The Growth Strategy of Shionogi

Mizuho Investment Conference

January, 2011

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- **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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Overview of the 3rd Medium-Term Business Plan

Strategy of Shionogi

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

SONG for you!

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* ～

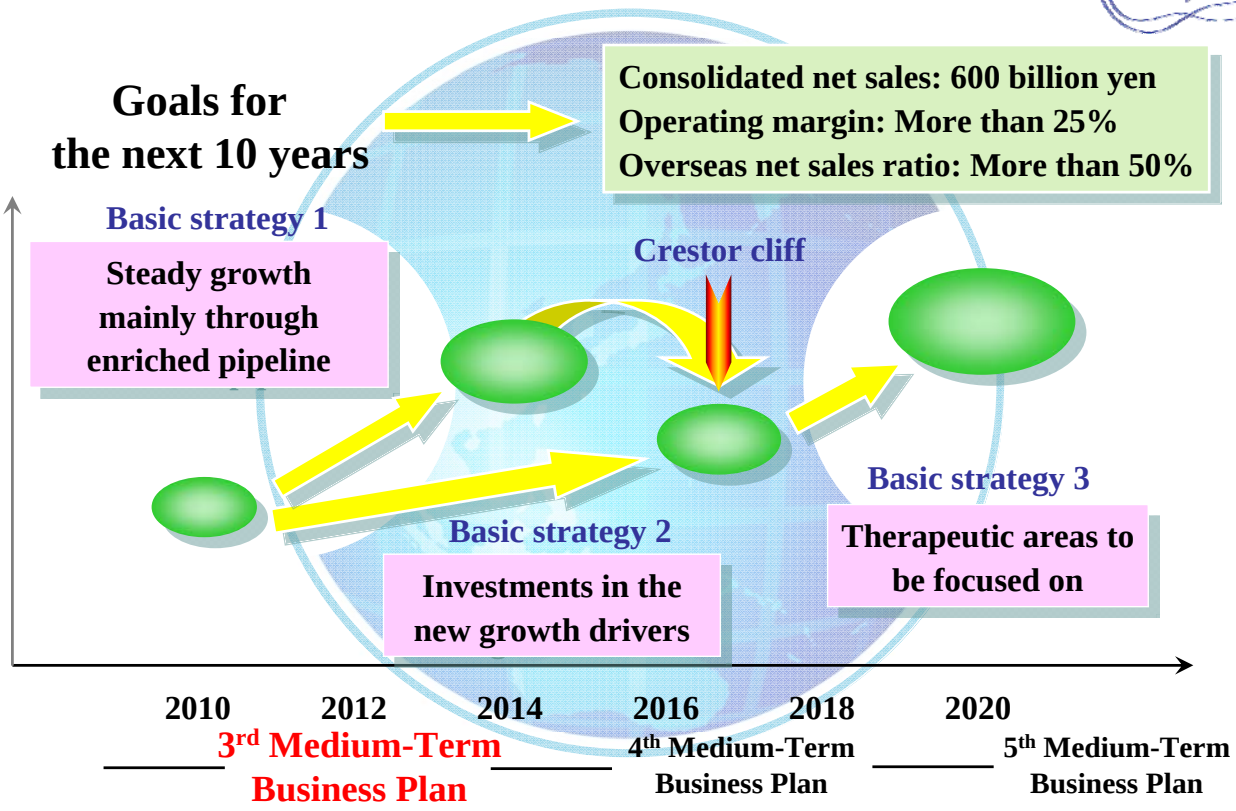
The 3rd Medium-Term Business Plan

(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



New Resolution

New image Shionogi aims for during the 3rd 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

