The Current Status at Shionogi

September 2008
Merrill Lynch Japan Conference

Isao Teshirogi, Ph.D.

President and Representative Director

S-O-N-G for you!

SHIONOGI & CO., LTD.

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Establishment of the 2nd Medium-Term Business Plan

The 1st Medium-Term Business Plan

(April 2000－March 2005)

～ Concentration on the prescription drug business ～

The 2nd Medium-Term Business Plan

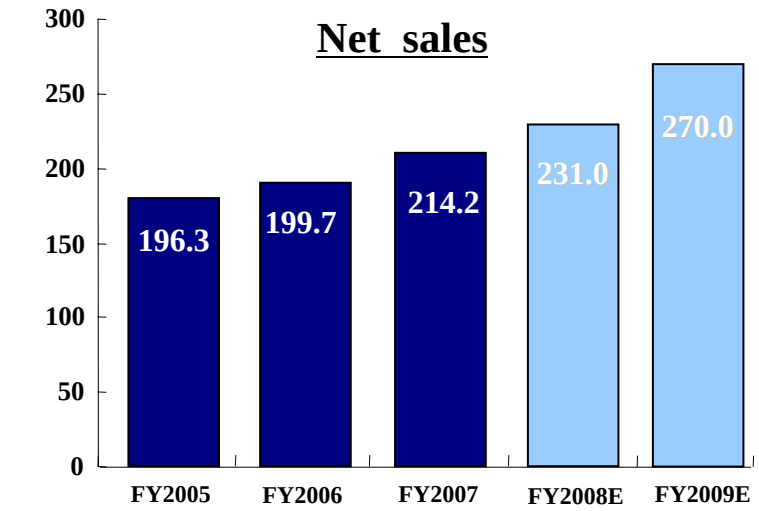
(April 2005－March 2010)

～ Entering a stage to accelerate toward significant growth ～

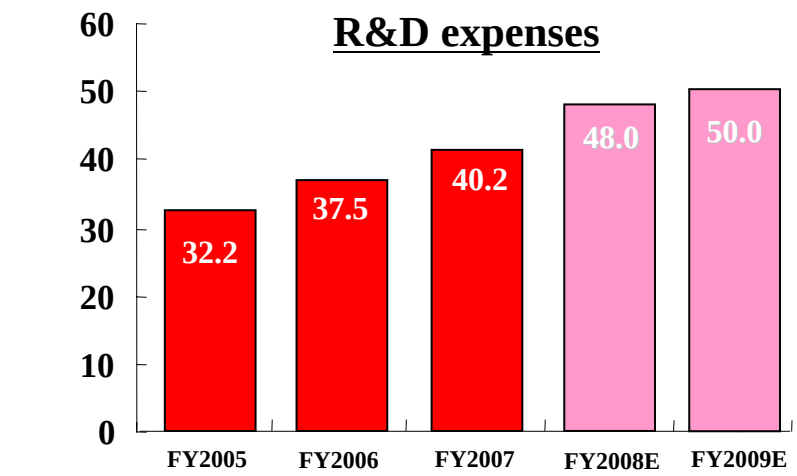
- **Full contribution of Crestor®**
  (royalty income and domestic sales)
- **Activating R&D activities**
- **Launching new products in domestic market**
  (10 products in total)

Consolidated Financial Targets for the 2nd Medium-Term Business Plan

(Billions of Yen)



(Billions of Yen)



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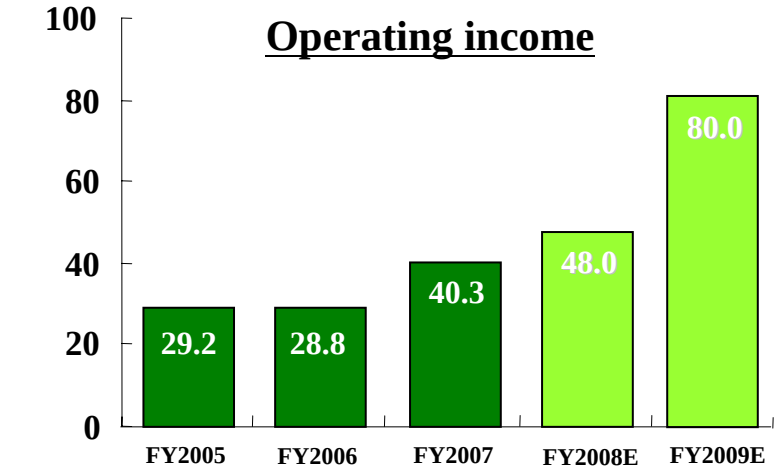
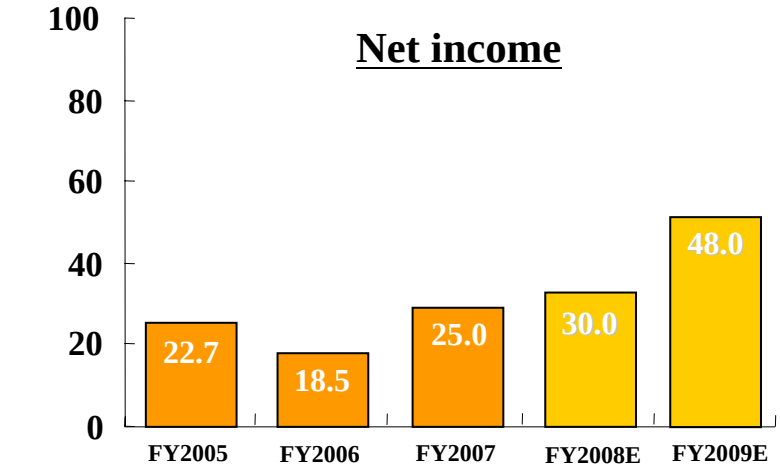
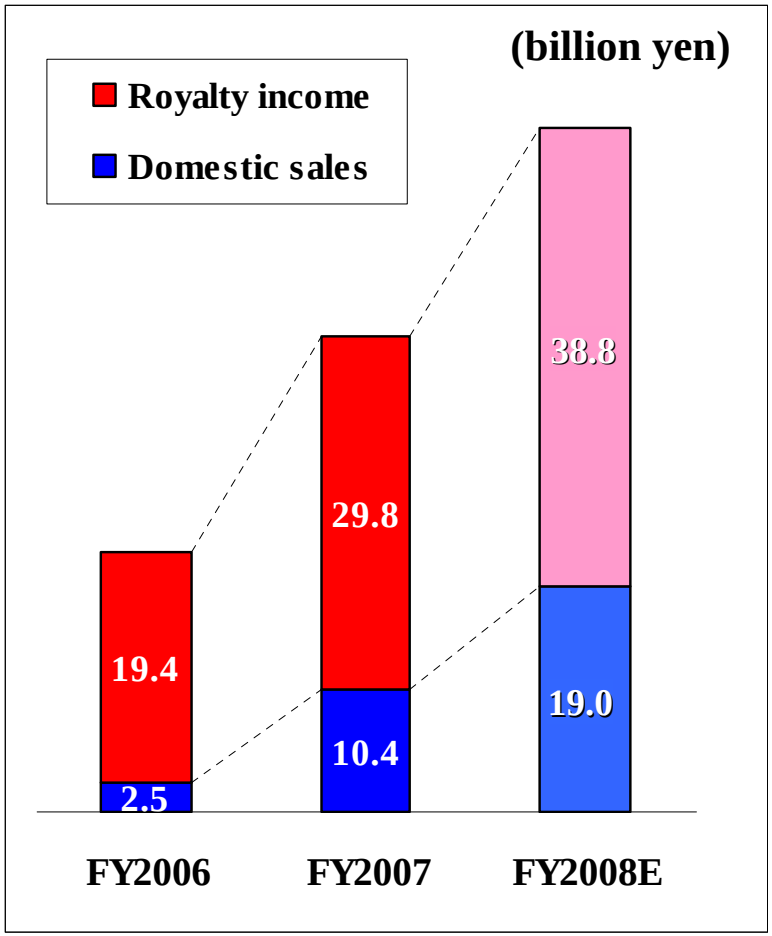


