

**Merrill Lynch Japan Conference 2010**



# **The Growth Strategy of Shionogi**

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**President and Representative Director**

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## *Forward-Looking Statements*



- **This presentation contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements.**
- **Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products.**
- **The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.**
- **This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.**



**Overview of the 3<sup>rd</sup>  
Medium-Term Business Plan**



*The 1<sup>st</sup> - 3<sup>rd</sup> Medium-Term Business Plan of Shionogi*

**The 1<sup>st</sup> Medium-Term Business Plan**

(April 2000 – March 2005)

*~ Concentration on the prescription drug business ~*

**The 2<sup>nd</sup> Medium-Term Business Plan**

(April 2005 – March 2010)

*~ Entering a stage to accelerate  
toward significant growth ~*

**The 3<sup>rd</sup> Medium-Term Business Plan**

(April 2010 – March 2015)

*~ SONG for the Real Growth ~*

- ◆ Steady growth mainly through enriched pipeline
- ◆ Investments in the new growth drivers
- ◆ Therapeutic areas to be focused on

# Basic Strategy in the 3<sup>rd</sup> Medium-Term Business Plan



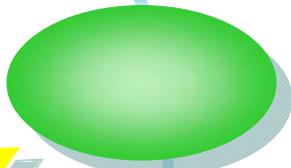
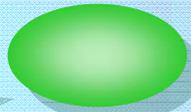
**Goals for the next 10 years**

**Consolidated net sales: 600 billion yen**  
**Operating margin: More than 25%**  
**Overseas net sales ratio: More than 50%**

**Basic strategy 1**

**Steady growth mainly through enriched pipeline**

**Crestor cliff**



**Basic strategy 3**

**Therapeutic areas to be focused on**

**Basic strategy 2**

**Investments in the new growth drivers**

2010

2012

2014

2016

2018

2020

**3<sup>rd</sup> medium-term business plan**

**4<sup>th</sup> medium-term business plan**

**5<sup>th</sup> medium-term business plan**



New image Shionogi aims for during the 3<sup>rd</sup> medium-term business plan

## ***SONG for the Real Growth***

### ***Speed***

**Quick decision and implementation**

### ***Open Mind***

**Flexible mind and out of box thinking**

### ***Never-Failing Passion***

**Persistent passion**

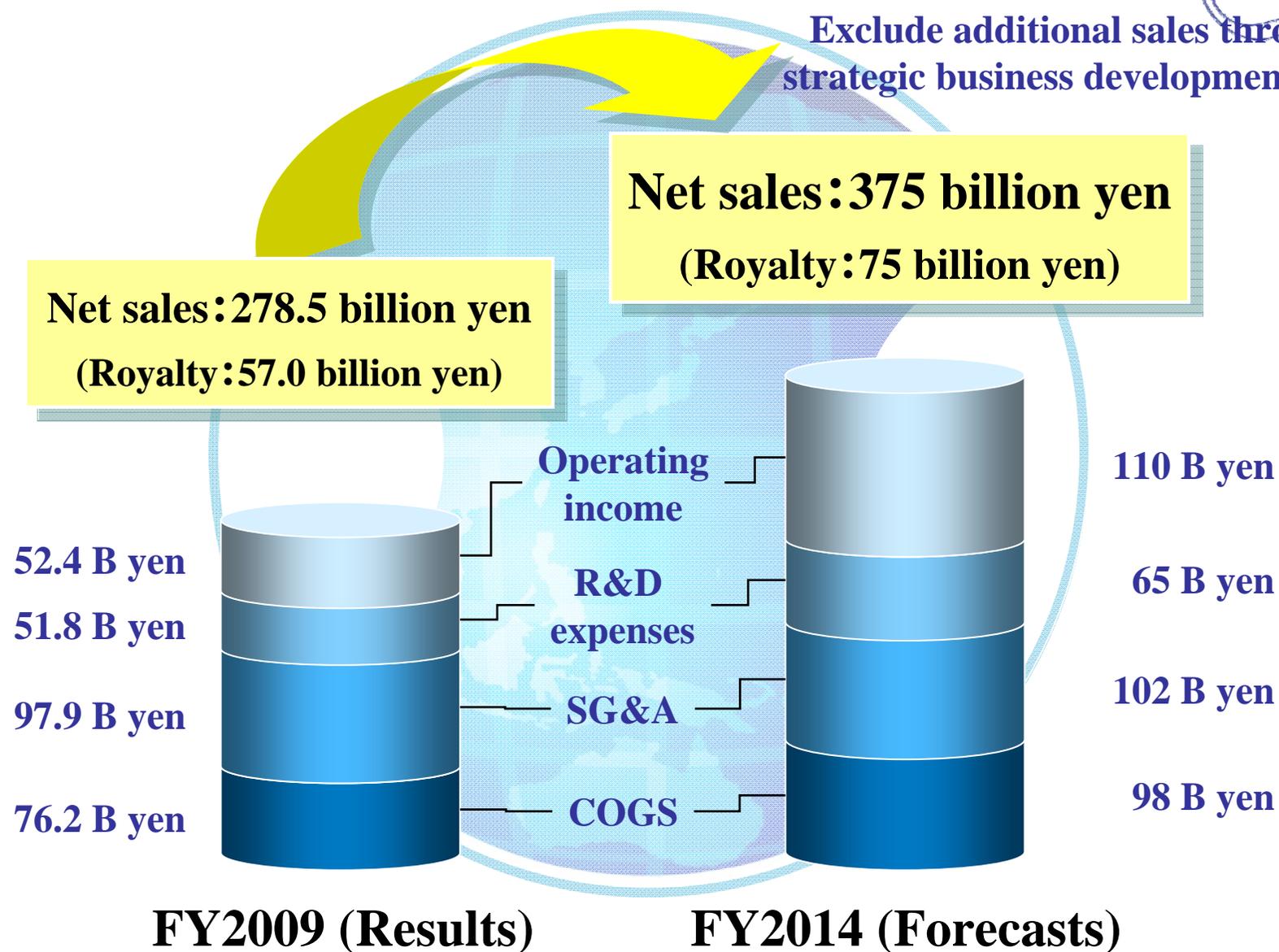
### ***Global Perspective***

**Higher and broader perspective**

# Financial Target for FY2014 (Consolidation)



Exclude additional sales through strategic business development deals



# *Strengthening of Operational Fundamentals and Shareholder Return*



**Put 3 Gears in Motion and Implement Both Strengthening of a Business Foundation and Shareholder Return While Balancing the Two Well**

