



astellas  
Leading Light for Life

# Toward Being A Global Category Leader

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May 14, 2009

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President & CEO

Astellas Pharma Inc.

# Cautionary Statement Regarding Forward-Looking Information

**This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.**

**Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.**

**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 kind.**

# Summary of FY 2008 Financial Results

(billion yen)

	FY2007	FY2008	Change	3Q/08 Forecasts for FY08	Difference	Factors
Net sales	972.5	965.6	-6.8	958.0	+7.6	Forex impact -62.0 NHI price revision -18.6
Cost of sales	279.3 28.7%	264.4 27.4%	-14.9 -1.3 ppt			Forex impact on elimination of unrealized gain -0.6 ppt Cost reduction -0.6 ppt
SG&A expenses	282.8	291.8	+8.9			Goodwill amortization +5.6 Advertising and promotional expenses
R&D expenses	134.4 13.8%	159.0 16.5%	+24.5 +2.7 ppt	157.0	+2.0	In-license fee Amortization of new research buildings in Japan Development costs
Operating income	275.9	250.3	-25.5	247.0	+3.3	Forex impact -16.8
Ordinary income	284.1	271.4	-12.7	270.0	+1.4	Exchange gain
Net income	177.4	170.9	-6.4	168.0	+2.9	

Forex	FY2007	FY2008	Change	3Q/08 Forecasts for FY08
YEN/USD	114	101	-14	100
YEN/EUR	162	143	-18	143

# Forecasts for FY2009

(billion yen)

	FY2008 Results	FY2009 Forecasts	Change
Net sales	965.6	968.0	+2.3
R&D expenses	159.0 16.5%	169.0 17.5%	+10.0 +1.0 ppt
Operating income	250.3	215.0	-35.3
Ordinary income	271.4	219.0	-52.4
Net income	170.9	135.0	-35.9

Forex	FY2008 Results	FY2009 Forecasts	Change
YEN/USD	101 yen	100 yen	-1 yen
YEN/EUR	143 yen	130 yen	-13 yen

## Factors Behind Decrease in Operating Income

- Gross profit -20 billion yen
  - Prograf patents expire (US & EU)
  - Harnal patent expires (US)
  - Forex impact on elimination of unrealized gain (FY2008)
- R&D expenses +10 billion yen
  - YM178, YM150, Antibody costs
  - Research costs
- SG&A +5 billion yen
  - Goodwill amortization +2.1 billion yen
  - Sales promotional costs

### Forex Impact

Net sales -28 billion yen  
 Operating income -18 billion yen

\*Including forex impact on elimination of unrealized gain<sub>3</sub>

# Cash on Hand Policy

- ▶ Top priority on investment for growth in Rx business
- ▶ Dividends to be increased continuously and share buyback to be implemented in a flexible manner
- ▶ Cash balance to be slightly increased owing to the change in business circumstances