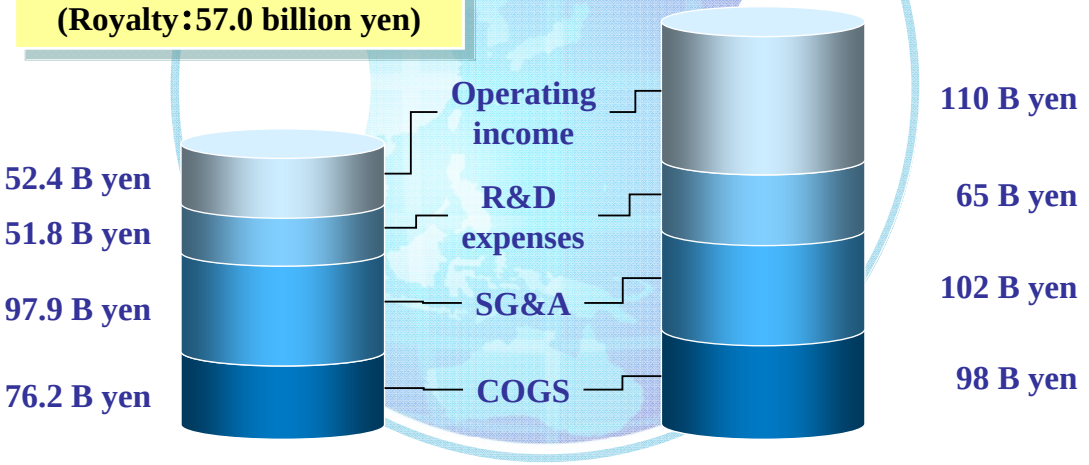
Higher and broader perspective

Financial Target for FY2014 (Consolidation)

Exclude additional sales through strategic business development deals

Net sales：375 billion yen
(Royalty：75 billion yen)

Net sales：278.5 billion yen
(Royalty：57.0 billion yen)



FY2009 (Results) **FY2014 (Forecasts)**

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

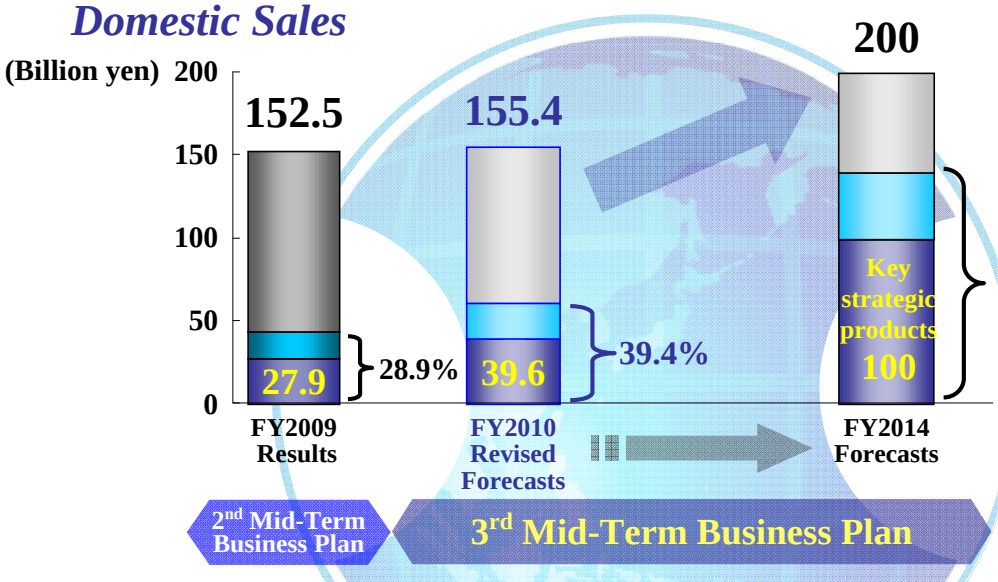
Improvement of B/S for financial strategy

