

Merrill Lynch Japan Conference 2010

The Growth Strategy of Shionogi

September 8, 2010

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Overview of the 3rd Medium-Term Business Plan



The 1st - 3rd Medium-Term Business Plan of Shionogi

The 1st Medium-Term Business Plan

(April 2000—March 2005)

~ Concentration on the prescription drug business ~

The 2nd Medium-Term Business Plan

(April 2005—March 2010)

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

The 3rd 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 3rd 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 2

**Investments in the
new growth drivers**

Basic strategy 3

**Therapeutic areas to
be focused on**

2010

2012

2014

2016

2018

2020

**3rd medium-term
business plan**

**4th medium-term
business plan**

**5th medium-term
business plan**



New image Shionogi aims for during the 3rd medium-term business plan

SONG for the Real Growth

***S**peed*

Quick decision and implementation

***O**pen Mind*

Flexible mind and out of box thinking

***N**ever-Failing Passion*

Persistent passion

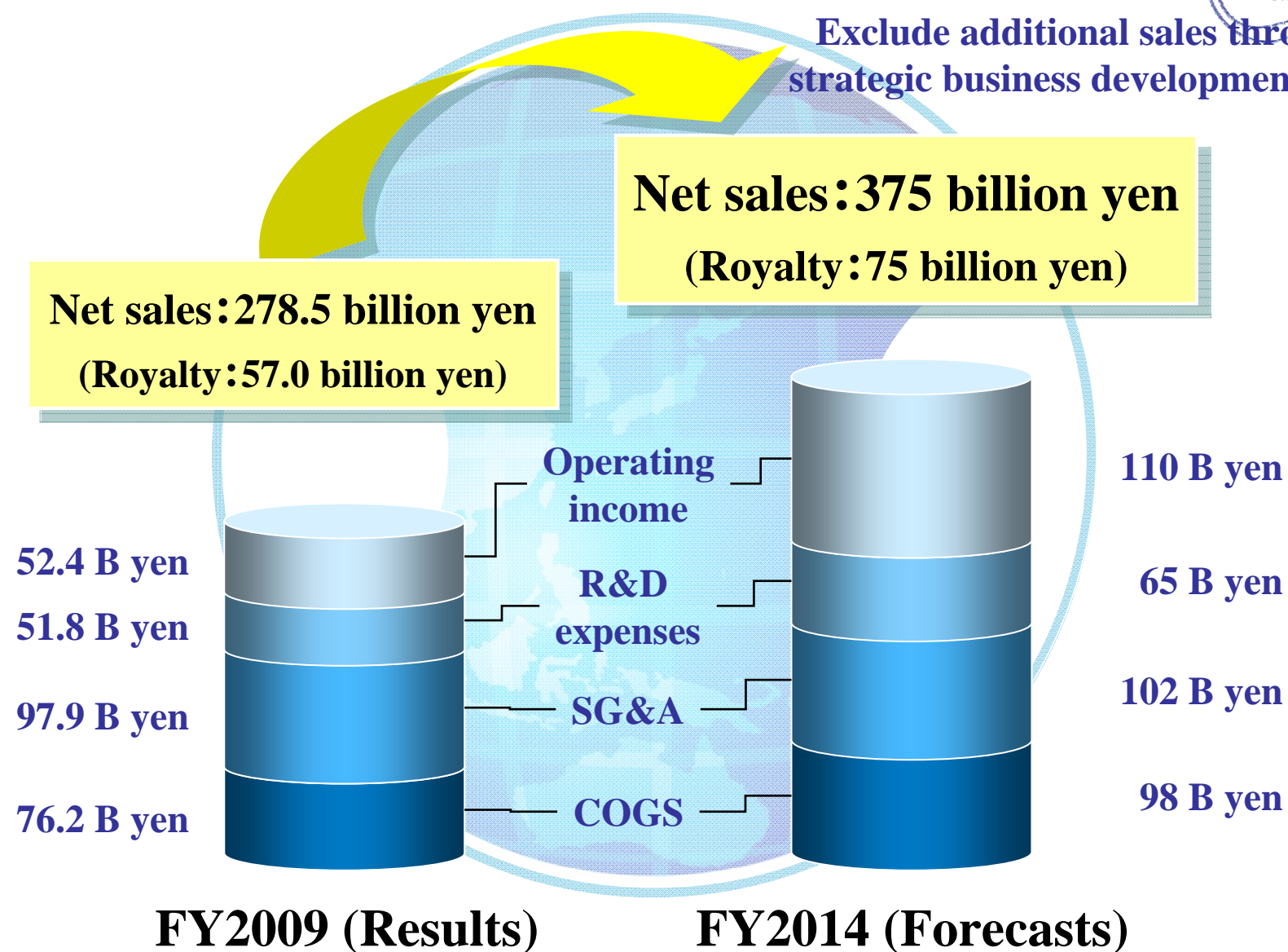
***G**lobal Perspective*

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

Investment toward the future

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

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 \Rightarrow 78 yen

Improvement of B/S for financial strategy

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



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

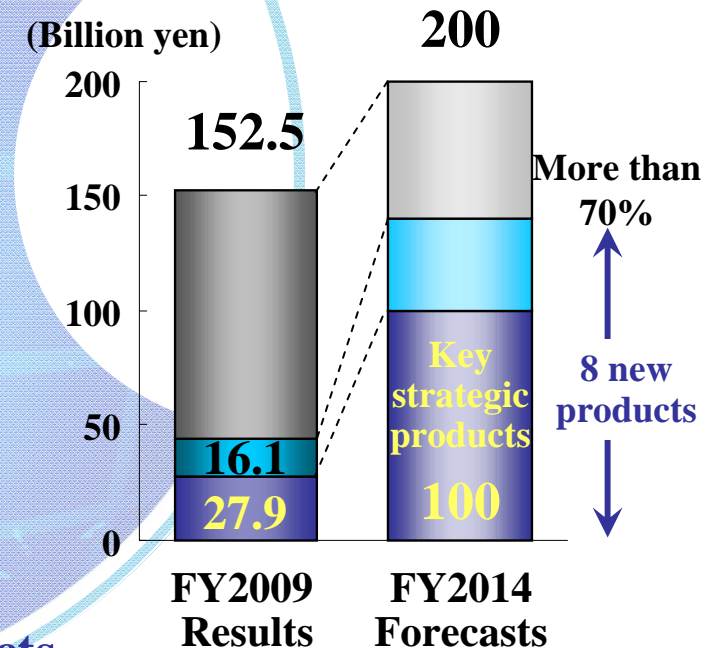
Key strategic products

Crestor
Irbetan
Cymbalta

Pirespa, Differin
Rapiacta, Finibax
OxyContin/OxiNorm

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

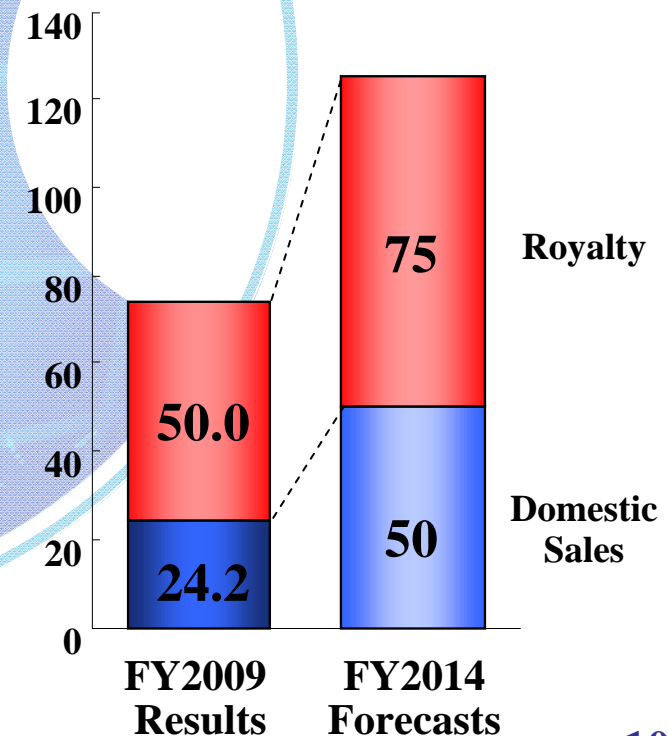
- **FY2011** Establish top share in statin market*
- **FY2014** Net sales target: 50 billion yen

Crestor sales by AstraZeneca

(Billion dollar)

Global Sales	2006	2007	2008	2009
	2.0	2.8	3.6	4.5

(Billion yen)