(Billions of Yen)



Expansion of Crestor® Sales

Expansion of royalty income and domestic sales



◆ Royalty income

- Global sales by AstraZeneca increased

(Unit:billion dollar)

Crestor Global Sales	2006	2007	1H 2008
	2.0	2.8	1.68

◆ Domestic sales

- Market share increased smoothly

(Unit:%)

	2006	2007				2008
	4Q	1Q	2Q	3Q	4Q	1Q
Crestor Total	4.0	5.3	7.0	8.5	10.5	11.2

(Based on NHI Price)

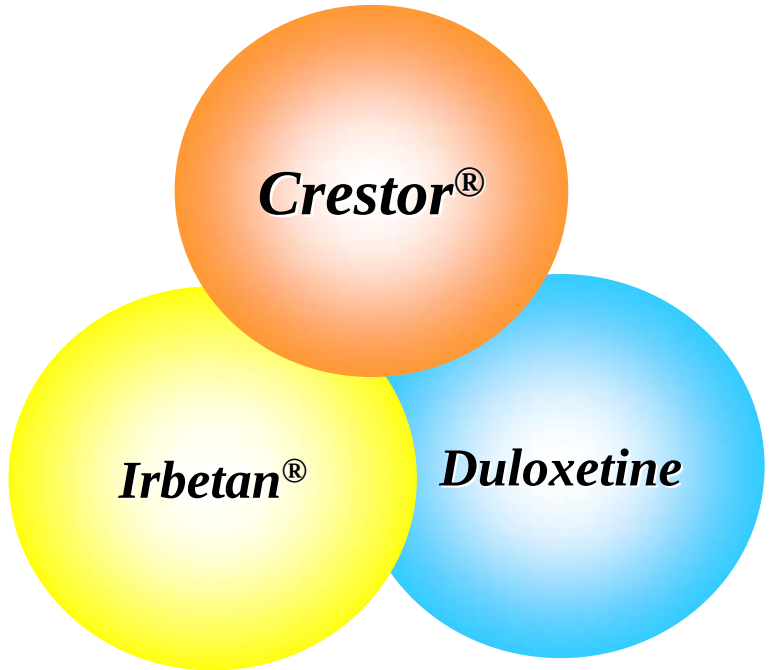
Launching 10 New Products in the Domestic Market during the 2nd Mid-Term Business Plan

Filing & Launch (as of today 2008)

	Filing	Launch
Three targeted R&D areas **Infectious Diseases**		Finibax® (FY2005)
		Avelox® (FY2005)
Pain		OxiNorm® (FY2006)
		Crestor® (FY2005)
Metabolic Syndrome		Irbetan® (Hypertension)
		(Launch, July 2008)
Frontier areas **Allergies**		Claritin® (New formulation) (FY2007)
	Pirfenidone (Idiopathic Pulmonary Fibrosis)	*(FY2008)*
	Differin® (Acne vulgaris)	*(Approval, July 2008)*
Others	Duloxetine (Depression)	*(FY2009)*
		Cetrotide® (FY2006)

In-house | In-licensed

◆ Growth Driver beyond 2010

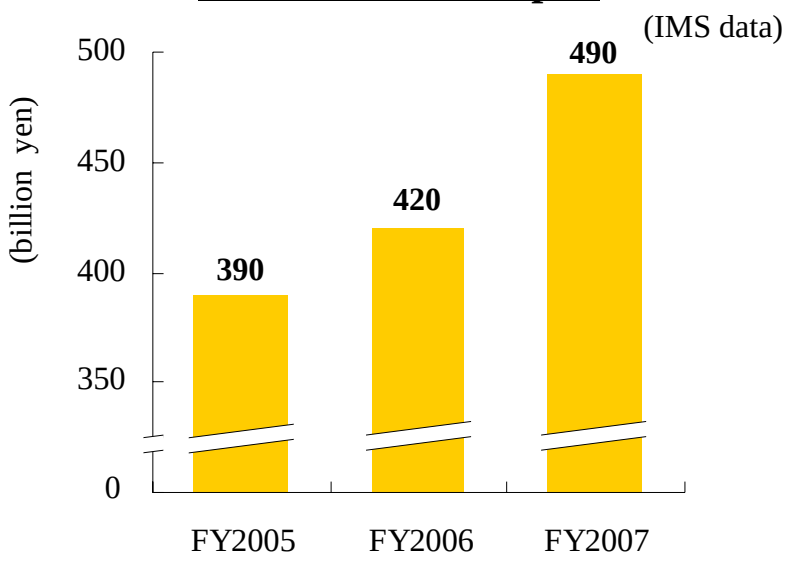


Growth Driver beyond 2010

Irbetan® (Hypertension)

- Approved in 109 countries and launched in 86 countries worldwide by Sanofi-Aventis and Bristol Myers Squibb as of today
- ARB* market in Japan has grown by double digits every year

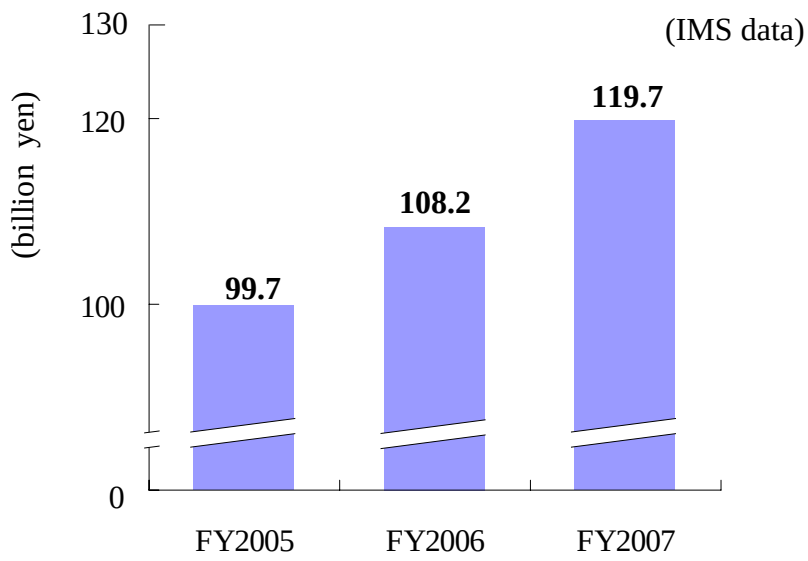
ARB market in Japan



Duloxetine (Depression & DNP)

- Approved for depression in more than 90 countries, and for DNP (diabetic peripheral neuropathic pain) in more than 70 countries
- The market of treatment for depression has been expanding