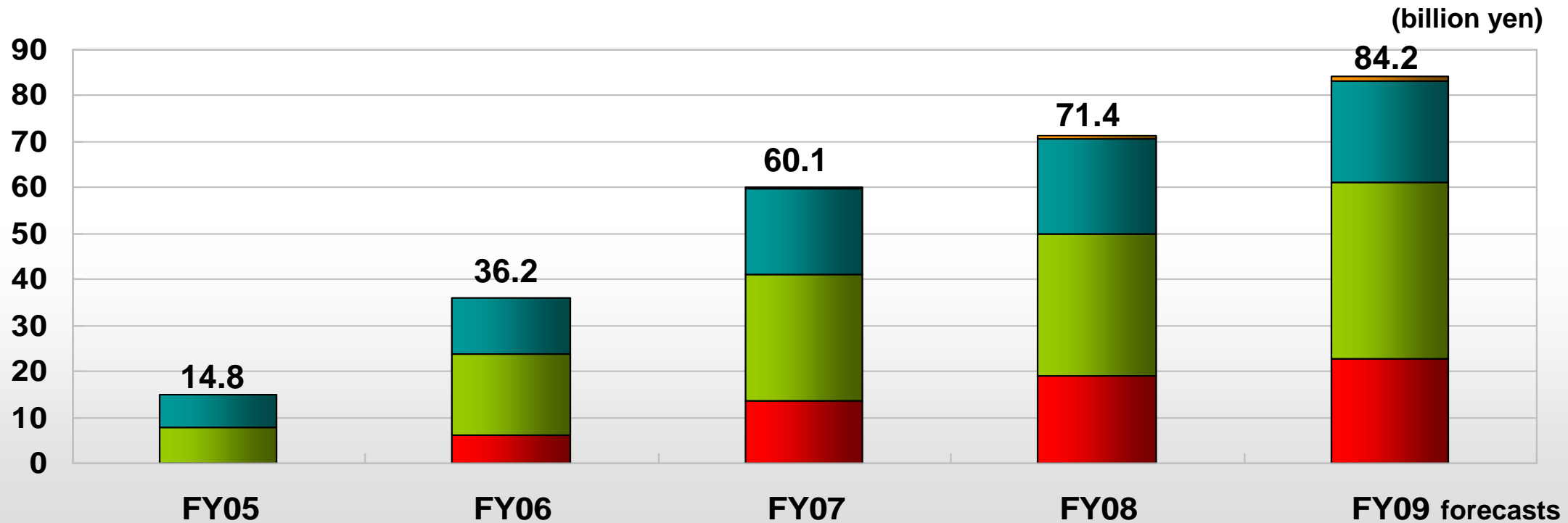
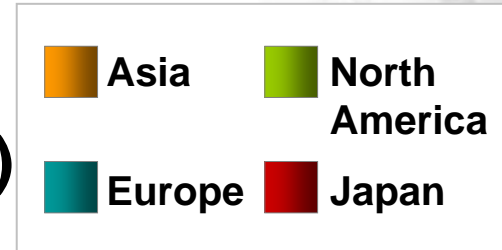
	FY2007	FY2008	FY2009 forecasts
Earnings per share	349.89 yen	356.11 yen	287.22 yen
Dividends per share	110 yen	120 yen	125 yen
ROE	16.1%	16.0%	-
DOE	5.0%	5.4%	-
Share buyback	81.7 bil. yen	123.4 bil. yen	to be implemented flexibly