## **Shareholder return**

- Keep 35% of payout ratio  
Expected total dividend amount: 94 B yen
- Dividend enable to feel the real growth  
Expected dividend per share: 36 ⇒ 78 yen

## **Investment toward the future**

- R&D expenses: 305 B yen
- Capital investments: 75 B yen

## **Improvement of B/S for financial strategy**

- Dept refund/bond retirement: 111 B yen  
Term-end balance: 121 ⇒ 10 B yen
- Strategic business development funds: 150 B yen  
Term-end balance: 100 ⇒ 250 B yen



# Basic Strategies

# Basic Strategy 1



## Steady Growth of Domestic Sales

Realize steady growth by expanding sales of 8 new products

Conversion of revenue structure



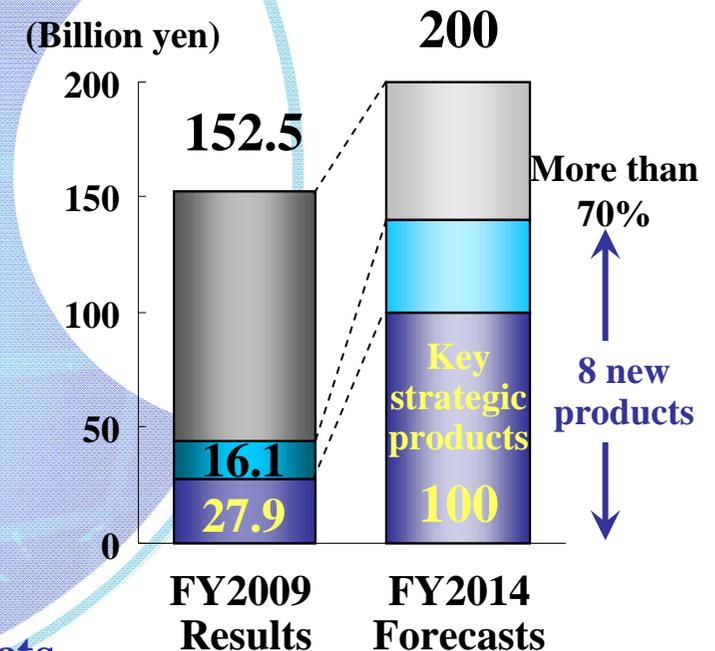
Establish robust revenue foundation independent from the "Legacy products"

**8 new products**

<b>Key strategic products</b> Crestor Irbetan Cymbalta	Pirespa, Differin Rapiacta, Finibax OxyContin/OxiNorm
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### Domestic Sales Forecast

- Net sales target: 200 billion yen
- Total 100 billion yen with 3 key strategic products
- More than 70% of net sales generated by 8 new products
  - From legacy product dependent to newer product dependent growth



# Basic Strategy 1



## Global Growth of Crestor

**Increase in royalty revenue**

Further sales expansion by AZ through collaboration with Abbott



**FY2014 forecast: More than 75 billion yen**

**A challenge for No. 1 in domestic market**

Continue high-quality collaboration with AZ

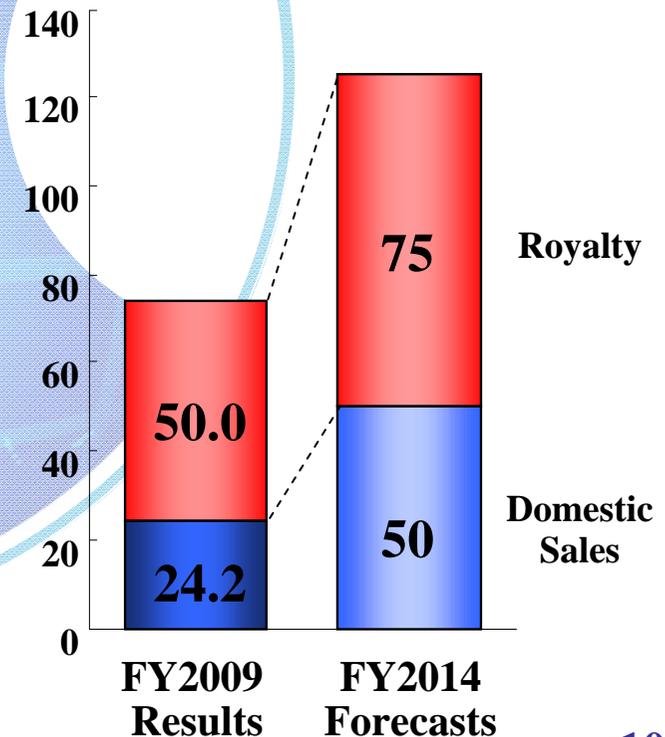
- FY2011 Establish top share in statin market\*
- FY2014 Net sales target: 50 billion yen

### Crestor sales by AstraZeneca

(Billion dollar)

Global Sales	2006	2007	2008	2009
	2.0	2.8	3.6	4.5

(Billion yen)