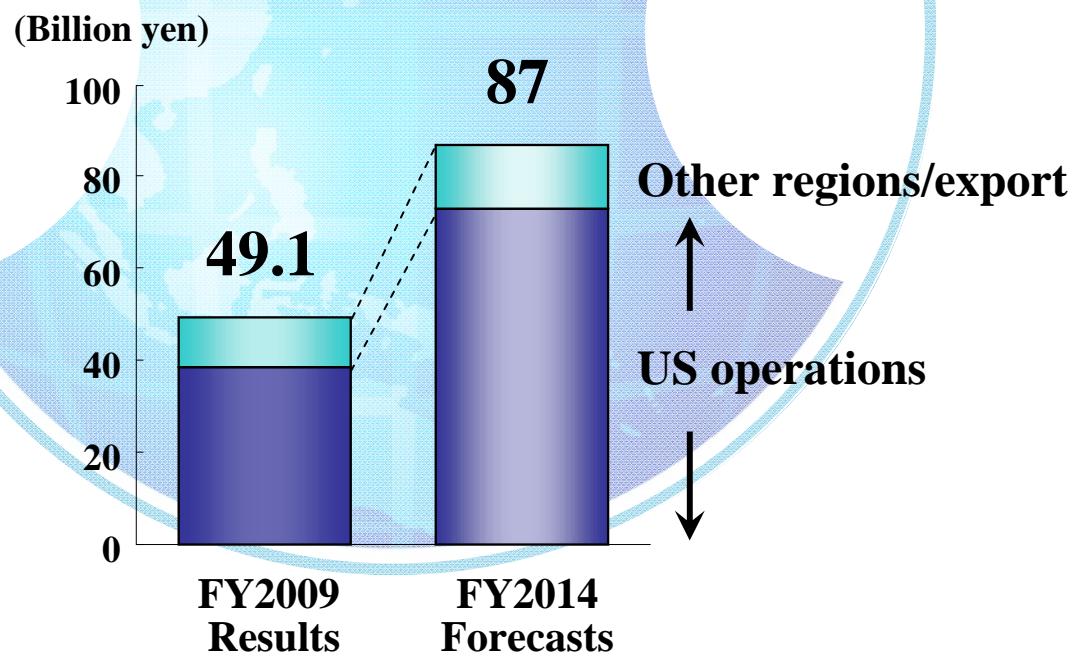


Basic Strategy 1



Overseas Sales Forecasts

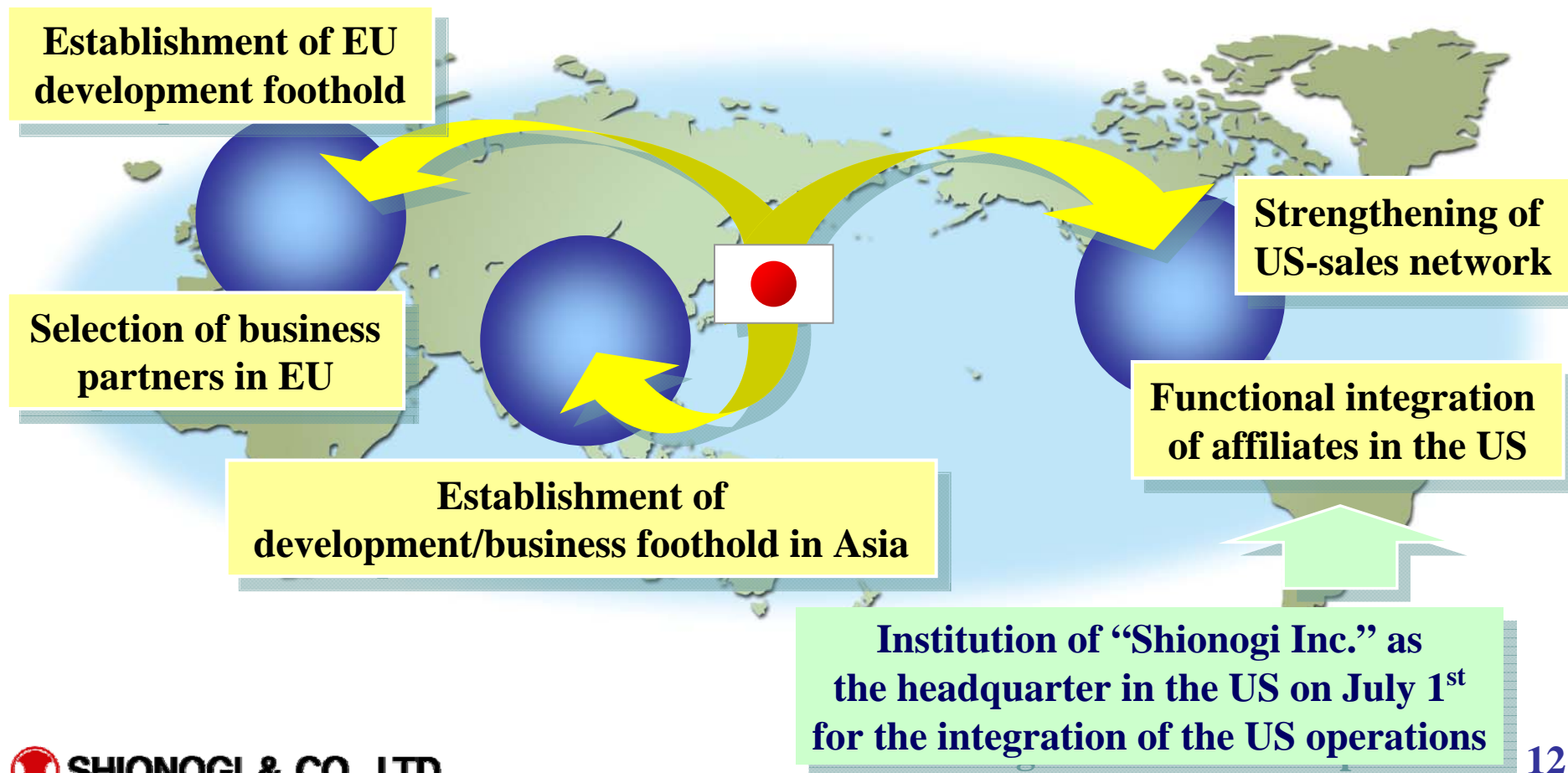
- Net sales target for marketed and products in development: 87 billion yen
 - Exclude additional sales through strategic business development deals
- Expand consolidated overseas net sales ratio excluding royalty to approximately 30%
 - FY2009: 22% \Rightarrow FY2014: 29%