Market of treatment for depression



* Angiotensin II receptor blocker

Overseas Strategy

Second Medium-term Management Plan

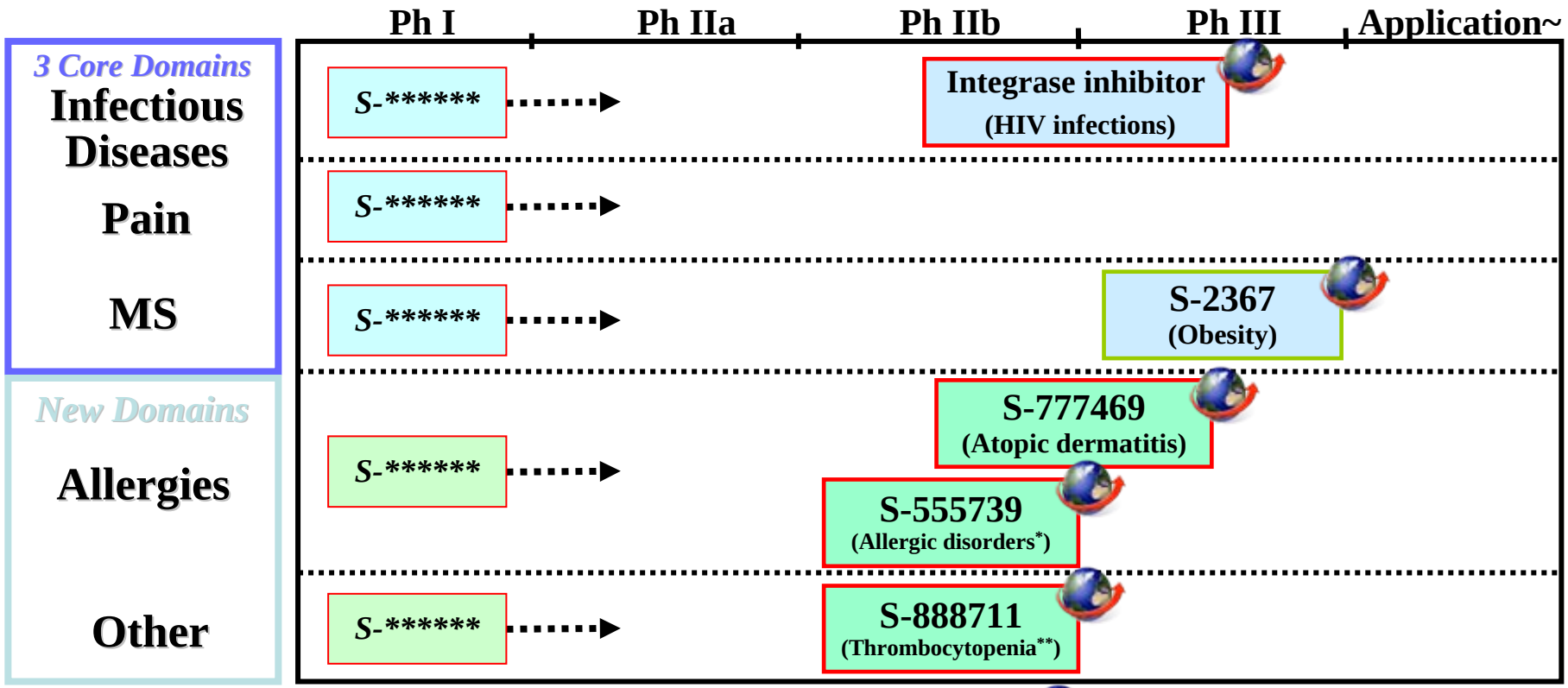
- Acquire at least 5 products in Phase II or later by the end of FY 2009
- Simultaneous development of multiple proprietary products in Japan, the U.S., and Europe
- Forge strategic alliances for each product

Medium/Long-term Goals

- Establish a sales infrastructure in the U.S.
- Continued expansion of the proprietary product pipeline
- Educate personnel to enable adaptation to globalization

Pipeline of Proprietary Global Development: Development Goals for FY 2009

- Steady progress in clinical trials of proprietary products
- Increased focus on establishing an overseas infrastructure



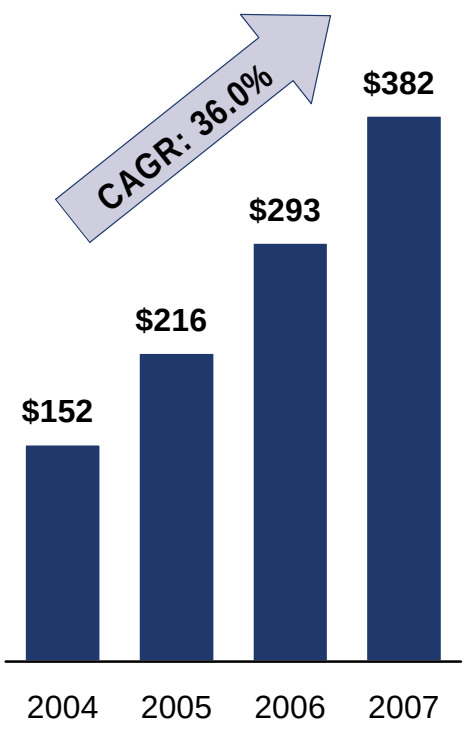
* *Allergic rhinitis, asthma, etc.*

** *Idiopathic thrombocytopenic purpura, hepatitis C, carcinoma chemotherapy, etc.*

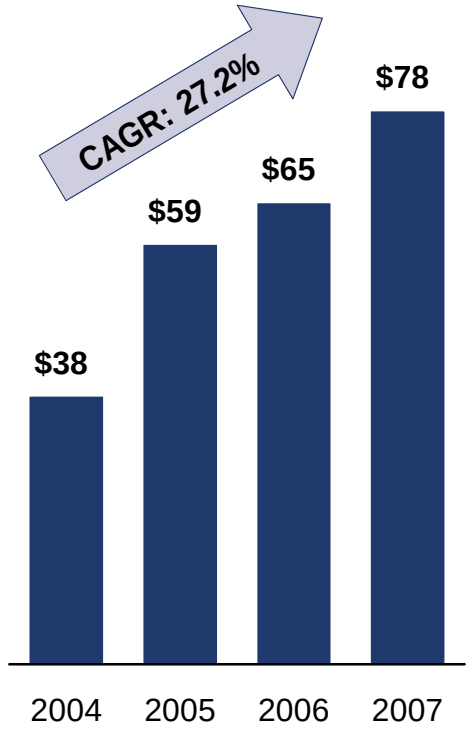
Overview of Sciele: High Growth Rate and Stable Profitability

Revenue	Operating Profit	Net Income

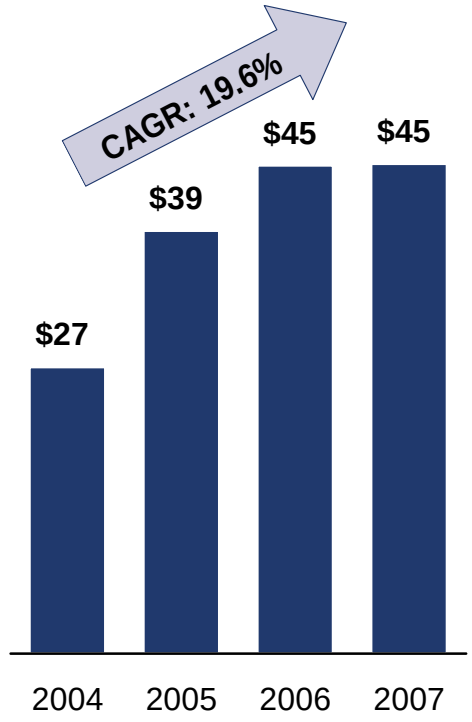
(USD in millions)



(USD in millions)



(USD in millions)



CAGR = Compound Annual Growth Rate during 2004-2007
Source: Company disclosures, 2007 SEC 10K Filings

Overview of Sciele: Sciele's Strengths

Sales and Marketing Capability

- Over 700 sales representatives across the U.S.
- Ability to retain capable personnel and enhance sales capabilities based on performance-based compensation and clear quantitative targets
- Ability to maintain product prices based on strong relationships and negotiations with healthcare organizations