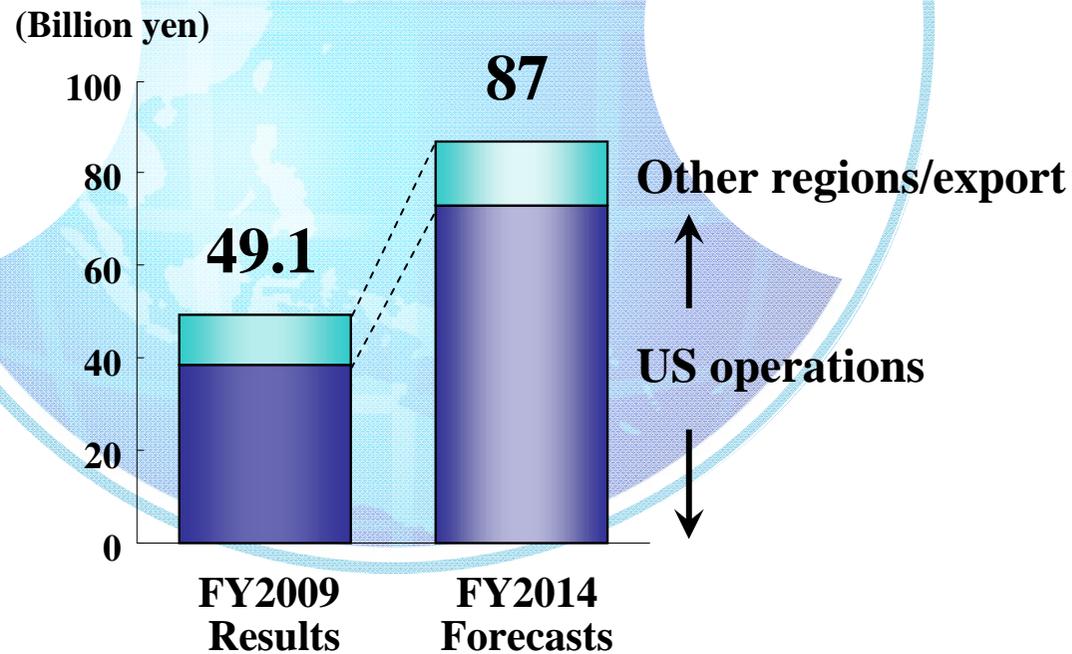


# Basic Strategy 1



## Overseas Sales Forecasts

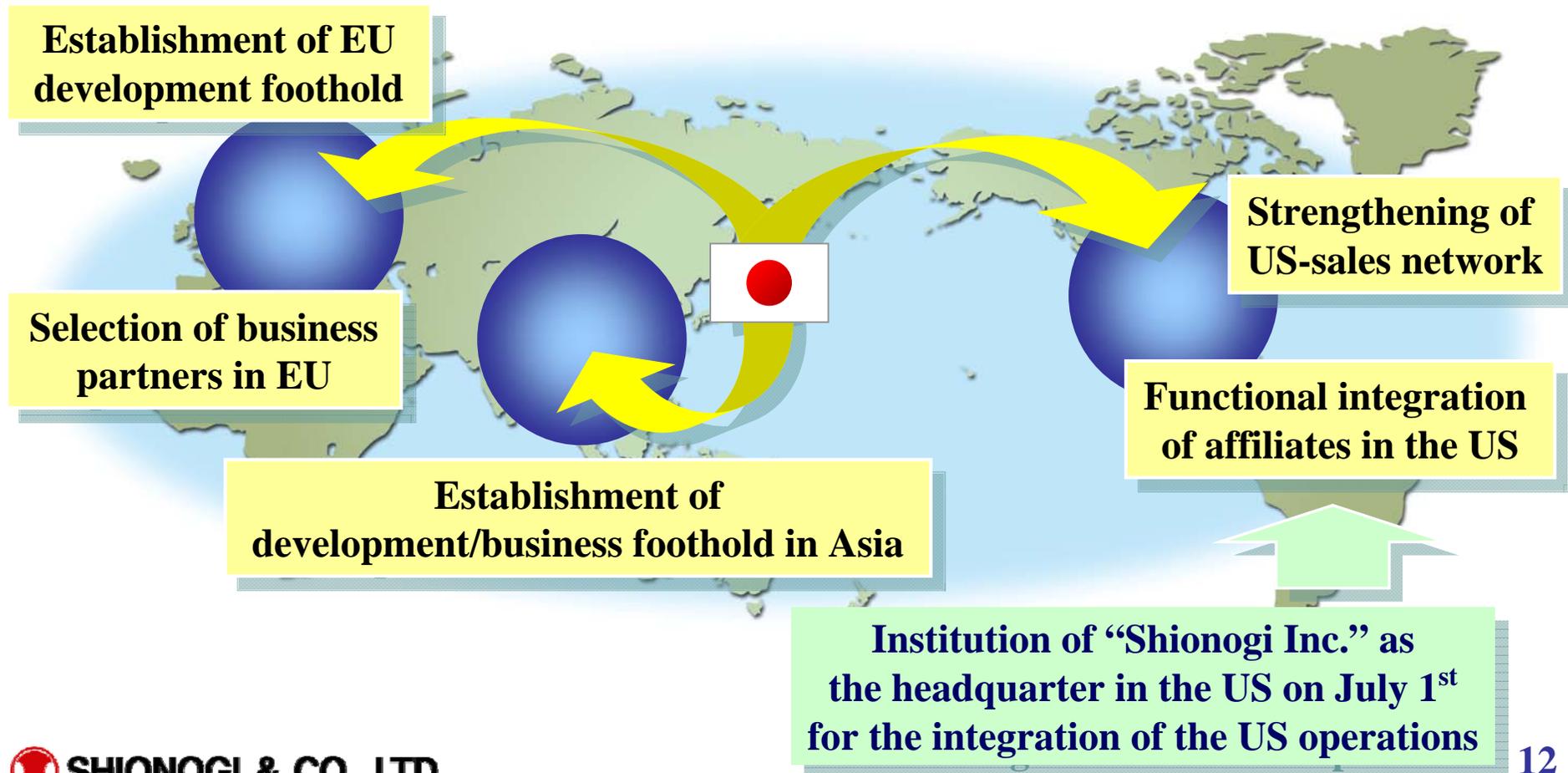
- Net sales target for marketed and products in development: 87 billion yen
  - Exclude additional sales through strategic business development deals
- Expand consolidated overseas net sales ratio excluding royalty to approximately 30%
  - FY2009: 22% ⇒ FY2014: 29%



# Globalization during the 3<sup>rd</sup> Medium-Term Business Plan

S-O-N-G  
for you!