- 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

Current Status

Progress Situation of FY2010

Domestic Sales



More than 70%

8 new products

Key strategic products

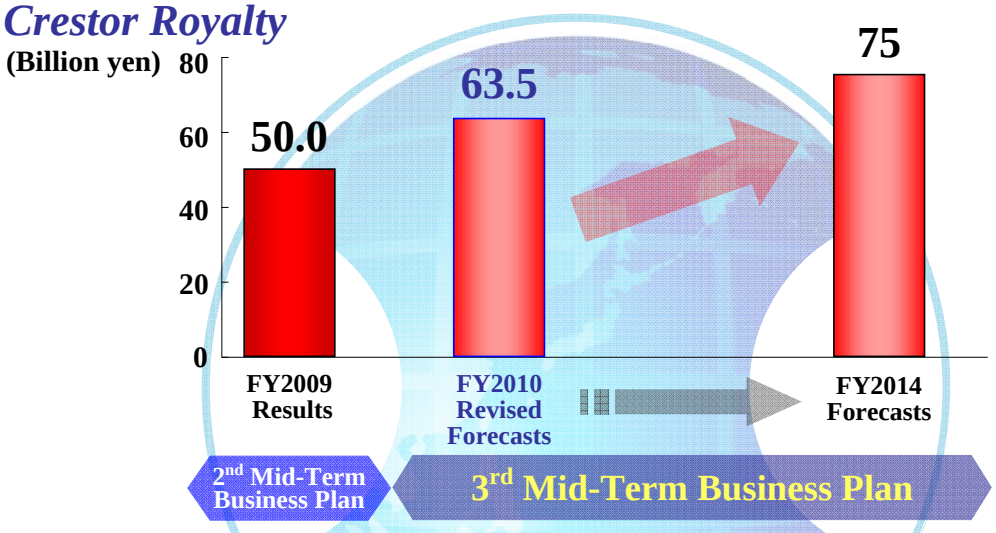
Crestor
Irbetan
Cymbalta

OxyContin
Finibax
Differin
Pirespa
Rapiacta

- **1st half results**
  - **Robust sales increase despite the reduction in NHI drug prices by the drug price revision (achievement: 48.3% vs. FY2010 full year revised forecasts)**
  - **Higher proportion of 8 new products in prescription drug sales by focusing on 8 new products (36.2%)**

Progress Situation of FY2010

Crestor Royalty



Crestor sales by AstraZeneca

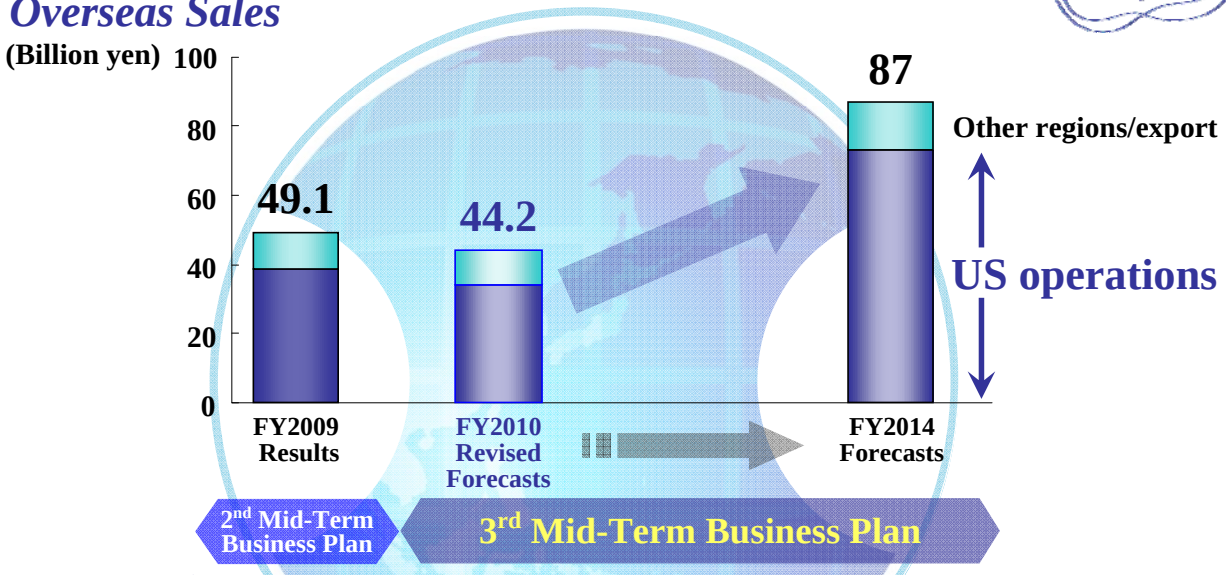
(Billion dollar)

Year	2006	2007	2008	2009	2010 (Jan.-Sep.)
Global sales	2.0	2.8	3.6	4.5	4.1

- **1st half results**
  - **Steadily growth of global sales by AstraZeneca (actual rate: 26.0% vs. Jan.-Sep. 2009)**

Progress Situation of FY2010

Overseas Sales



- **US operations**

  Stabilize current P&L through aggressive cost cutting
  - **Reduced sales force in Primary Care, administrative and R&D personnel**
  - **Discontinuation of clinical development of selected US assets**
  - **Rationalized marketed portfolio**

Forecasts of FY2010 for the US subsidiaries include 15 months from Jan. 2010 to Mar. 2011.