Product Portfolio

- Balanced portfolio built around products in the cardiovascular disease, diabetes, women's health, and pediatrics domains
- Stable growth and profitability in each area of specialization

Sourcing/Launching Pipeline Products

- Focusing on niche products in Phase II and III of development
- Business development team has an industry-wide network and has know-how based on many years of experience
- Speedy acquisition of pipeline products and proven ability to bring pipeline products to market

Experienced Management and Personnel

- Speedy decision-making and execution
- Strong experience in the pharmaceutical industry
- Strong leadership and teamwork

High growth rate and stable profitability

Expected Benefits from the Acquisition

- **Significant strengthening of U.S. sales infrastructure**
  - **Immediate addition of a nationwide sales network of over 700 MRs**
- **Reduce overall time and expense required to establish and advance a U.S. sales infrastructure**
  - **Leverage strong know-how concerning product launch and sales in the U.S.**
- **Pursue synergies based on complementary product domains**
  - **Proven track record of both Shionogi and Sciele in areas of focus, such as the cardiovascular disease and diabetes domains**
- **Enhanced profitability based on proprietary sales of strong pipeline products**
  - **Ability to develop proprietary pipeline products in addition to allowing for sales efforts in the U.S.**
- **Potential to advance skills of Shionogi personnel**
  - **Access to a Sales team with proven track record in the U.S. market**

Toward the Achievement of the 2nd Medium-Term Business Plan

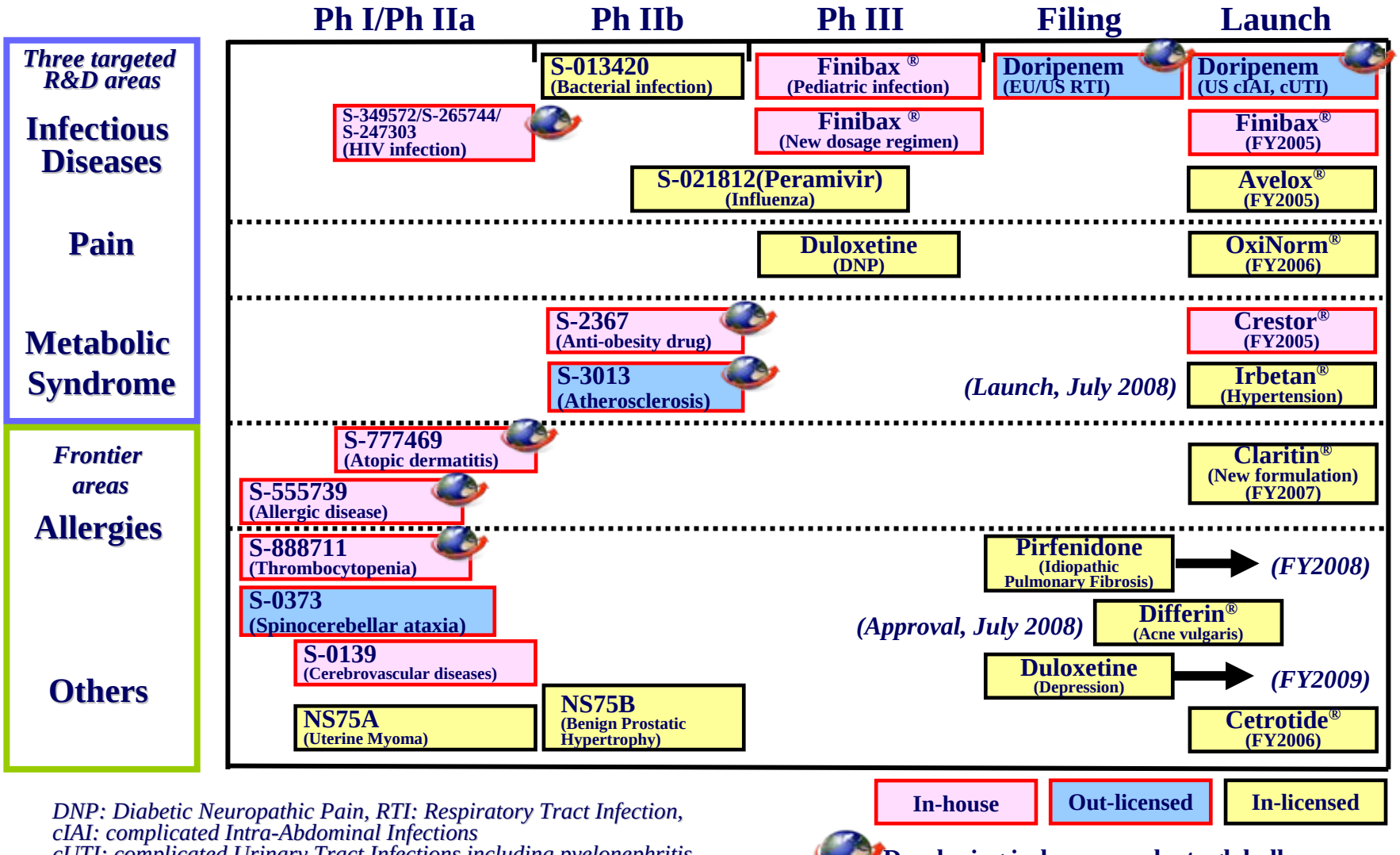
- **Further concentration on research and development area**
  - **S-2367 / S-349572 / S-777469**
  - **S-555739 / S-888711**
  - **Scheduled to move another 3 novel compounds to Phase I within FY2008**
- **Steady development of domestic sales : improvement of SFE**
  - **Crestor® / Irbetan®**
  - **New products: Finibax® / Defferine® / Pirfenidone**
- **Smooth transition of Sciele**

Reference Materials

- *Pipeline*
- *Overview of Sciele Pharma, Inc.*

Pipeline

Drug Pipeline (As of September, 2008)



DNP: Diabetic Neuropathic Pain, RTI: Respiratory Tract Infection,
cIAI: complicated Intra-Abdominal Infections
cUTI: complicated Urinary Tract Infections including pyelonephritis

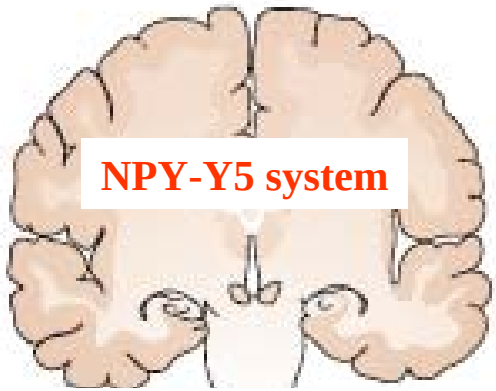
S-2367: Profile

- **Anti-obesity (oral)**
- **Neuropeptide Y Y5 receptor antagonist**
- **Key findings from pre-clinical studies**
  - Increased energy consumption
  - Suppressed visceral fat accumulation and improved blood glucose and serum lipid levels
  - Expected product profile: sustainable weight suppression without rebound
  - Confirmed excellent safety
- **Key findings from clinical studies to date**
  - Once-daily administration (T½: about 20 hours)
  - Achieved positive Phase IIa proof of concept in the USA study
  - Favorable safety profiles without adverse effects on central nervous system
    - No effect on depression or anxiety scores

Phase IIb studies in progress in the US

S-2367: Energy Balance and Neuropeptide Y

Neuropeptide Y (NPY) in the brain plays a significant role in energy homeostasis



Feedback

Control of energy homeostasis

Food Intake

Energy Expenditure

Energy Balance

NPY-Y5 system has been implicated as a key regulator of energy homeostasis

Function of NPY through Y5 receptor

1. Appetite (energy intake) ↑
2. Energy expenditure ↓

Modern life style, high-calorie food, etc.