- Establish footholds in EU, US and Asia for global development of new drugs
- Establish aggressively a business platform in Asia aiming for direct sales
- Select multiple alliance partners in EU for sales



## Basic Strategy 2



### *Portfolio Management of Development Products and Numerical Targets*

- **Persistence with portfolio management of development products**
  - **Reassess the potentials of all development products every 6 months**
  - **Reassess the investment allocation for each product and focus strategically on the priority products**
- **Contingency Plan**
  - **Back-up strategy**
    - **Create seamlessly back-up/follow-up compounds**
    - **Promote rapid decision-making and enhance flexibility in resource allocation**
  - **In-license strategies**
    - **Prioritize late-stage development products in the target areas**
    - **Assume Shionogi direct sales overseas**
    - **Strengthen business development activities by integrating Japan and US business development**

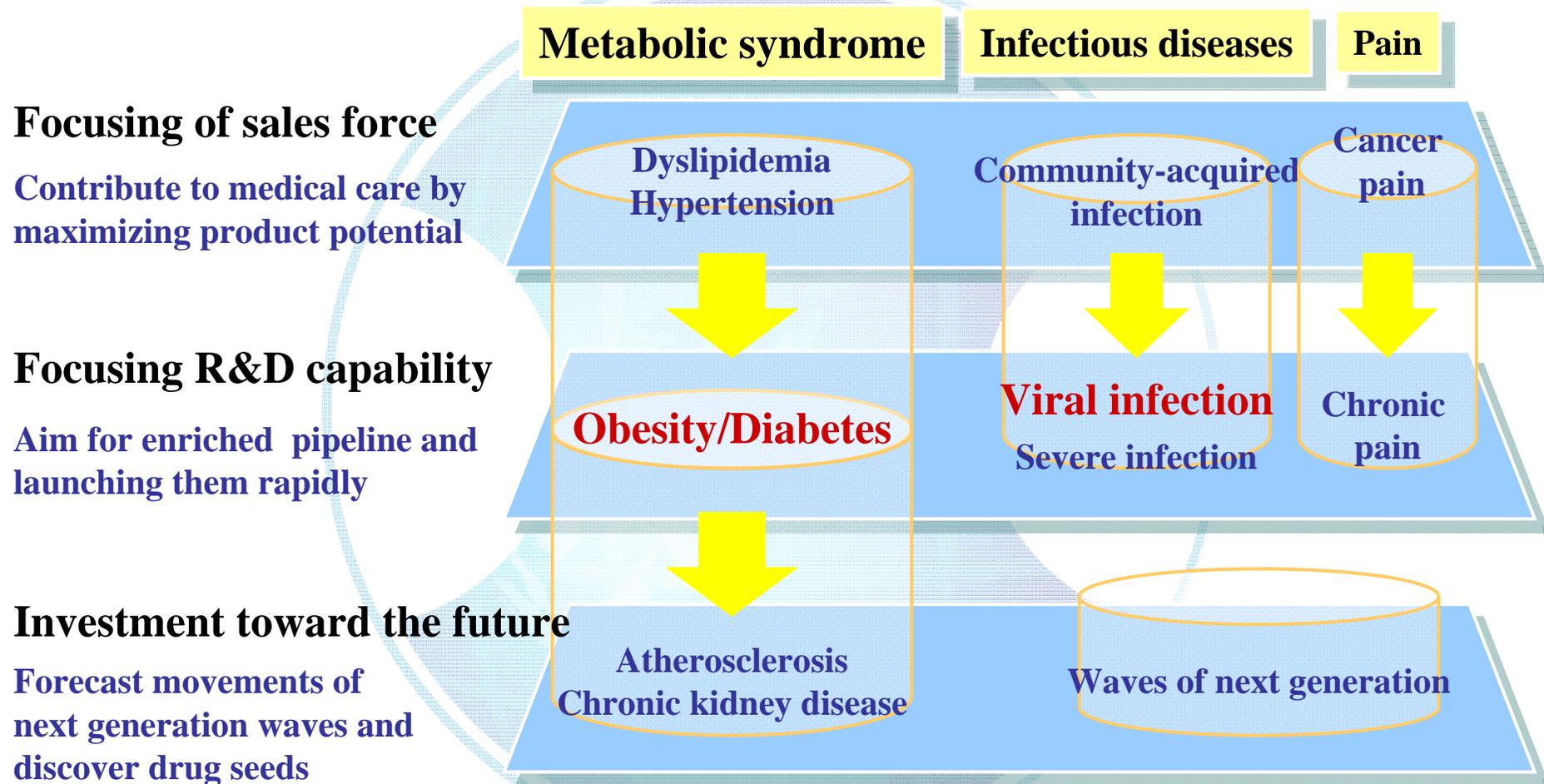
### **Numerical target for the 3<sup>rd</sup> medium-term business plan**

- ◆ **Globally develop more than 5 products in the late stage (Ph 2b and beyond)**
- ◆ **Achieve NDA submission overseas for 4 products (originate from Shionogi or Japanese research institutes), and launch of more than one product by FY2014**

# Basic Strategy 3



## Therapeutic Areas to Be Focused on



**R&D priority areas during the 3<sup>rd</sup> medium-term business plan are**  
**Obesity/Diabetes and Viral infection**