Further Plans of US Operations

Shift focus to new products to sustain US business

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

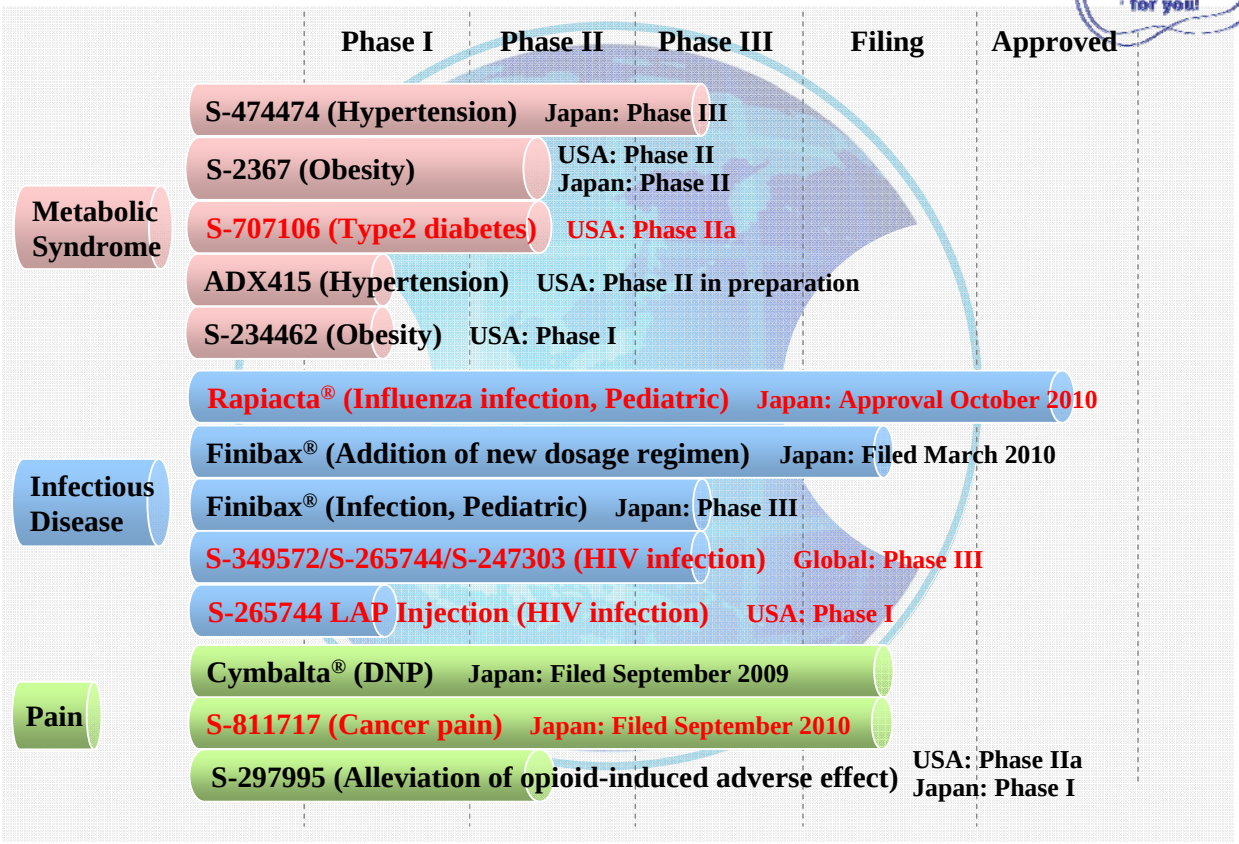
Accelerate US growth with in-house assets for long-term future