➡ **Overactivation of NPY-Y5 system**

➡ **Disorder of energy homeostasis**

➡ **Obesity**

S-2367

NPY-Y5 receptor antagonist

⬇

Normalize NPY-Y5 system

S-2367: Outline of Phase IIb Study

- **Study 1**
  - RCD (reduced calorie diet) lead-in followed by RCD with S-2367 or placebo treatment
  - Number of patients: 750
  - Maximum dose: 1600 mg
- **Study 2**
  - LCD (low calorie diet) lead-in followed by RCD with S-2367 or placebo treatment
  - Number of patients: 750
  - Maximum dose: 1600 mg
- **To assess efficacy and safety of treatment over a one-year period**
  - Reduce Phase III development risk
  - Interim analysis at 6 month time point
  - Completion of drug treatments: within 2008

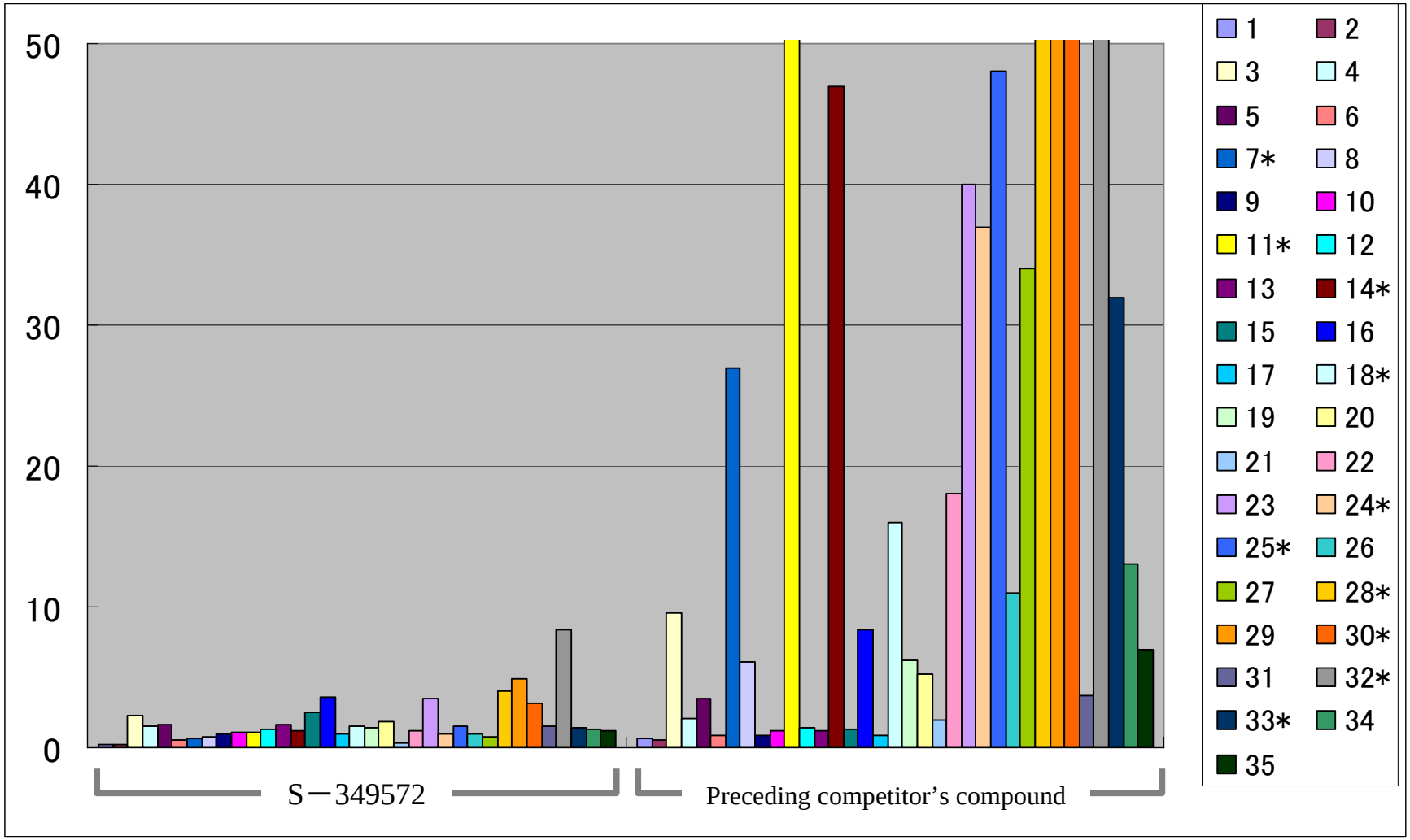
May 2008, Shionogi received the recommendation that both RCD and LCD studies (both dose arms) should continue

S-349572 / S-265744 / S-247303: Profile

- **Developed by Shionogi-GlaxoSmithKline Pharmaceuticals, LLC**
- **HIV Integrase Inhibitor (oral)**
- **Characteristics**
  - Strong anti-HIV activity in inhibiting virus replication *in vitro*
  - Good resistant virus profile *in vitro*
  - Good pharmacokinetic profile
  - Low risk of drug-drug interactions
- **Marketability**
  - Estimated 33 million HIV patients worldwide

Started Phase IIa for S-349572 in June, 2008

S-349572: In vitro Activity against Highly Resistant Viruses for Preceding Competitor's Compound



** Resistance mutations reported in clinical trials of preceding competitor's compound*

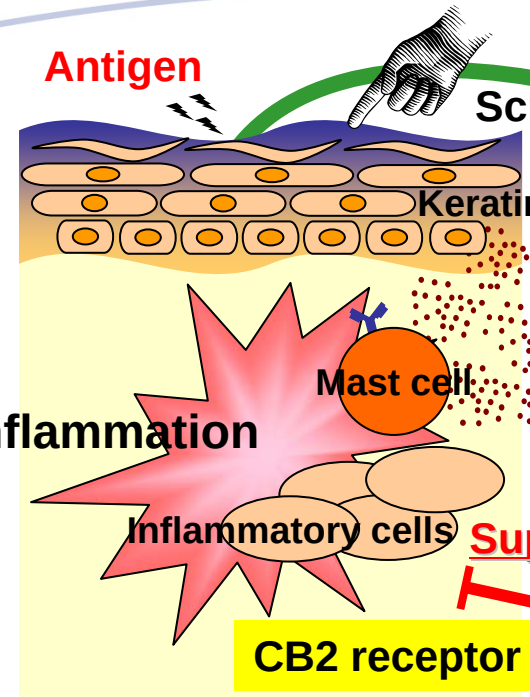
S-777469: Profile

- **Indication: Atopic dermatitis (AD)**
- **Selective cannabinoid 2 receptor agonist (oral)**
- **Characteristics (non-clinical)**
  - Reduces scratching behavior induced by various pruritic agents in mouse model
  - Improves dermatitis scores in animal AD model
  - Good safety profile
- **Positioning**

  ⇒ First-in-Class therapeutic agent for AD
- **Marketability**
  - Predicted number of patients with eczema/dermatitis including AD is 30 million (Japan, the USA, the EU)

Phase IIa studies in progress both in Japan and the US

S-777469: Mechanism of Action



Antihistamines

Histamine

Substance P

Other mediators

Nerves related to transmission of pruritus (c-fiber)