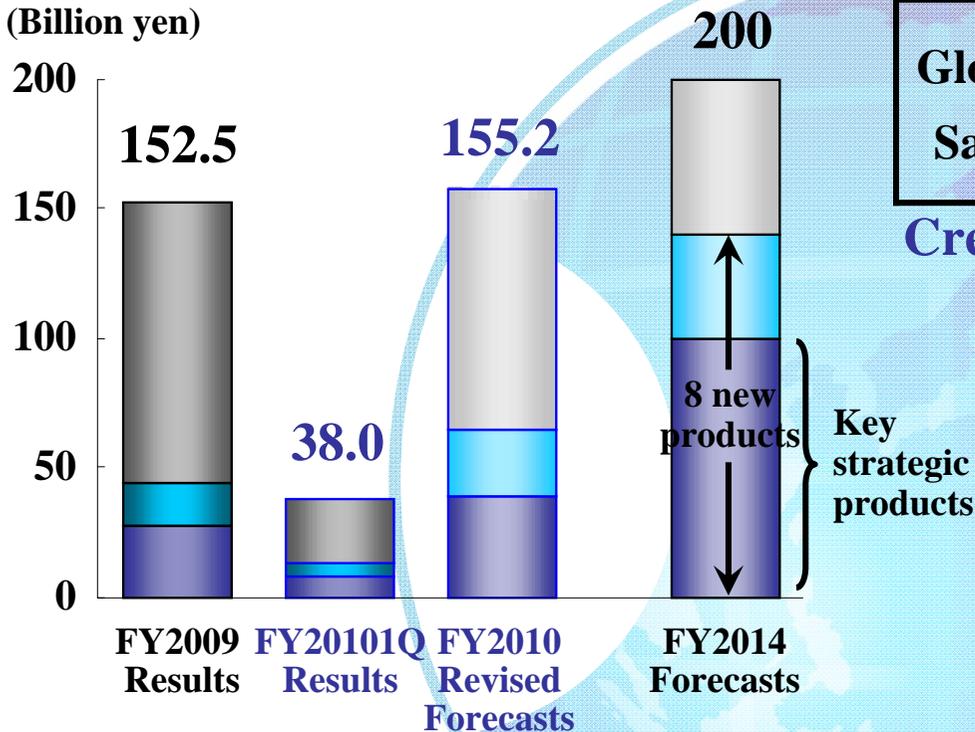
**Current Status**

# Progress Situation of 1<sup>st</sup> Quarter FY2010



## Domestic sales

(Billion yen)

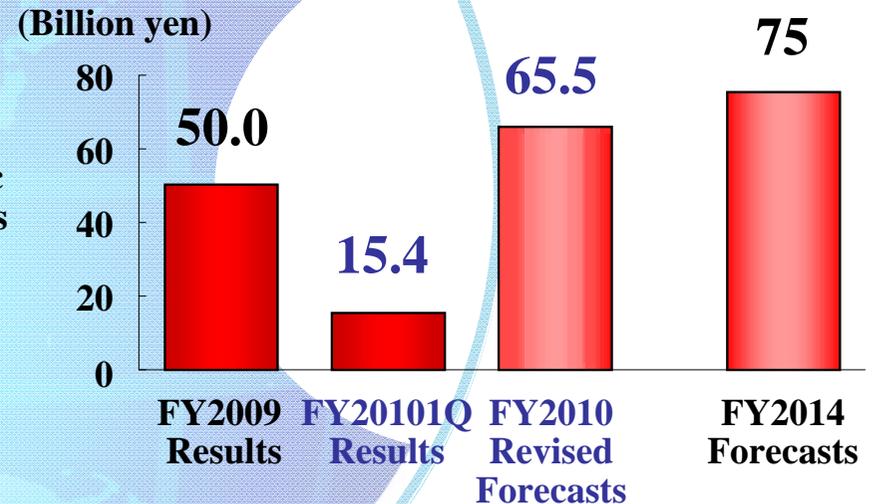


## Crestor sales by AstraZeneca (Billion dollar)

Global Sales	2006	2007	2008	2009	2010 Jan.-Jun.
	2.0	2.8	3.6	4.5	2.7

## Crestor royalty

(Billion yen)



### ● Domestic sales

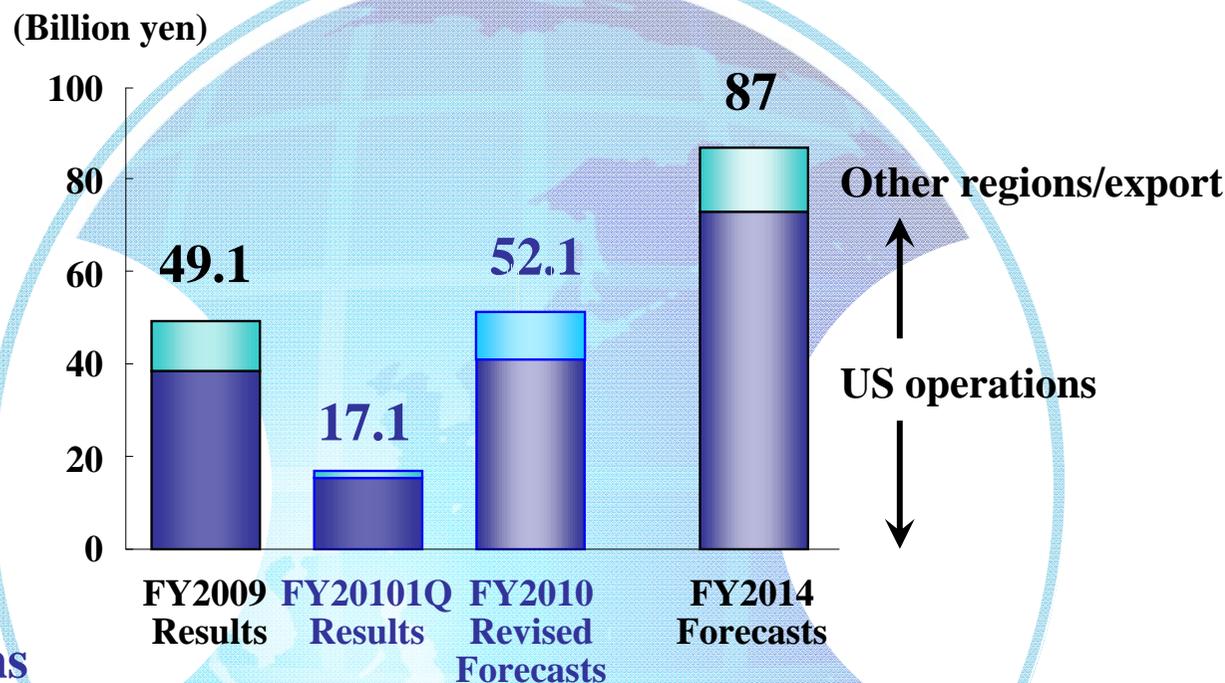
- Robust sales increase despite the reduction in NHI drug prices by the drug price revision (achievement: 24.7% vs. FY2010 full year original forecasts)
- Higher proportion of 8 new products in prescription drug sales by focusing on 8 new products

### ● Crestor royalty

- Continuous expansion of global sales by AstraZeneca



## Sales of overseas subsidiaries and export



- **US operations**

- Institution of “Shionogi Inc.” as the headquarter in the US in July to operate the US business integrally and efficiently
- Sales and Operating income of FY2010 forecasts were revised down due to the multiple factors occurred from April to June

- **R&D**

- Announcement of the positive outcomes of Phase IIb interim analysis in July after steadily development of S/GSK1349572

1<sup>st</sup> quarter results of FY2010 include 6 months from Jan.1 to Jun.30 for the US subsidiaries.