Globalization during the 3rd 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

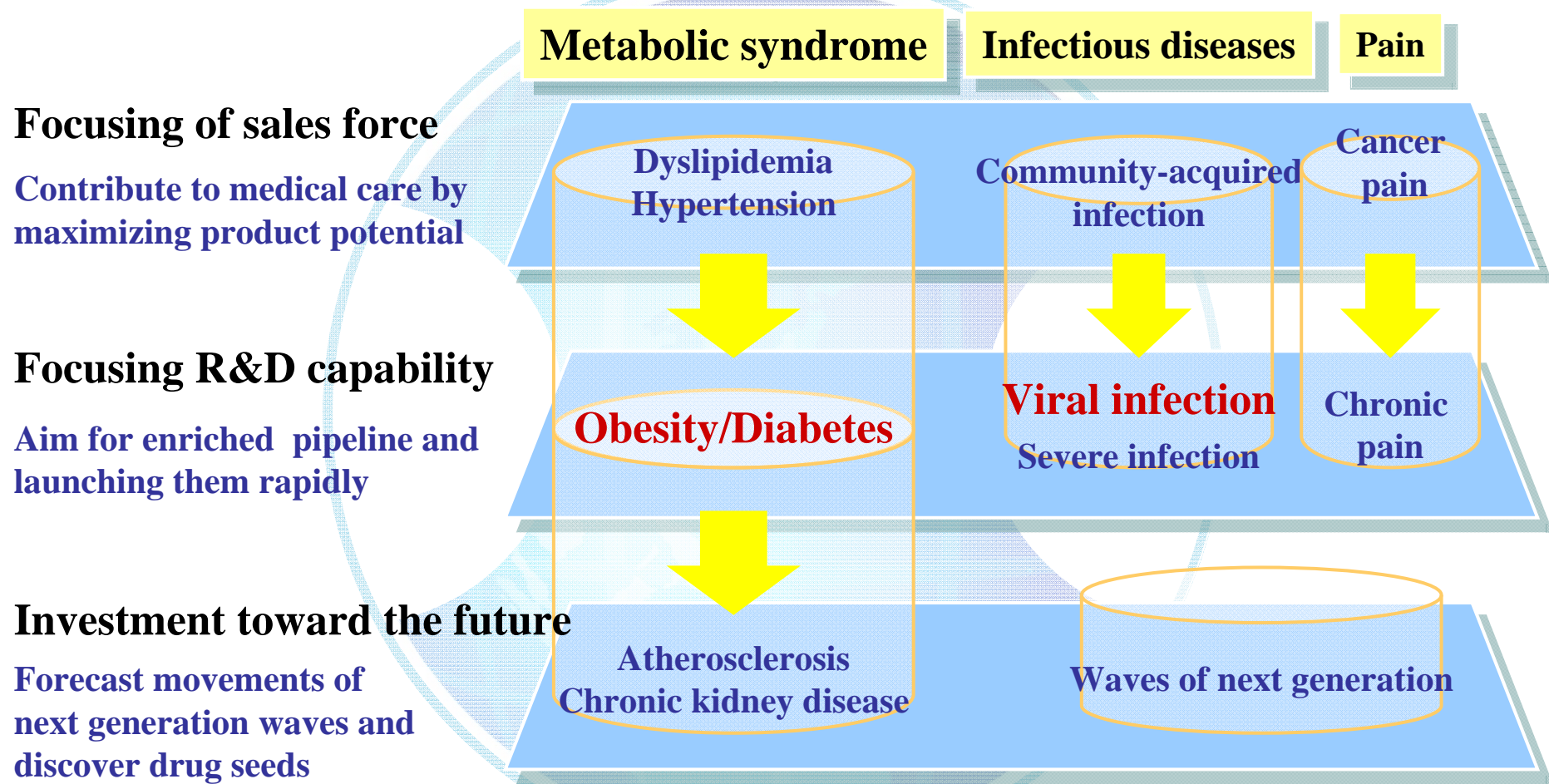
Numerical target for the 3rd medium-term business plan