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

ADHD: Attention Deficit Hyperactivity Disorder

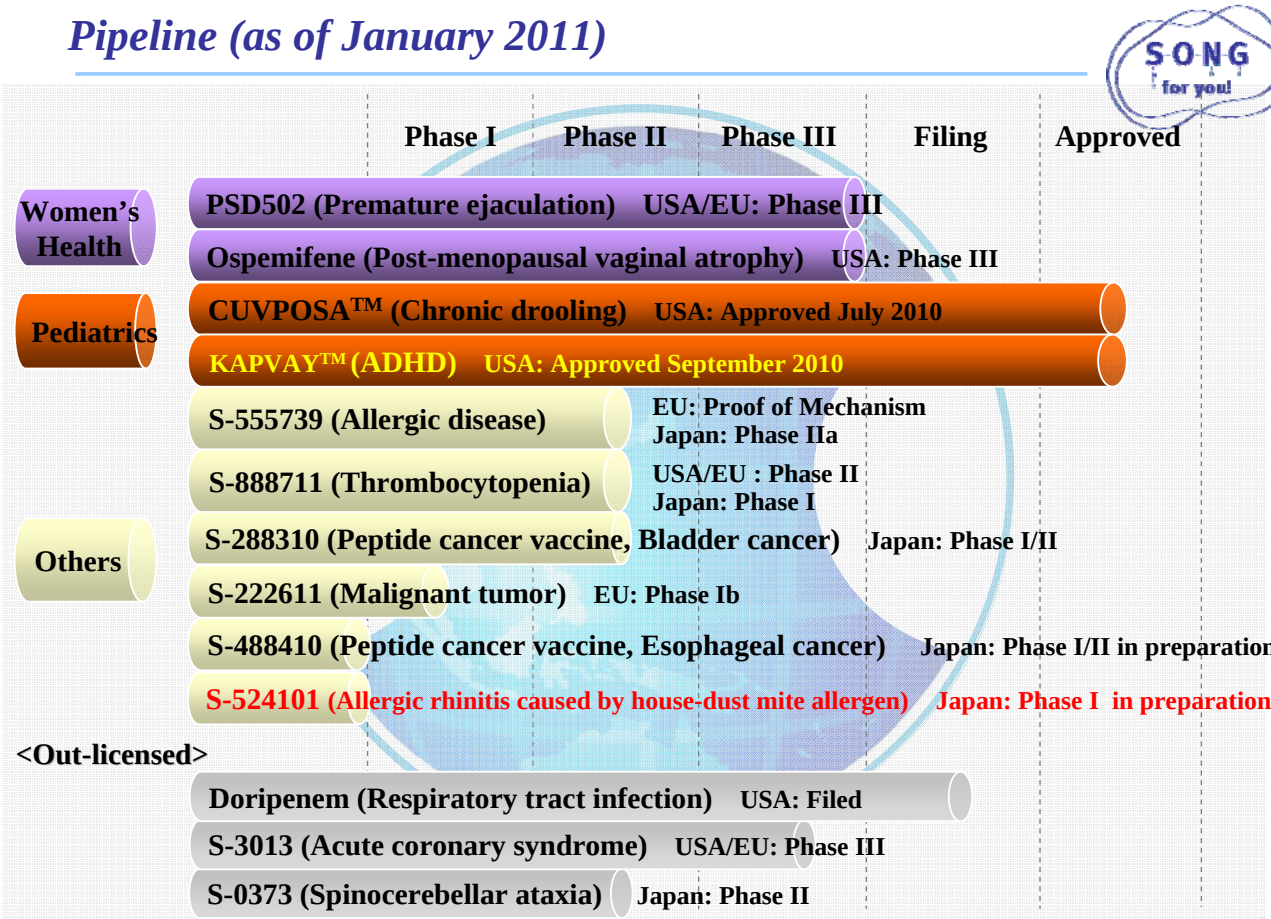
Core Development Products

Pipeline (as of January 2011)



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

Pipeline (as of January 2011)



ADHD: Attention deficit and hyperactivity disorder

Progress Situation of R&D (since August 2010)

- **Approval**
  - **RAPIACTA®: Influenza Infection for Pediatric Use, Japan: Approved Oct. 2010**
  - **KAPVAY™: ADHD, Pediatric, USA: Approved Sep. 2010**
- **Change of phases in clinical studies**
  - **S-811717: The treatment of moderate to severe pain in patients with cancer pain (Injection), Japan: NDA filed Sep. 2010**
  - **S-349572: HIV infection, Global: Ph III**
  - **S-707106: Type2 diabetes, USA: Ph IIa**
- **Newly added development compounds**
  - **S-265744 LAP (long acting parenteral formulation): HIV infection, USA: Ph I**
  - **S-524101: Allergic rhinitis caused by house-dust mites allergen, Japan: Ph I in preparation**