## *Improvement of US Operations*



### *Current Situation*

- On August 2<sup>nd</sup> Shionogi reported Financial Results for its US operations, which outlined an Operating Income loss for 1Q FY 2010 of \$50 million
- The operating loss was a result of multiple factors including deteriorating market conditions due to generics and reductions in wholesaler inventory levels

To restore the profitability and long-term health of our US operations, Shionogi is implementing a 3 step process for rebuilding and renewing growth:

- 1. Stabilize current P&L through aggressive cost cutting**
- 2. Shift focus from legacy products towards new products**
- 3. Accelerate growth through Shionogi's in-house pipeline**

## *Improvement of US Operations*



### *Step 1: Stabilize Current US P&L*

- **Aggressive cuts to the US cost base have been implemented**
  - **Field force reductions in Primary Care**
  - **Reductions in associated commercial and marketing personnel**
  - **Reductions of administrative and R&D personnel**
- **Clinical Development expenses have been reduced**
  - **Discontinuation of clinical development of selected US assets**
  - **Development costs effectively managed as one global R&D budget under Shionogi Japan**
- **Other potential savings measures are being evaluated further as necessary**
  - **Consolidation of functions across US operating sites**
  - **Additional headcount reductions**
  - **Rationalization of marketed portfolio**

**Target is to achieve financial results committed to analysts at August 2<sup>nd</sup> 1Q 2010 results conference**

## *Improvement of US Operations*



### *Step 2: Shift Focus to New Products*

- **Accelerate launch of new products utilizing sales infrastructure**
  - **CUVPOSA™/glycopyrrolate for chronic drooling**
  - **Clonidine for ADHD**
- **Accelerate development and approval of late stage pipeline assets**
  - **PSD502 for premature ejaculation**
  - **Ospemifene for vaginal vulvar atrophy**
- **Aggressively seek in-licensing or product acquisitions to restore the US commercial portfolio**
  - **Focus on specialty areas, leveraging existing sales infrastructure**

**Goal is to “build a bridge” to sustain our US business until Shionogi’s in-house pipeline matures**

## *Improvement of US Operations*



### *Step 3: Accelerate US Growth with In-house Assets*

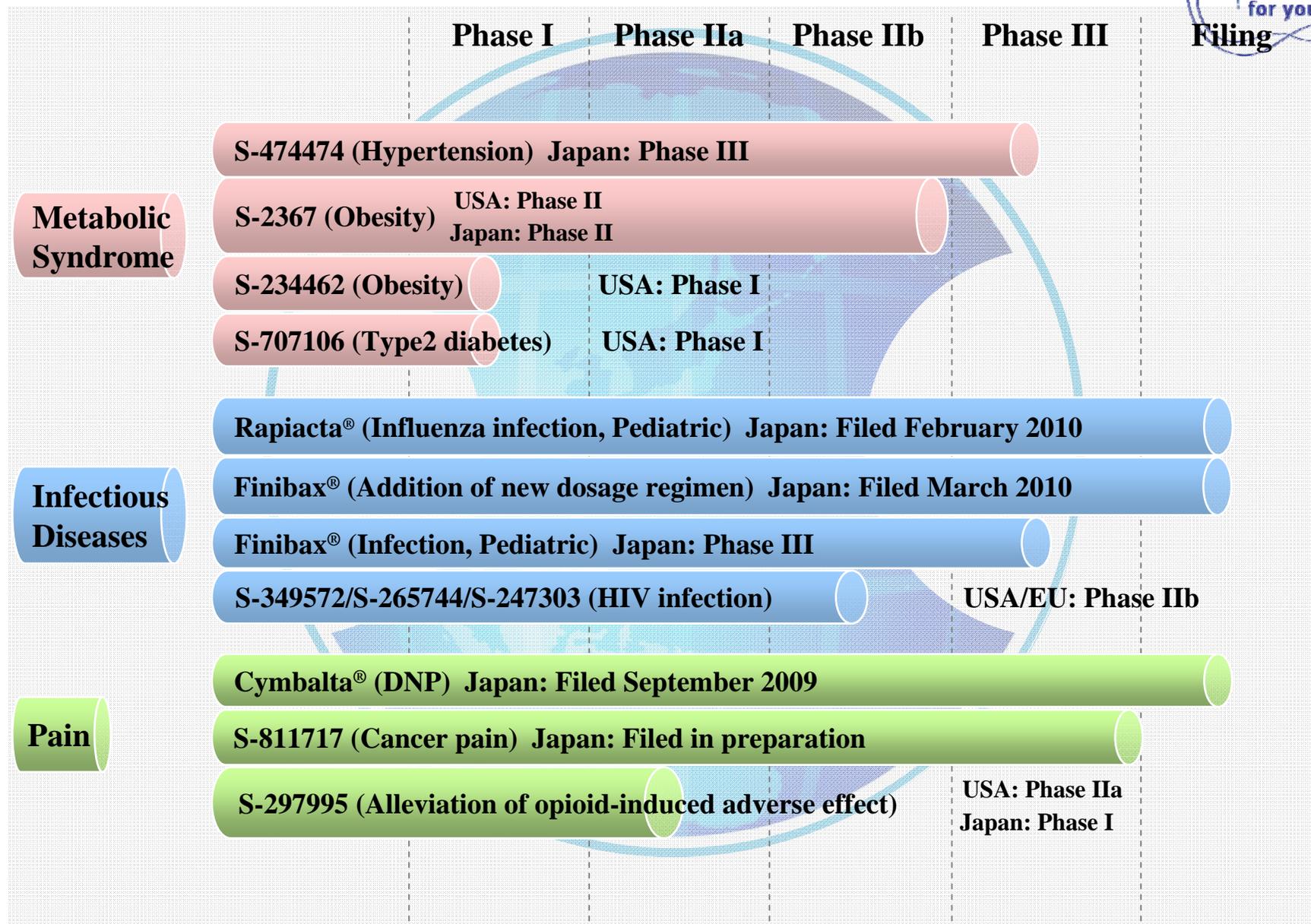
- **Leverage US commercial infrastructure to launch key products currently in mid to late-stage development**
  - **S/GSK1349572 for HIV**
  - **S-2367 for obesity**
  - **S-888711 for thrombocytopenia**
  - **S-297995 for opioid-induced nausea and constipation**
- **Continue with selected in-licensing or product acquisitions that complement in-house portfolio**