- ◆ 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 3rd medium-term business plan are
Obesity/Diabetes and Viral infection

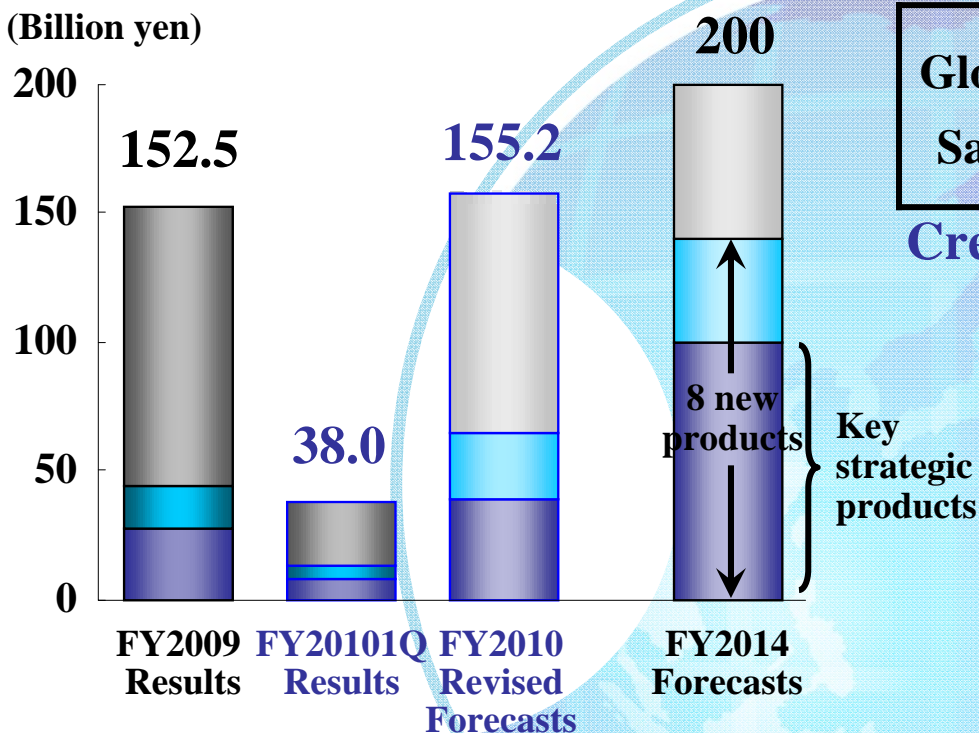


Progress Situation of 1st Quarter FY2010



Domestic sales

(Billion yen)