Progress Situation of R&D (since August 2010)

- **License agreement**
  - **Sublingual tablet of allergen extracts for immunotherapy with Stallergenes (Allergic rhinitis caused by house-dust mite, S-524101)**
  - **Sublingual tablet of allergen extracts for immunotherapy with Stallergenes (Allergic rhinitis caused by Japanese cedar pollen)**
  - **Novel antibiotics targeting drug-resistant Gram-negative bacteria with GSK**
  - **Peptide vaccines for ophthalmic disease with OncoTherapy Science, Inc.**
  - **NF-kappa B decoy oligodeoxynucleotide for atopic dermatitis with AnGes MG, Inc.**
- **Discontinued development**
  - **Priority reassessment: Pravastatin/Fenofibrate, Jenloga XR**
  - **Discontinuation of development: S-444823**

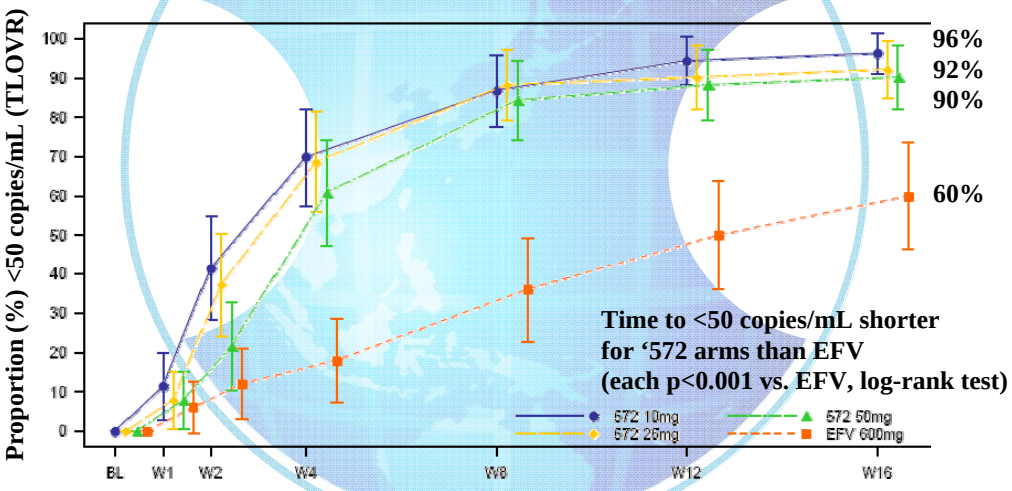
Shionogi's Direction in The 3rd Medium-Term Business Plan

- **Domestic sales**
  - **Continuous concentration on 8 new products**
- **Crestor**
  - **Sustainable growth in the world**
- **US operations**
  - **Improvement plans to accelerate the growth are on track**
- **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

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**

NNRTI: Non-nucleoside Reverse Transcriptase Inhibitor, NRTI: Nucleoside Reverse Transcriptase Inhibitor

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_{10} 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)