**Long-term future of the US business will be based on the success of Shionogi's R&D pipeline**

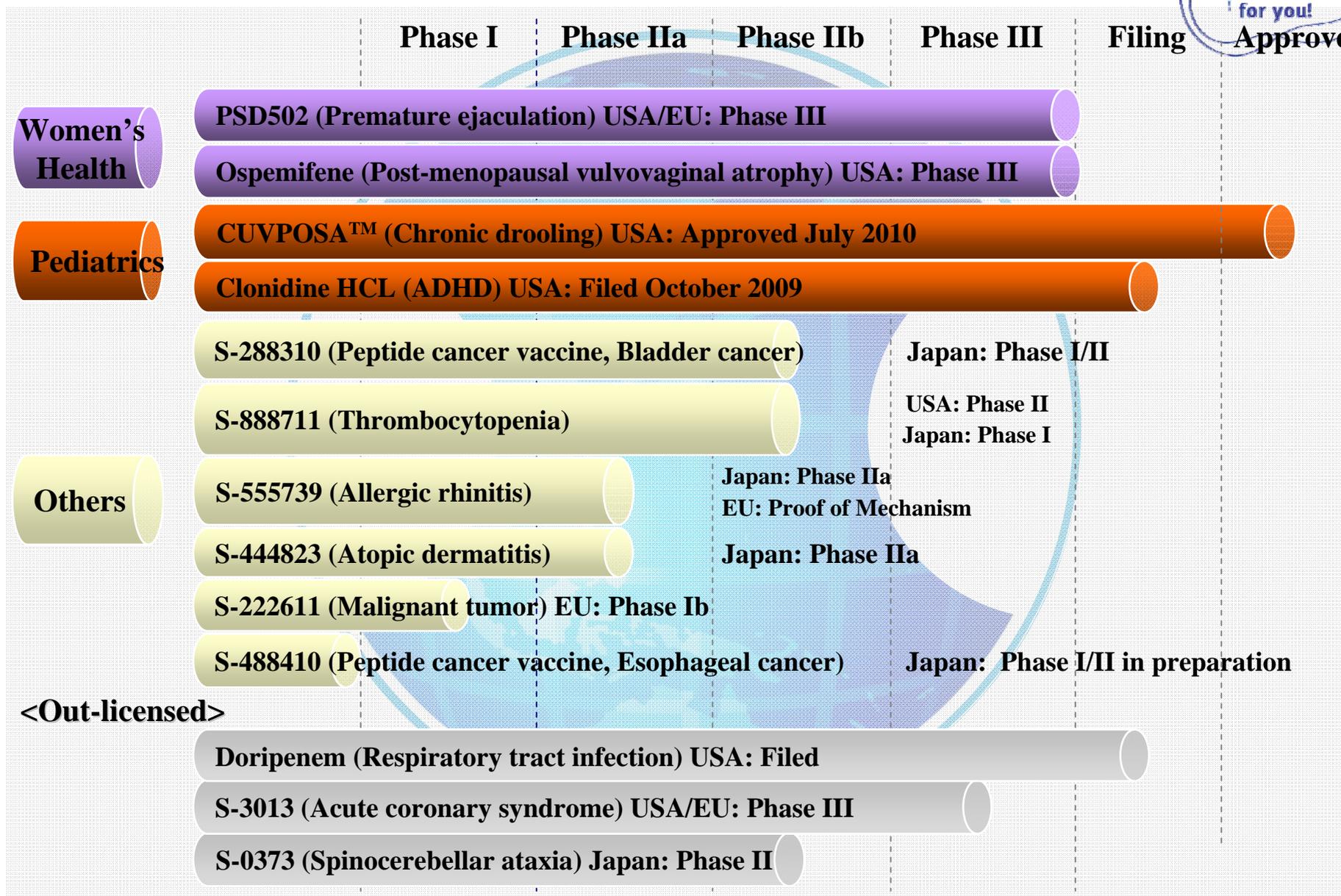


**Core Development Products**

# Development Pipeline (As of September 2010)



# Development Pipeline (As of September 2010)



## Core Development Products



### Target Milestones for FY2010

Progress in global development products	
<b>S-2367</b>	<b>Dosing in Phase II (used in combination with Orlistat) completed (USA)</b> <b>Dosing in two Phase II studies completed (Japan)</b>
<b>S/GSK1349572*</b>	<b>Phase IIb completed, Phase III initiated (USA, EU etc.)</b>
<b>S-555739</b>	<b>Additional therapeutic exploratory study to be planned</b>
<b>S-444823</b>	<b>Phase IIa completed (Japan)</b>
<b>S-888711</b>	<b>Phase II to be initiated (except immune thrombocytopenia)</b>
<b>S-234462</b>	<b>Phase I completed, Phase II to be initiated (USA)</b>
<b>S-297995</b>	<b>Phase IIa completed (USA)</b>
<b>S-707106</b>	<b>Phase I completed, Phase IIa study to be initiated (USA)</b>
<b>S-288310</b>	<b>Phase I/II completed (Japan)</b>
<b>S-488410</b>	<b>Phase I/II initiated (Japan)</b>

