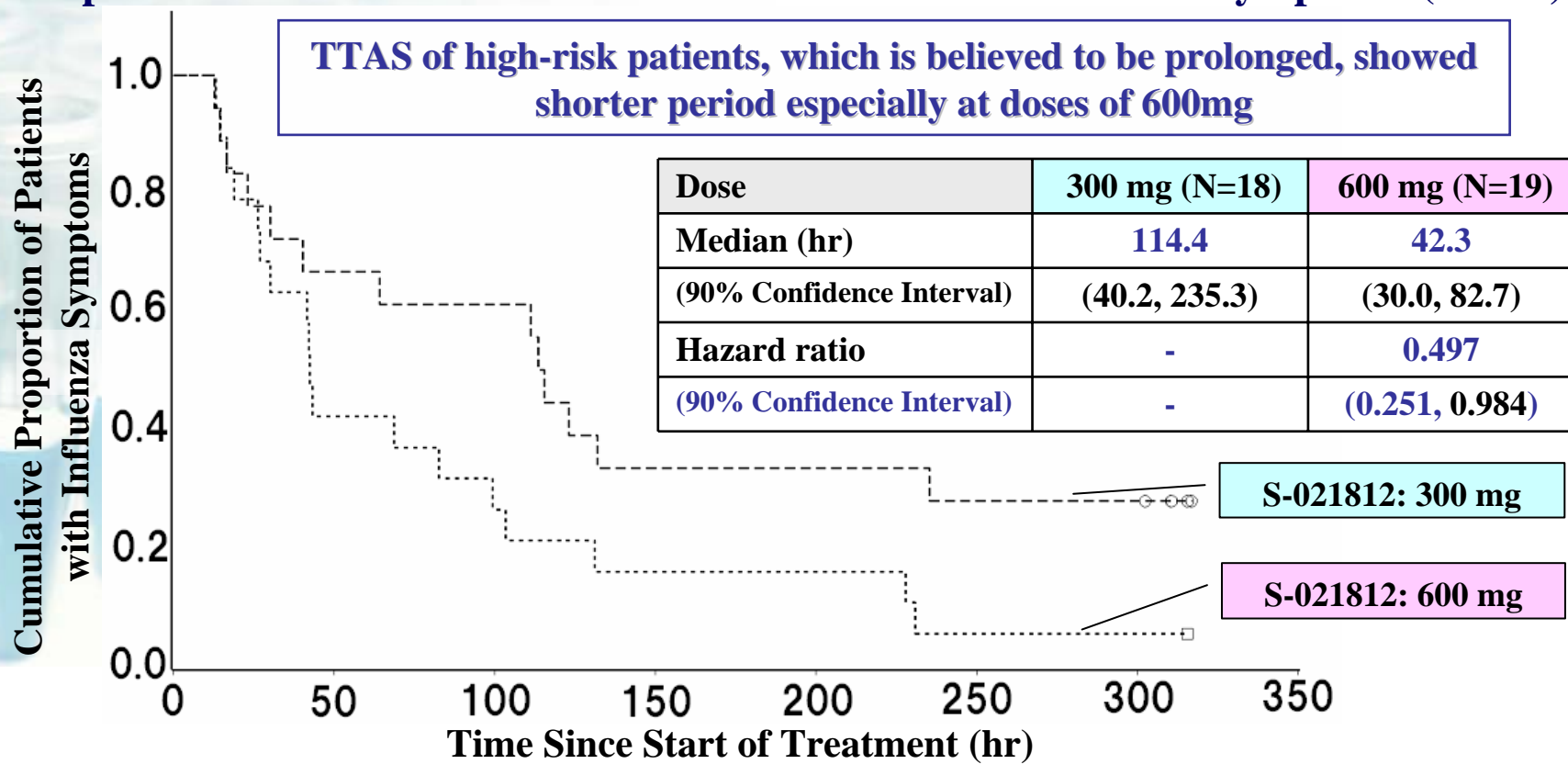
- On October 23, 2009, the FDA issued an EUA for the emergency use of peramivir administered intravenously for the treatment of certain patients infected with the 2009 H1N1 influenza virus
- The basis of the EUA issuance by the FDA was that:
  1. The 2009 H1N1 influenza infections can cause serious or life threatening disease or conditions
  2. The totality of scientific evidence available, which includes Shionogi's phase II and III studies, has led the FDA to believe that peramivir would be effective
  3. There is no adequate, approved and available alternative in the identified patient population
- Under the EUA, peramivir is authorized for use only in specific adult and pediatric hospitalized patients
- The US government controls distribution of peramivir

## Development of Peramivir (S-021812)

- Neuraminidase inhibitor (Influenza infection)
- NDA filing for adult October, 2009 (Single and repeated administrations)
- Pediatric Phase III study has been initiated in Japan (expected to file an additional application by the end of 2010)