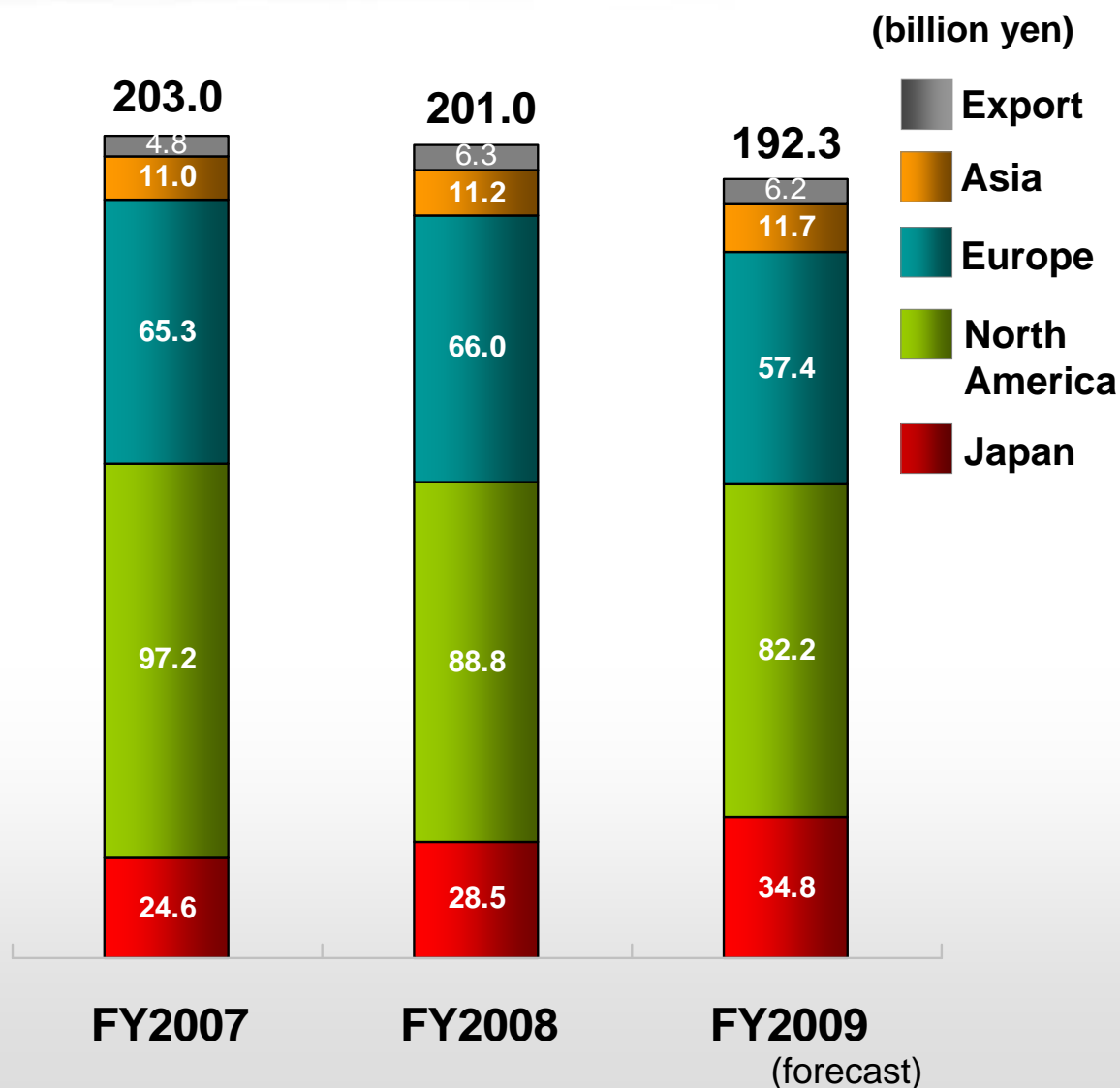
# Global Business Expansion

# Maximize Vesicare Sales

- ▶ **Japan: No. 1 (Growth Rate 20%\*)**
- ▶ **U.S.: No. 2 (Branded, Growth Rate 24%\* on USD)**
- ▶ **Europe: No. 1 (Growth Rate 17%\* on EUR)**



# Prograf



## Growth Rate in FY2008

- Japan: 16%
- North America: 4% (USD)
- Europe: 16% (EUR)
- Asia: 20% (Local currency)