## *S/GSK1349572: Profile*

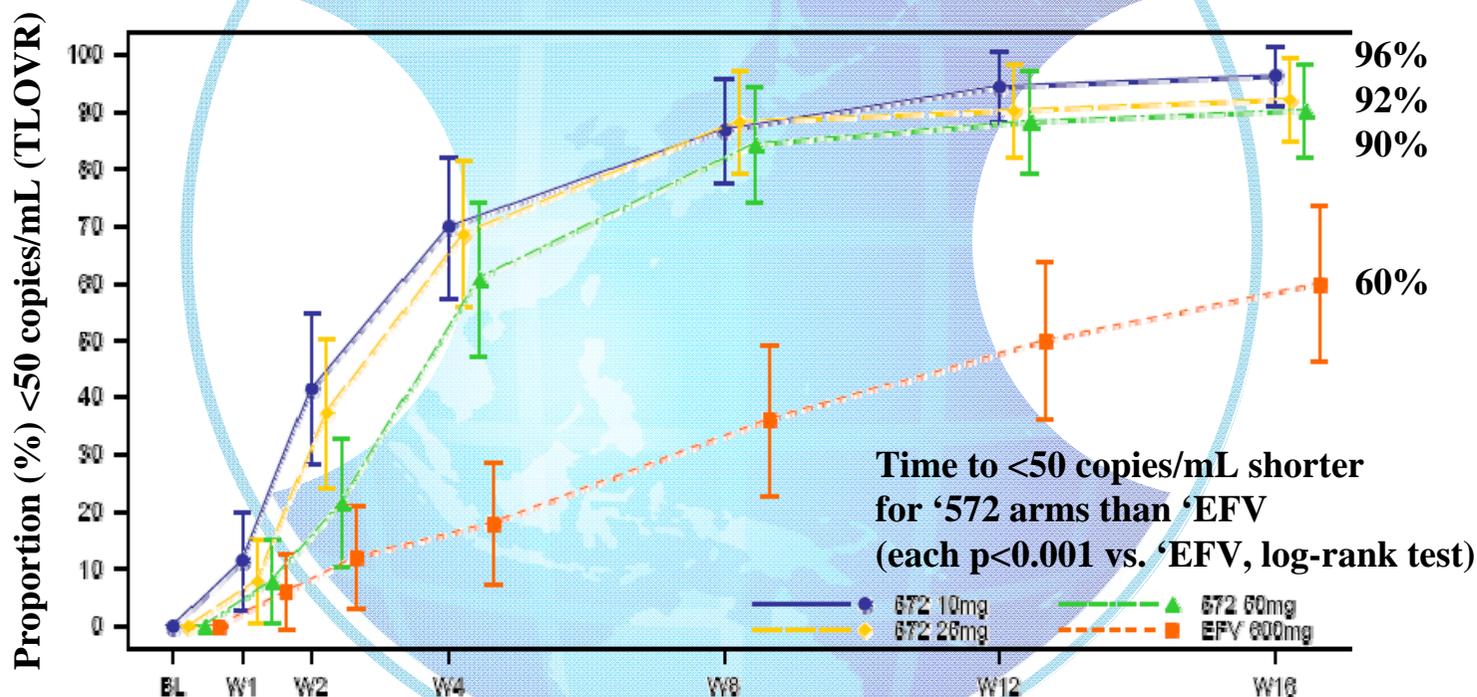


- **Development:** Developed by Shionogi-ViiV Healthcare LLC.
- **Mechanism:** HIV integrase inhibitor (oral)
- **Characteristics:**
  - **Highly potent antiviral activity**
  - **Good resistance profile (in vitro)**
  - **Once daily, without PK booster, low dose**
  - **Low risk of drug-drug interactions**
- **Development Stage:**
  - **Phase IIb in the USA and the EU ongoing and Phase III study to be started in 2010**
- **Market Situation in 2009:**
  - **Global value sales: more than \$14,000 million, US: \$7,000 million, 5 EU: \$4,000 million, Rest of world: \$3,100 million (*Reference: EvaluatePharma*)**
  - **Market forecast of anti-HIV drugs in the 7 major markets in 2019: \$14.4 billion (*Reference: DATAMONITOR*)**
  - **First Integrase inhibitor, Raltegravir was launched at the end of 2007. Sales in 2008 was \$361 million and \$752 million in 2009, and currently growing**

# S/GSK1349572: SPRING-1 Study (Phase IIb)



- **SPRING-1 Study Design (Interim 16-week analysis)**
  - 205 therapy-naïve patients
  - ‘572 10, 25, 50 mg/Efavirenz (‘EFV, NNRTI) 600 mg + backbone drugs (2 NRTIs)
  - Primary endpoint: % <50 copies/mL at 16 weeks
- **Proportion (%) of subjects with <50 copies/mL (undetectable) at 16 weeks**



Note: 95% confidence intervals are derived using the normal approximation.

◆ In all of ‘572 arms vs. ‘EFV, more potent antiviral activity was shown and time to undetectable viral load was significantly shorter

## S/GSK1349572: VIKING Study (Phase IIb)



### ● VIKING Study Design (Initial results at Day 11)

- 27 Subjects: Current or historic Raltegravir ('RAL)-failures with evidence of 'RAL-resistance. At least 3 anti-HIV drug classes resistant (including integrase inhibitor)
- To Day10: '572 50 mg + failing background regimen  
From Day11: '572 50 mg + optimized background therapies
- Primary endpoint: % <400 copies/mL or at least 0.7 log<sub>10</sub> copies/mL below their baseline value at Day 11

### ● Plasma HIV-RNA response

	Primary End-point <400copies/mL or ≥0.7 log <sub>10</sub> copies/mL decline n/N (%)	Secondary End-point log <sub>10</sub> copies/mL change from baseline Mean (SD)
All subjects	21/27 (78%)	-1.45 (SD 0.76)
Group A: Q148H/K/R + ≥1 Q148 associated mutations at L74, E138 or G140 (n=9)	3/9 (33%)	-0.72 (SD 0.63)
Group B: All other genotypes from N155H and Y143H pathways or Q148H/K/R single mutants (n=18)	18/18 (100%)	-1.82 (SD 0.53)

◆ Despite the high level resistance to 'RAL, the majority of subjects showed good antiviral responses through Day 11



- **Domestic sales**
  - **Continuous concentration on new products**
- **Crestor**
  - **Growth story is on track with the good situation of ANDA litigation in the US**
- **R&D**
  - **Achieve steady development toward the launch of pipeline 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*