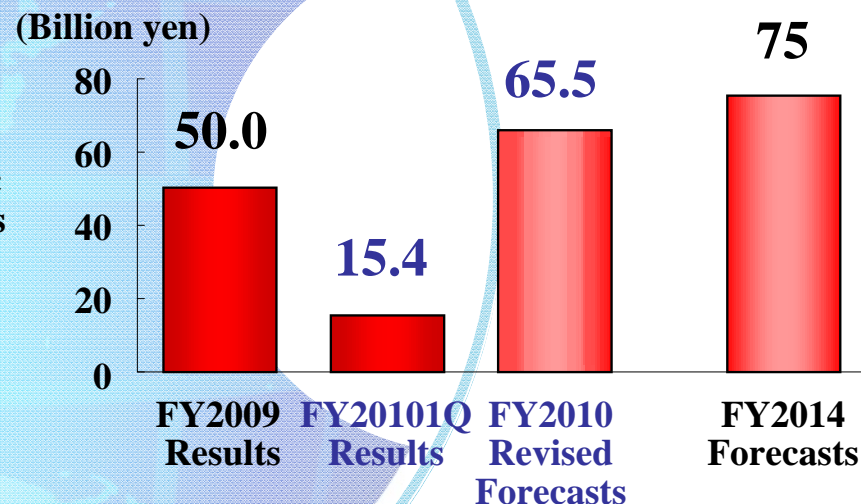
Crestor sales by AstraZeneca

(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

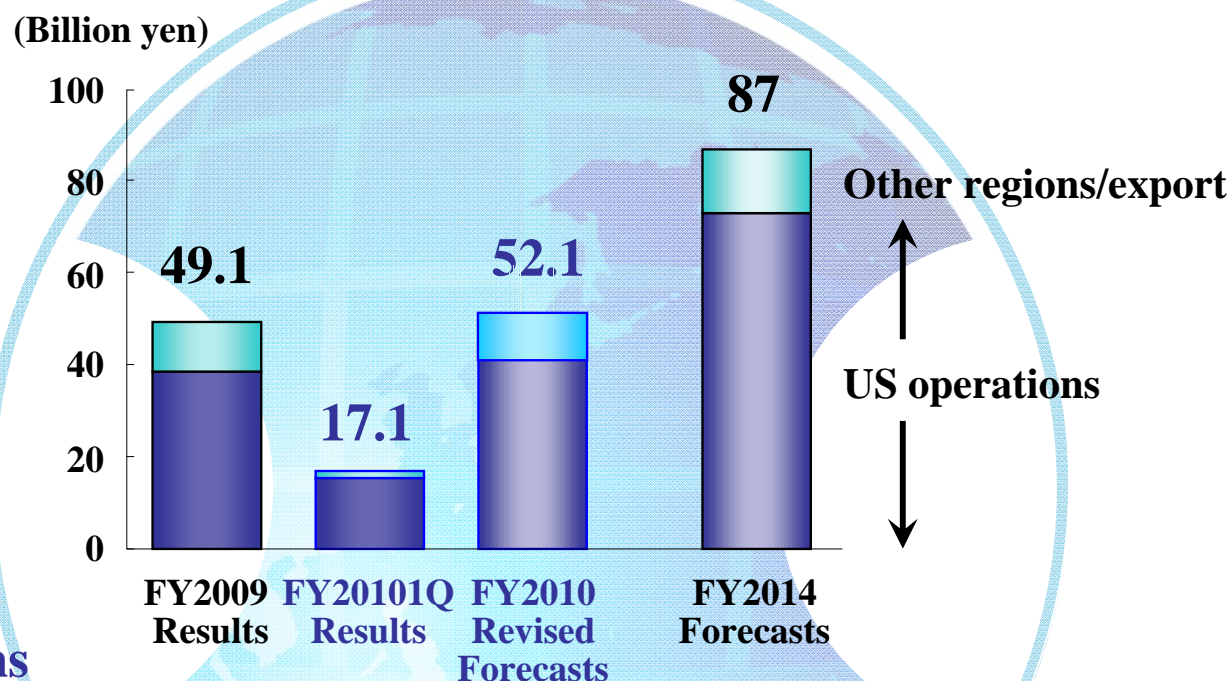
Crestor royalty

- Continuous expansion of global sales by AstraZeneca

Progress Situation of 1st Quarter FY2010



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

1st 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 2nd 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 2nd 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

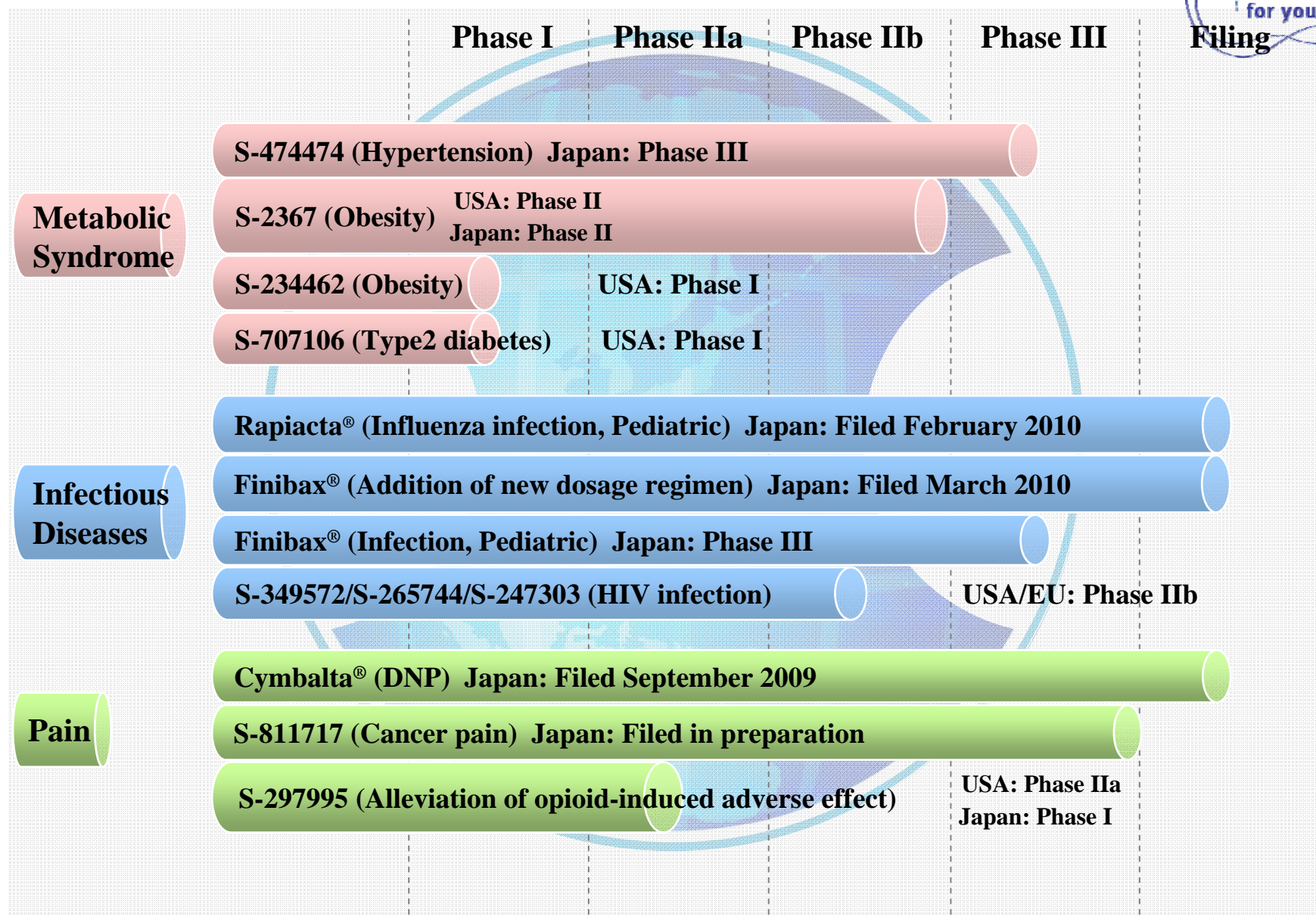
- **Leverage US commercial infrastructure to launch key products currently in mid to late-stage development**
 - **S/GSK1349572 for HIV**
 - **S-2367 for obesity**
 - **S-888711 for thrombocytopenia**
 - **S-297995 for opioid-induced nausea and constipation**
- **Continue with selected in-licensing or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