### Repeated Dose Study for High-Risk Patients

#### Comparison between 2 Doses in Time to Alleviation of Influenza Symptoms (TTAS)



## *Environmental Change in Development of Anti-Obesity drugs*

- **Announcements of clinical study results by competitors since February 2009 when S-2367 Ph IIb study results were disclosed**
  - **March: Arena Pharmaceuticals, Inc.; Lorcaserin**
  - **July: Orexigen Therapeutics, Inc.; Contrave (Combination of Bupropion and Naltrexone)**
  - **September: VIVUS, Inc.; Qnexa (Combination of Phentermine and Topiramate)**
  - **September: Orexigen Therapeutics, Inc; Empatic (Combination of Bupropion and Zonisamide)**
- **Efficacy: 6 - 10% body weight reductions compared with placebo**
- **Safety: Still have work to do**



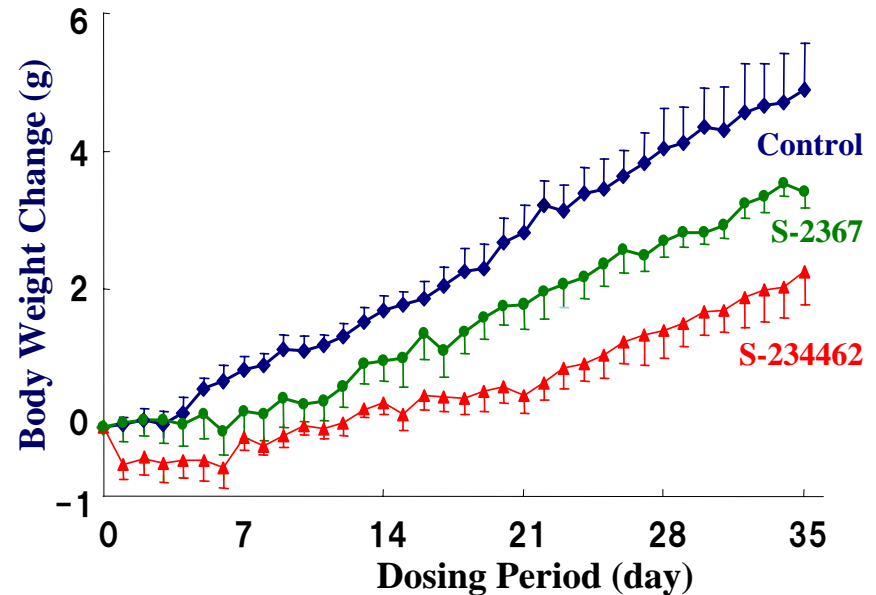
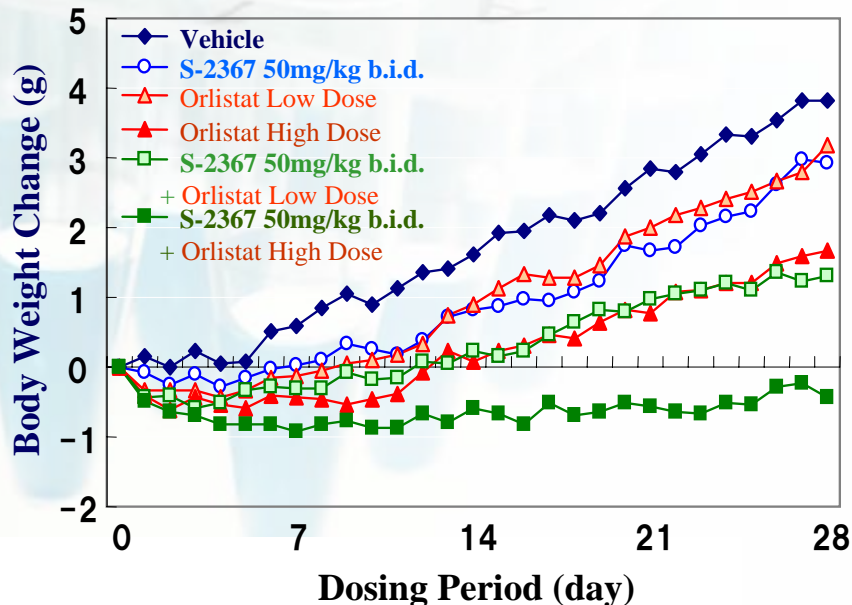
**The need to aim at higher pharmacological effect with expressing the safety of S-2367**