CB2 receptor

Block transmission of pruritus

Suppress inflammation

S-777469

Itch-scratch cycle

Spinal Cord

Irritation

Brain

- Anti-pruritic effect by directly suppressing c-fiber firing
- More potent anti-pruritic effect can be expected than antihistamine products
- Anti-inflammatory effect through direct action on inflammatory cells
- Prevent becoming chronic of atopic dermatitis by blocking both inflammation and pruritus

S-777469: Outline of Clinical Studies

Update of Phase I studies

- **Japan**
  - Completed a 14-day, multiple-dose study in healthy volunteers
    - **Good tolerability**
    - **Dose-dependent increase in plasma concentration from 50 to 800 mg**
- **USA**
  - Conducting a 14-day, multiple-dose study in patients with atopic dermatitis (Phase Ib/IIa)
    - **Treatment completed**

Update of Phase II studies

- **Japan**
  - Phase IIa study
    - **Patients enrolment commenced in Jan. 2008**
    - **Pruritus and skin manifestations to be evaluated as primary endpoints**
    - **Top-line results: 3Q 2008 (scheduled)**
- **USA**
  - Phase IIa study (Atopic dermatitis)
    - **Top-line results: 2Q 2009 (scheduled)**

S-555739: Profile

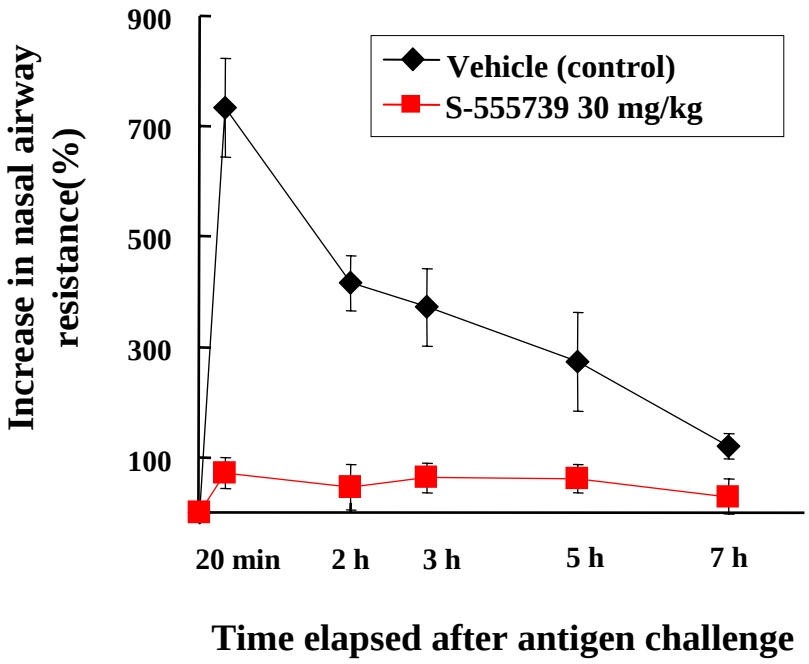
- **Indication: Allergic rhinitis (as the first indication target)**
- **Prostaglandin D2 receptor antagonist (oral)**
  - Backup compound of S-5751: More potent receptor antagonist activity and good pharmacokinetic profile
- **Characteristics (non-clinical)**
  - More suppressive effect against nasal congestion than existing anti-allergy drugs
  - Effective with once-daily dosing
  - Good safety profile
- **Positioning**
  - New therapeutic drug against nasal congestion that is not relieved by existing anti-allergy drugs
- **Marketability**
  - Predicted total number of allergic rhinitis patients in Japan, the USA, and the EU is 64 million, 60% of which are estimated to have nasal congestion

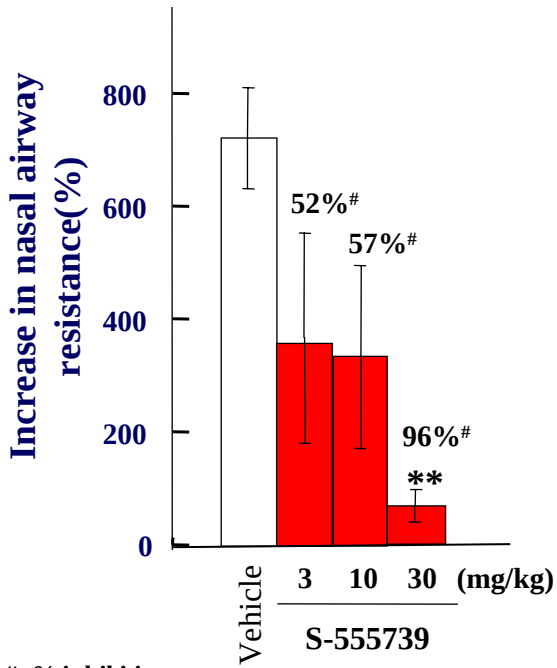
Phase I studies are ongoing both in Japan and Europe

S-555739: Efficacy in Allergic Rhinitis Model

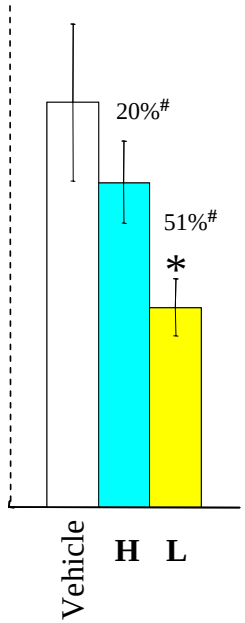
S-555739 strongly suppressed antigen-induced nasal congestion, and the efficacy of S-555739 was much stronger than that of existing anti-allergy drugs

Guinea pig rhinitis model





H: Anti-histamine
L: Leukotriene antagonist



#: % inhibition
**, **: P < 0.05, P < 0.01 vs. vehicle*

S-888711: Profile

- **Indications: Various diseases with thrombocytopenia**
- **Thrombopoietin receptor agonist (oral)**
- **Potential pharmacological properties from non-clinical studies**
  - Excellent efficacy and safety with once-daily dosing
  - No food effects
  - More moderate dose-response curve than preceding compounds
- **Development stage**
  - Phase I single dose study (Japan): in progress
    - **Good pharmacokinetic profiles; increases Cmax and AUC dose-dependently**
    - **Good tolerability up to the maximum dose**

Phase I multiple dose study in preparation in Japan

S-7701 (Pirfenidone): Profile

- **Licensed from Marnac, Inc., (USA) and KDL, Inc. (Japan)**
- **Indication: Idiopathic pulmonary fibrosis**
- **Anti-fibrosis (oral)**
  - Significantly prevented worsening of vital capacity vs. placebo
- **Designated as an orphan drug**
- **NDA filed in Mar. 2007**
  - Completed onsite GCP compliance inspection at Medical Institutions and Shionogi
  - May 2008: American Thoracic Society (ATS), Toronto
    - **Announced results of Phase III**

Under review by the agency

S-021812 (Peramivir): Profile

- **Licensed from BioCryst Pharmaceuticals, Inc. (USA)**
- **Anti-influenza virus drug (neuraminidase inhibitor) (injection)**
- **Characteristics**
  - Highly active against influenza A and B viruses
    - More potent against influenza B virus than Tamiflu®
  - Strong activity against highly pathogenic avian influenza virus (H5N1)
  - Strong affinity to influenza neuraminidase and slow off-rate
    → Possibly effective with a single-dose administration
  - Potency of "Delay Dosage" (administration later than 48 hrs after onset of infection)
  - Broad indications from ordinary seasonal influenza to severe or life-threatening influenza
  - Award of US$102.6 million from DHHS* to BioCryst for advanced development of peramivir.
  - Designated as a Drug Product for Priority Consultation in Japan

Phase III study in preparation

∗ *The U.S. Department of Health and Human Services*

S-021812: Results of Phase II Study

- **Results of Phase II Study (Intravenous Injection)**
  - **Indication**
    - **Influenza virus infection**
  - **Study design**
    - **Multicenter, double-blind, placebo controlled study**
    - **Administration of 300mg and 600mg**
  - **Efficacy**
    - **Confirmed its primary endpoint of improvement in the median time to alleviation of symptoms compared to placebo alone**
  - **Safety**
    - **Generally well-tolerated**

Developing a subcutaneous formulation for potential market

Overview of Sciele Pharma, Inc.