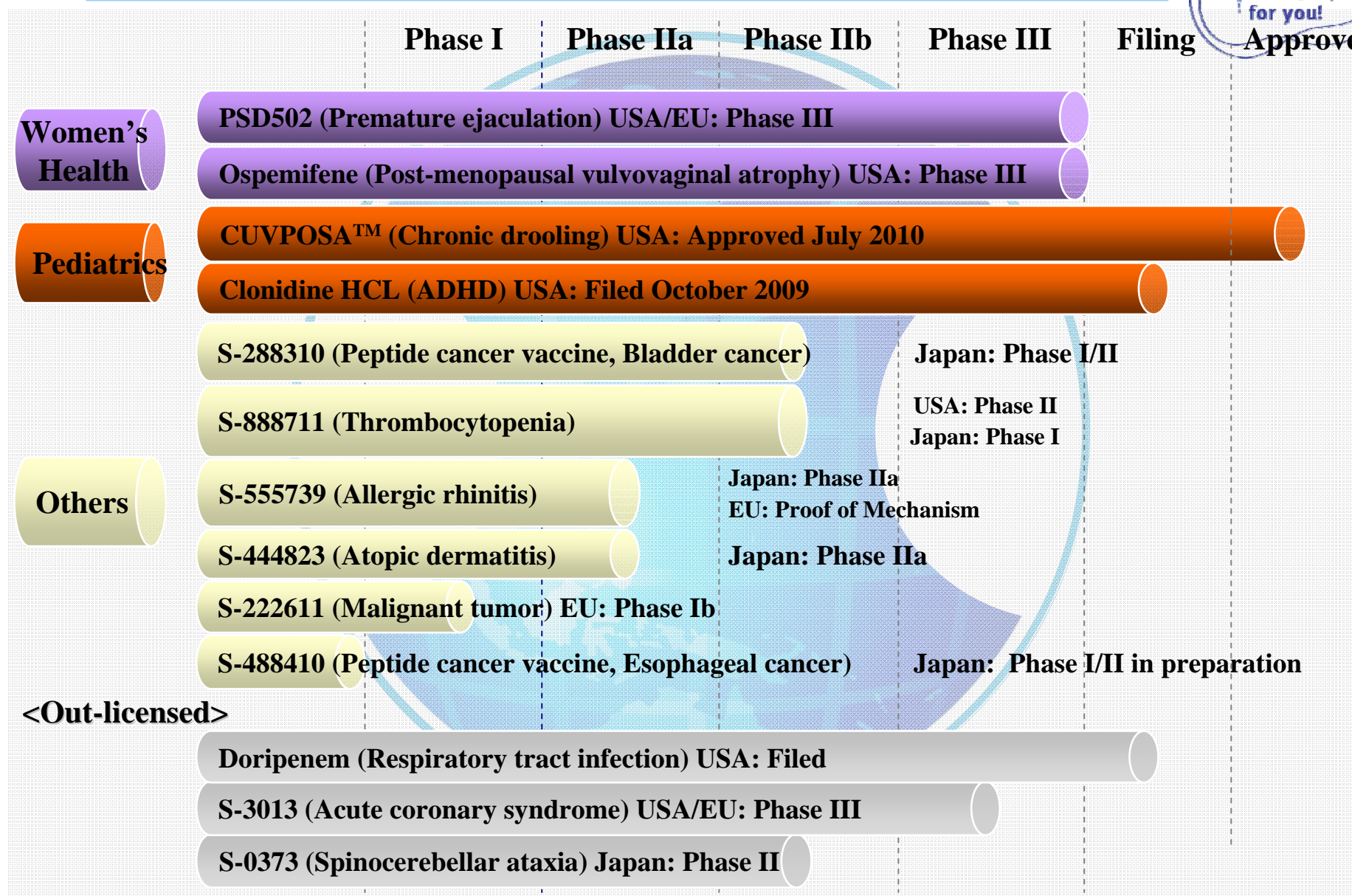


Core Development Products

Development Pipeline (As of September 2010)