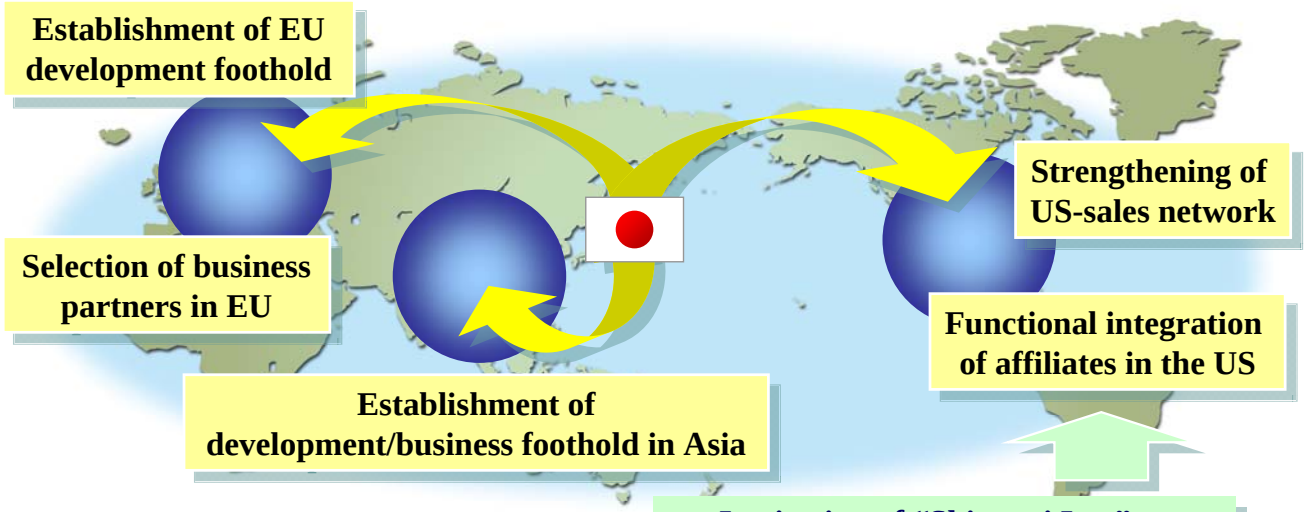
◆ **Despite the high level resistance to RAL, the majority of subjects showed good antiviral responses through Day 11**

S/GSK1349572: Phase III Study Designs

- **SPRING-2 study design**
  - 788 HIV-1 infected treatment-naïve patients
  - '572 50mg (once-daily) vs. Raltegravir (RAL) 400mg (twice-daily)
  - Primary Objective: Comparison of antiviral activity over 48-weeks
- **SAILING study design**
  - 688 treatment experienced, but integrase inhibitor-naïve
  - '572 50mg (once-daily) vs. RAL 400mg (twice-daily)
  - Primary Objective: Comparison of antiviral activity at 48-weeks

Globalization during the 3rd Medium-Term Business Plan

- 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



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

Therapeutic Areas to Be Focused on

Focusing of sales force

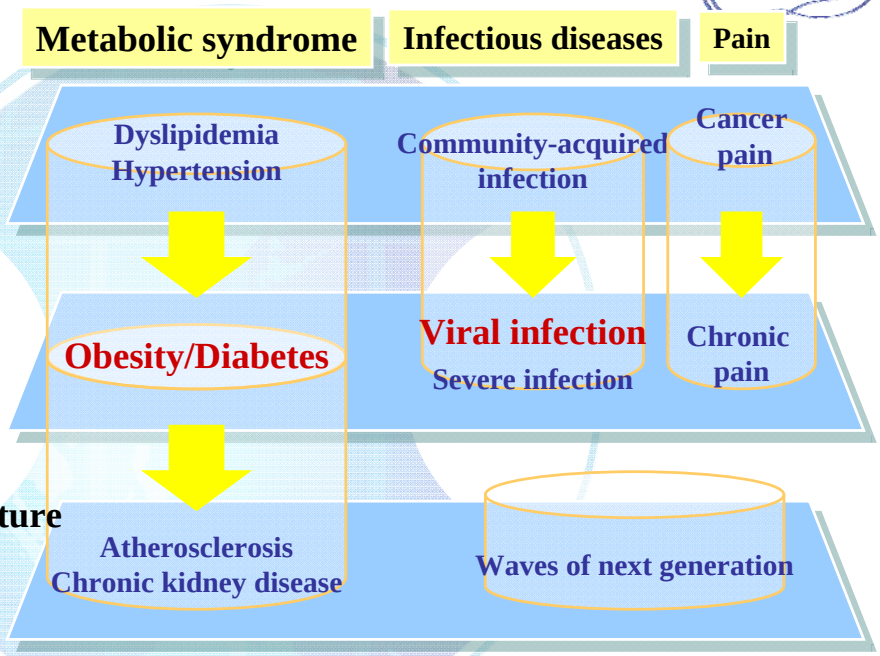
Contribute to medical care by maximizing product potential

Focusing R&D capability

Aim for enriched pipeline and launching them rapidly

Investment toward the future

Forecast movements of next generation waves and discover drug seeds



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