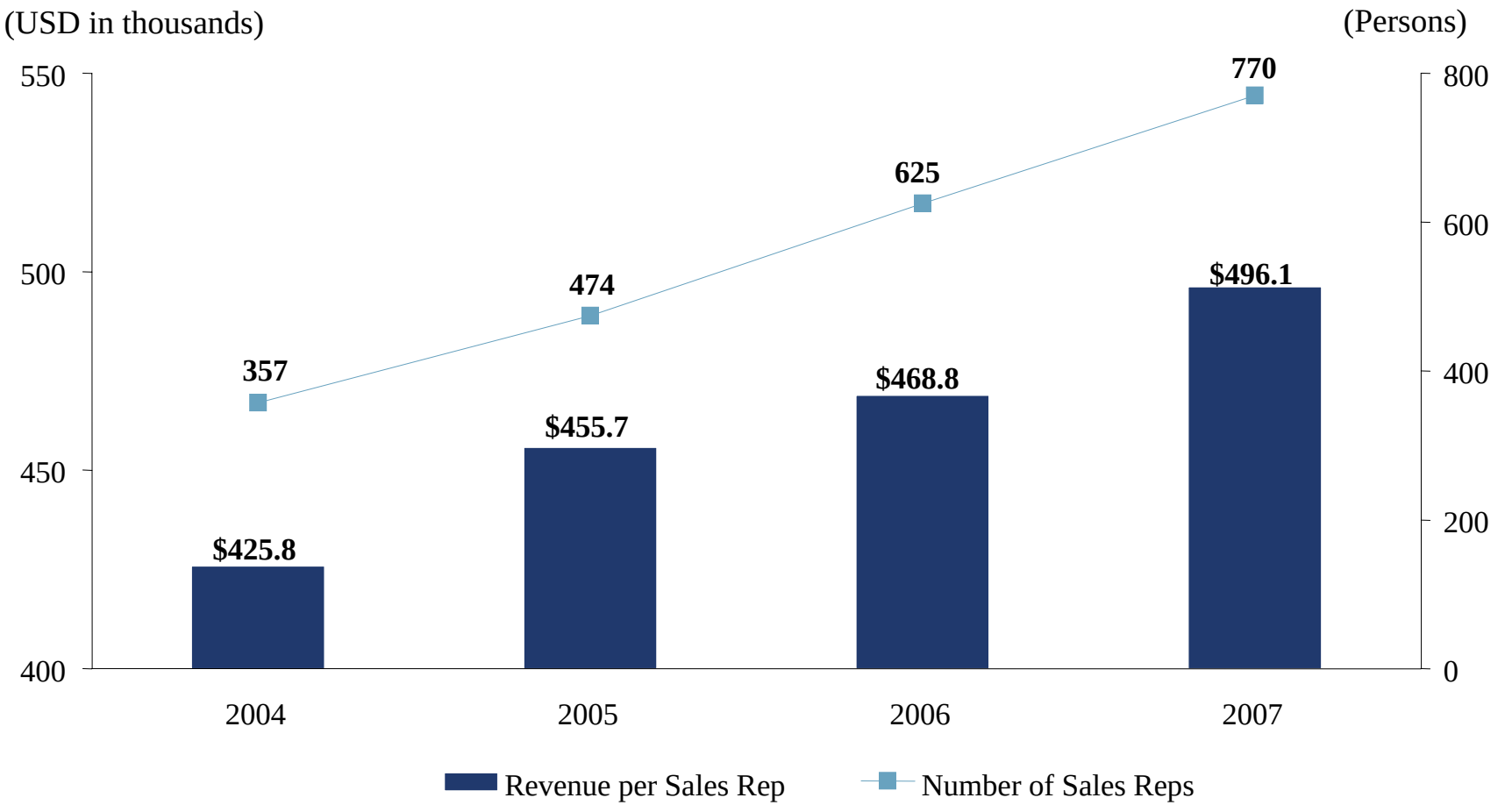
Overview of Sciele: Company Overview

- **Established in 1992 in the U.S., listed on the NASDAQ since 2000**
- **Nationwide operations, based in Atlanta, Georgia**
- **Engages in the development and sales of prescription drugs in the cardiovascular disease, diabetes, women's health, and pediatrics domains**
  - **Acquires rights to manufacture and market products from development partners**
  - **Proven ability to bring products in later phases to the market**
  - **Strong nationwide sales network**
- **Total number of employees: 920 (as of 12/31/2007)**
  - **Of which, sales reps: 770**

Source: Company disclosures, 2007 SEC 10K Filings, Company website

Overview of Sciele: Sales Force Productivity

Number of Sales Reps and Revenue per Sales Rep



Source: Company disclosures, 2007 SEC 10K Filings

Overview of Sciele: Product Portfolio, Pipeline and Sales Force

Sales Force		Key Products	Major Pipeline Products
Sales Division (718 sales reps)	**Cardio-vascular (223)**	•Sular CR (Nisoldipine) with Geomatrix Delivery System •Nitrolingual Pumpspray	•CloniBID (Phase III) •Duochol (Phase III) •ADX-415 (Phase II)
	Diabetes (174)	•Prandin •Fenoglide •Fortamet •PrandiMet (market launch planned during the current fiscal year)	
	Women's Health (177)	•Prenate Family (DHA and Elite) •Zovirax Ointment and Cream •Fosteum	•PSD502 (Phase III)
	Pediatrics (144)	•Allegra OS, Allegra ODT •Orapred ODT •Twinject •Methylin OS/CT	•Xytril (Completed Phase III safety trials) •Head Lice Treatment (Phase III) •Clonicel (Phase III)

Source: Company disclosures, Company website. Headcount data from Sciele's presentation material at Healthcare Conference held by Bank of America (5/13/2008)

Overview of Sciele: Experienced Management Team

Patrick P. Fourteau

- Chief Executive Officer and Director
- Over 25 years of industry experience, including years at Eli Lilly

Edward Schutter

- Chief Operating Officer
- Over 20 years of industry experience, including years at Solvay

Joseph J. Ciaffoni

- Chief Commercial Officer
- Over 15 years of industry experience, including years at Novartis

Darrell Borne

- Chief Financial Officer
- Over 15 years of experience in financial management, including years at Exxon/Mobil

Larry M. Dillaha M.D.