# Development of NPY Y5 Receptor Antagonists

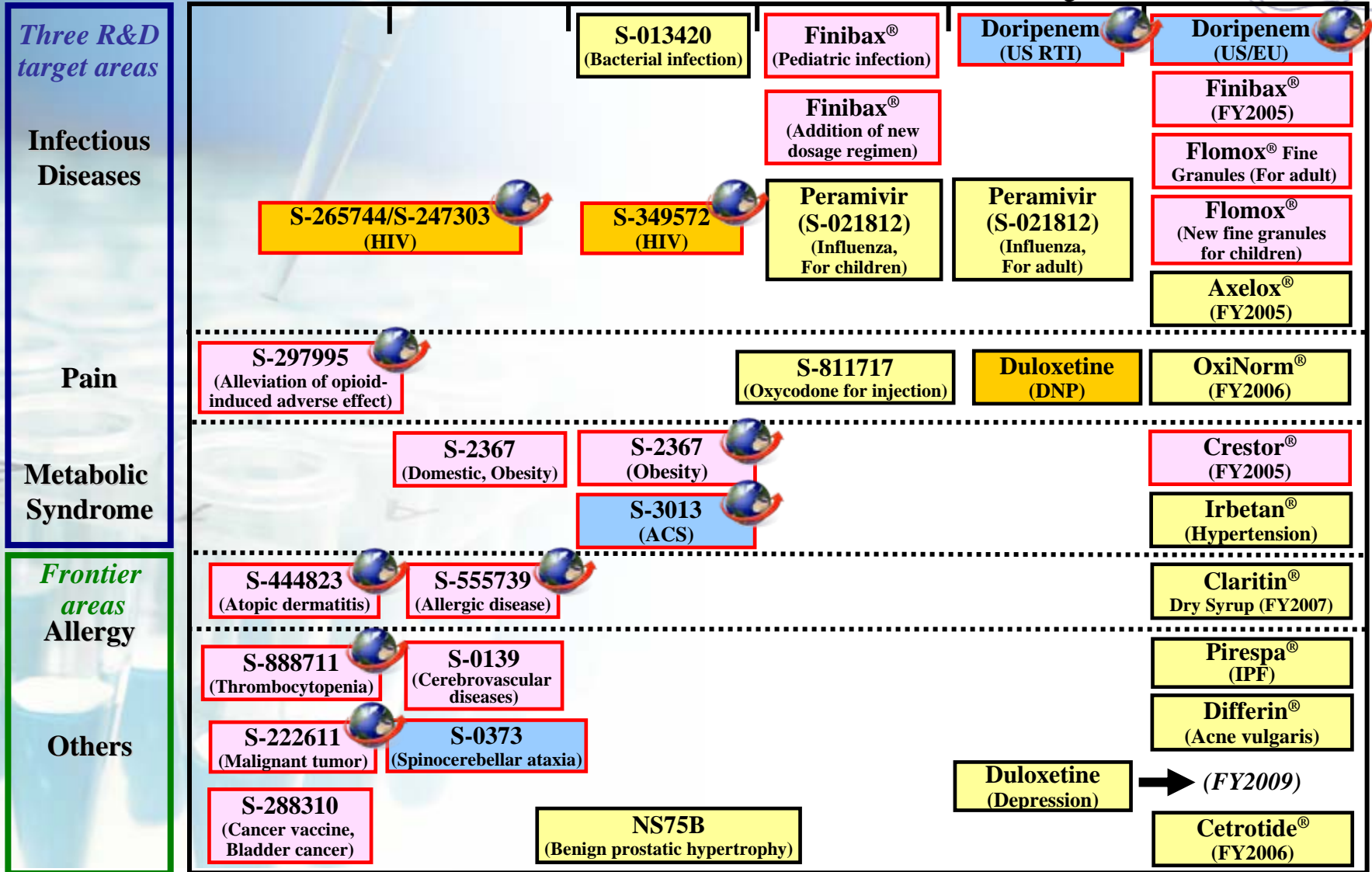
NPY: Neuropeptide Y

- In October 2009, pending partnering discussions, and focusing on the combination study with Orlistat in the U.S. and clinical studies in Japan
  - S-2367/Orlistat combination PK study initiated in the U.S.
  - Phase II study of S-2367 for obesity patients initiated in Japan
- Conduct POC study of the follow-up compound, S-234462 at the fastest rate
  - In preparation for Phase I study

## Body Weight Suppressant Effect (Diet-Induced Obese (DIO) Mice Study)



# Pipeline (As of November 2009)



In-house Co-development Out-licensed In-licensed

Developing in-house products globally

IPF: Idiopathic pulmonary fibrosis, DNP: Diabetic Neuropathic Pain, RTI: Respiratory Tract Infection, ACS: Acute coronary syndromes

## *Update on Sciele's Pipeline*

### ● **Glycopyrrolate**

(Glycopyrrolate: Anticholinergic, Pediatric Chronic Drooling)

➤ **The U.S.: NDA filing September 2009**

### ● **CloniceL** (Clonidine hydrochloride:

Centrally acting alpha adrenergic agonist, ADHD)