Development Pipeline (As of September 2010)



Core Development Products



Target Milestones for FY2010

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

S/GSK1349572: Profile

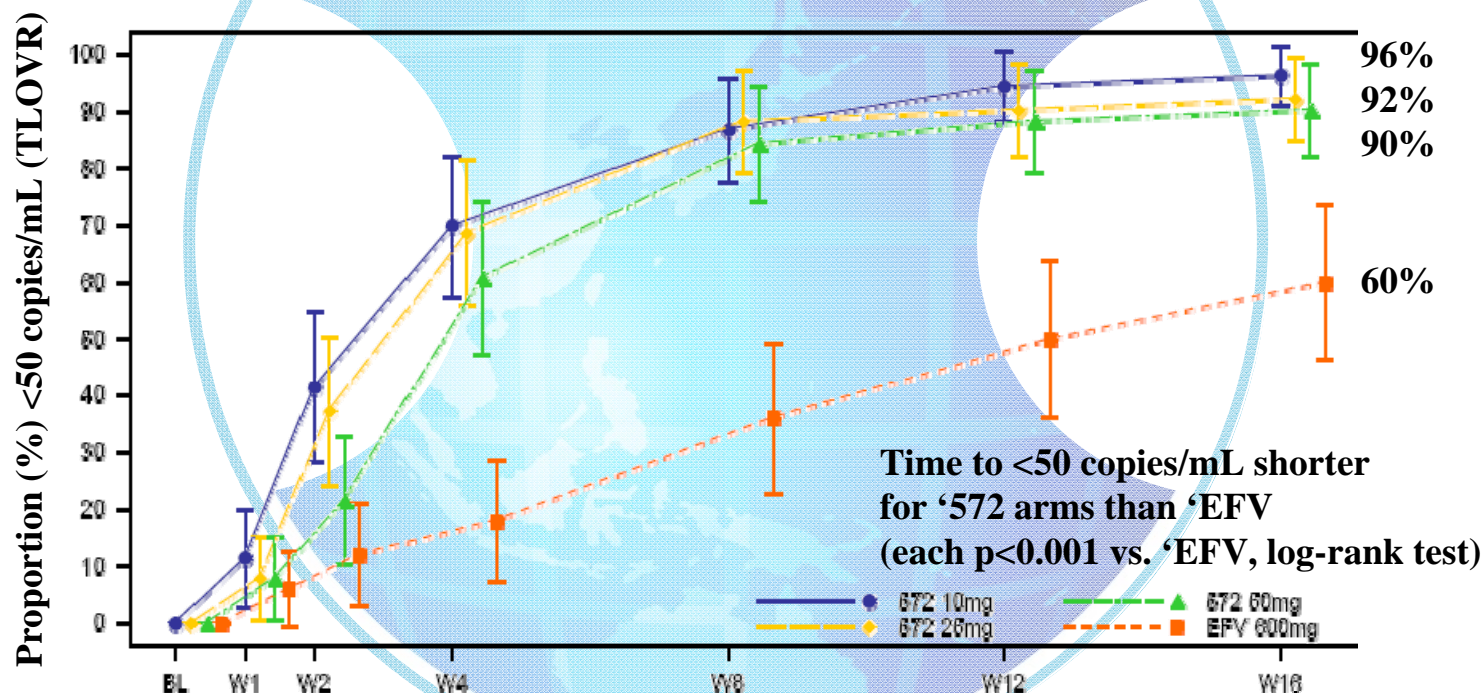


- **Development:** Developed by Shionogi-ViiV Healthcare LLC.
- **Mechanism:** HIV integrase inhibitor (oral)
- **Characteristics:**
 - Highly potent antiviral activity
 - Good resistance profile (in vitro)
 - Once daily, without PK booster, low dose
 - Low risk of drug-drug interactions
- **Development 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 log₁₀ copies/mL below their baseline value at Day 11

● Plasma HIV-RNA response

	Primary End-point <400copies/mL or ≥0.7 log ₁₀ copies/mL decline n/N (%)	Secondary End-point log ₁₀ 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

Shionogi's Direction in The 3rd Medium-Term Business Plan



- **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*