- Chief Medical Officer
- Over 15 years of industry experience, including years at Sanofi-Aventis

Leslie Zacks

- Chief Legal and Compliance Officer
- Over 15 years of legal experience including years at Hunton & Williams LLP

Source: Company disclosures, company website

Sciele's Key Products

Product Name	Domain	Overview
Sular / Sular CR 	**Cardio-vascular**	◆ Sular is a dihydropyridine (DHP) calcium channel blocker that lowers blood pressure and provides consistent 24-hour control of hypertension ◆ A new Sular formulation was approved by the FDA in January 2008 and is now available in four lower dosage strengths ◆ Sular can be used alone or in combination with ACE inhibitors, beta blockers and diuretics
Nitrolingual Pumpspray 	**Cardio-vascular**	◆ This oral nitroglycerin spray offers acute relief in the event of heart attack or chest pain caused by coronary artery disease, a condition that affects 9.1 million Americans, according to the American Heart Association ◆ Nitrolingual Pumpspray is formulated to deliver fast pain relief with simple and reliable administration

Source: Company disclosures, Company website

Sciele's Key Products

Product Name	Domain	Overview
Triglide 	**Diabetes**	◆ Triglide offers an effective oral treatment for lipid disorders such as elevated cholesterol and triglycerides ◆ It can be administered under both fed and fasting conditions, allowing patients to take the drug at any time, which contributes to improved compliance
Fenoglide 	**Diabetes**	◆ Fenoglide offers the lowest dose of fenofibrate currently available on the market for the treatment of hyperlipidemia and hypertriglyceridemia ◆ Available in tablet form and two dosage strengths, Fenoglide utilizes LifeCycle Pharma's MeltDose® technology, which is designed to enhance absorption and bioavailability.

Source: Company disclosures, Company website

Sciele's Major Pipeline Products

Product	Domain	Overview	
CloniBID	**Cardio-vascular**	◆ Product	Extended release clonidine HCL
		◆ Indication	Hypertension
		◆ Market	Approx. 13mn TRx's written for clonidine products in 2007
		◆ Benefits	12 hour, sustained release formulation; little to no drowsiness, somnolence, or sedation
		◆ Status	PDUFA date of December 19, 2008
		◆ IP	Issued U.S. patent-expires in October 2013
		◆ Opportunity	Better formulation of an established anti-hypertensive
ADX-415	**Cardio-vascular**	◆ Product	Centrally acting alpha agonist, specific for 2-alpha
		◆ Indication	Hypertension, either as monotherapy or add-on
		◆ Market	Approximately 20mn Americans with HTN
		◆ Benefits	Specificity for 2-alpha should convey improved AE profile
		◆ Status	IND open 2H08, begin phase ll program 2H08
		◆ IP	Composition of matter through 2024
		◆ Opportunity	Growing HTN market, large number of uncontrolled patients

Source: Company disclosures, Company website

Sciele's Major Pipeline Products

Product	Domain	Overview
Head Lice Treatment	**Pedia-trics**	◆ First non-pesticide prescription head lice product ◆ No resistance ◆ Easy-to-use — 10 minute application — Repeat after 8 days — Similar consistency to hair conditioner ◆ The breathing spiracle remains open after exposure to product allowing the formulation to enter and clog the spiracle ◆ The destruction of the honeycomb breathing interface is apparent
Xytril	**Pedia-trics**	◆ Market: 150,000 Cerebral Palsy patients — Other patients with conditions such as Down's Syndrome also require treatment to avoid severe drooling (LCM opportunity) — Indicated for patients with severe drooling would limit the use to about 15% of all CP patients — Other treatment choices include Scopolamine patches, etc. ◆ Orphan drug status allows premium pricing (WAC $572 per pint bottle, 16 refills per year) ◆ 7 Years data exclusivity ◆ 15% share with favorable compliance will generate sales close to $175mn to $200mn in peak sales

Source: Company disclosures, Company website

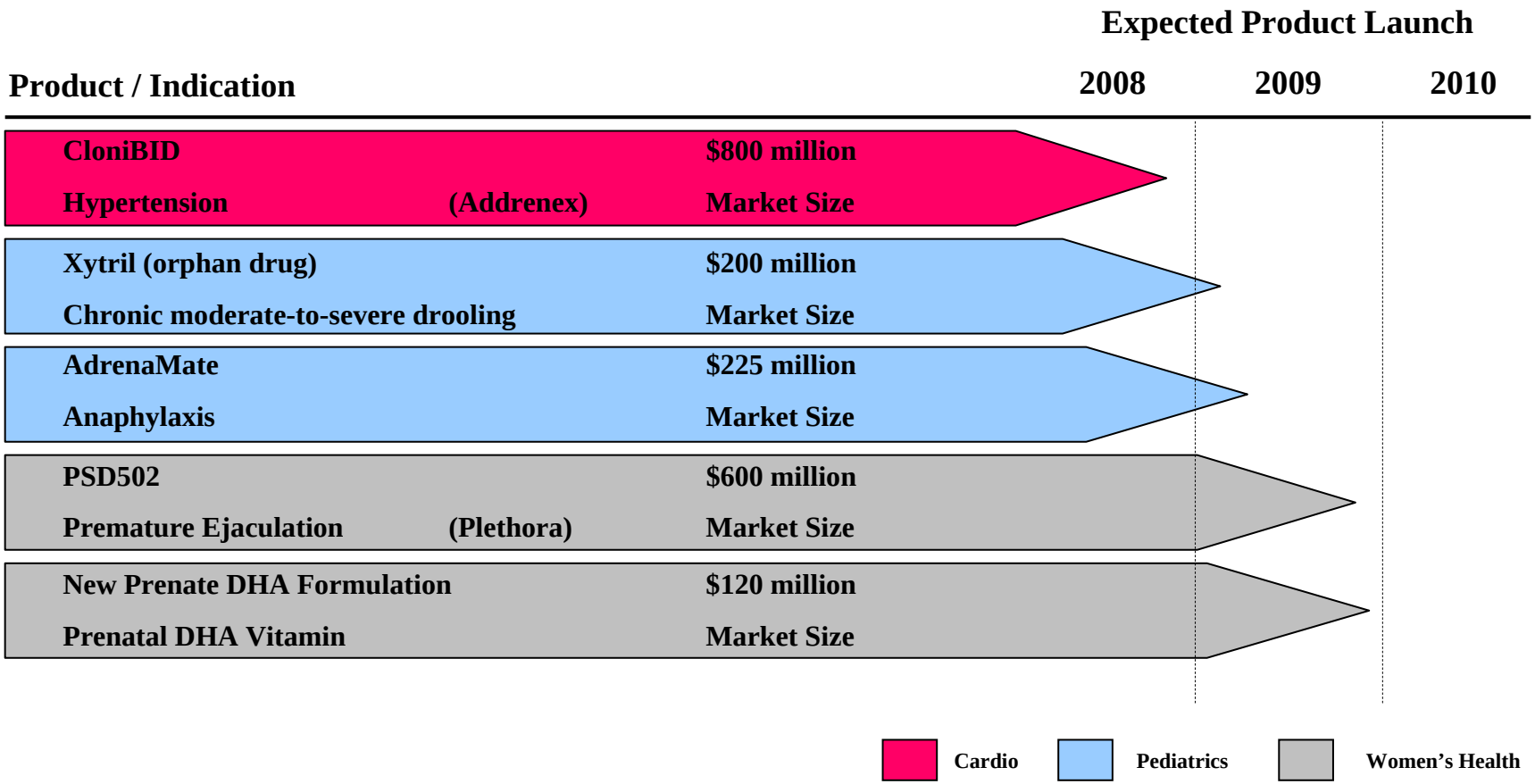
R&D Partnerships

Year	Partner Name	Product Name	Phase when Signed	Domain
2008	Addrenex	ADX-415	Phase II	Cardiovascular
2007	Addrenex	CloniBID Clonicel	Phase III Phase II	Cardiovascular Pediatrics
2007	Plethora Solutions	PSD502	Phase II	Urology, PCP
2007	Summers Laboratories	Head Lice Treatment	Phase III	Pediatrics
2006	Galephar	Duochol	Phase III	Cardiovascular, PCP

Source: Company disclosures

Pipeline Planned for Launch in FY 2009

2009 Product Launches



Source: Company disclosures. Market size is based on IMS Health's NPA data