➤ **The U.S.: sNDA filing October 2009**

– The twice daily clonidine for hypertension already approved

– The once daily clonidine for hypertension expected to be filed by the end of 2009

### ● **PSD502** (Lidocaine/prilocaine: Eutectic mixture of anesthetics, PE)

➤ **Phase III trials completed in the U.S., Canada and Europe**

➤ **The U.S.: NDA filing expected 1<sup>st</sup> Half 2010**

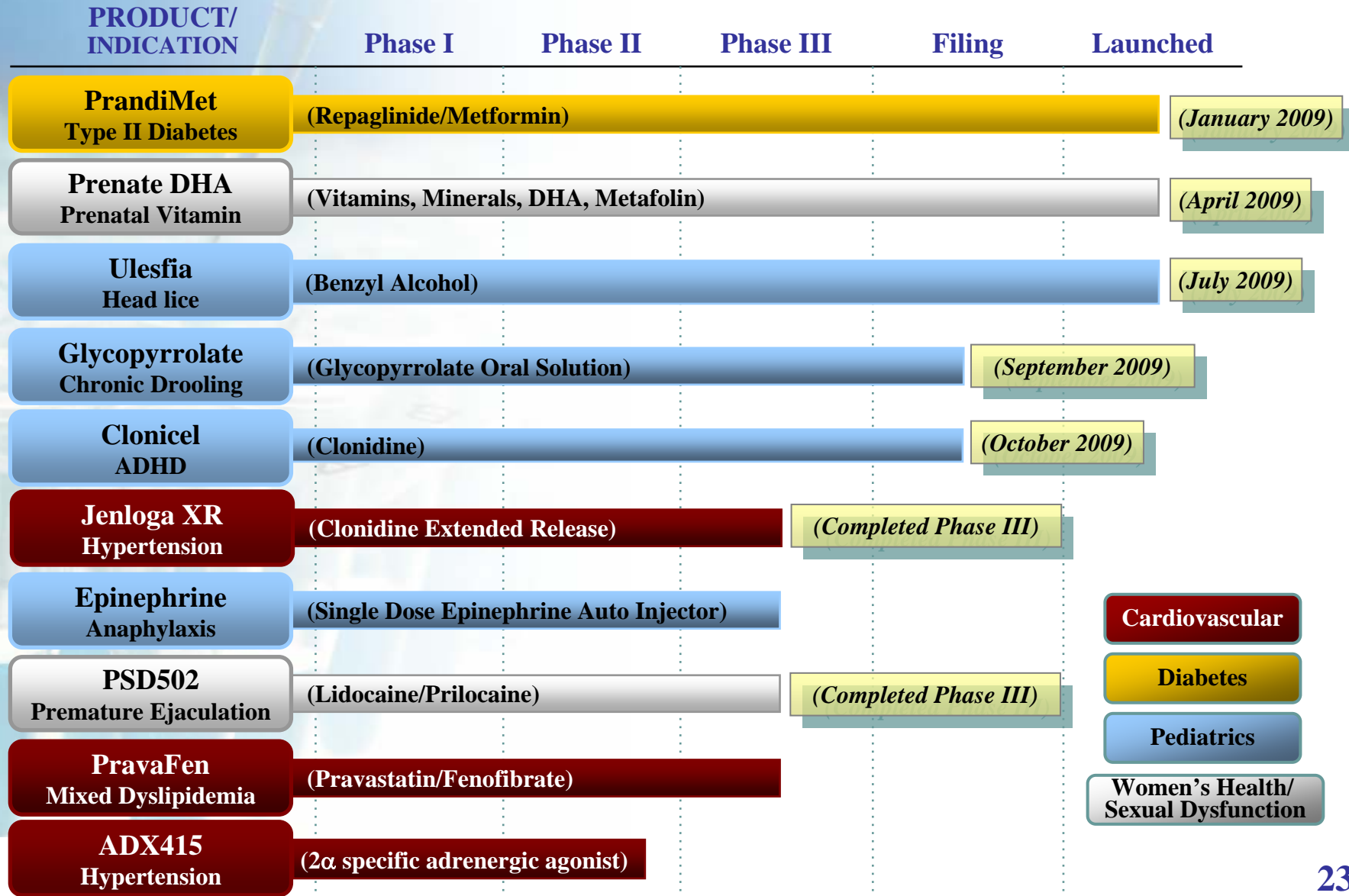
*NDA: New Drug Application, sNDA: Supplemental NDA*

*ADHD: Attention Deficit Hyperactivity Disorder*

*PE: Premature Ejaculation*



# Pipeline Leading Sciele's Growth



Cardiovascular

Diabetes

Pediatrics

Women's Health/  
Sexual Dysfunction