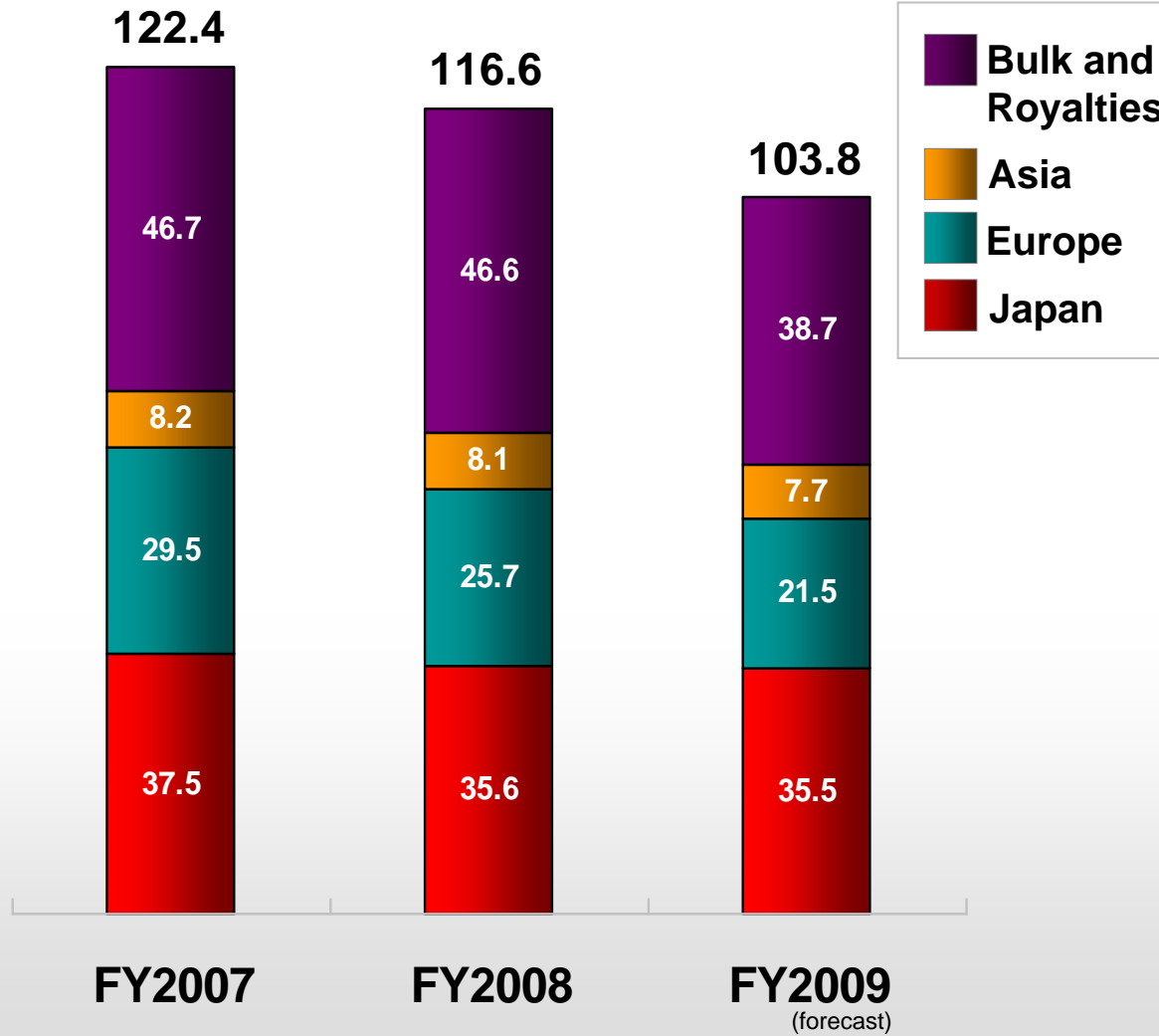


## After FY2009

- **Growth in Japan**  
Current indications: Transplants, RA, Lupus nephritis  
NDA filed: Ulcerative colitis, Myasthenia gravis (all)
- **Sales expansion in Asian countries**
- **Patents expiration in US and Europe**  
(US: Apr. 08, Europe: Jun. 09)
- **Sales decline relatively different compared to lifestyle improvement drugs**



(billion yen)



- **Patents expiration in Japan and Europe**  
 -After that, showed mild sales decline
- **Expansion in Asian countries**
- **Bulk and Royalties**  
 -US Flomax Sales: 588 million USD (CY2009 1Q, +34%)  
 -US patent expiration: Oct. 09  
 -After getting 6-month market exclusivity, Ranbaxy GE enters into the market (Mar. 10).  
 -Sales decline sharply

(License business in US)

# Top Ranked Sales Force

Japan

(billion yen)

	FY2007	FY2008	FY2009 <sup>*</sup>
<b>Total Rx Sales</b>	<b>478.2</b>	<b>491.5</b>	<b>507.8</b>
<b>Lipitor</b>	<b>97.7</b>	<b>95.3</b>	<b>99.0</b>
<b>Micardis</b>	<b>62.6</b>	<b>64.4</b>	<b>71.8</b>
<b>Gaster</b>	<b>60.9</b>	<b>53.0</b>	<b>50.6</b>
<b>Harnal</b>	<b>37.5</b>	<b>35.6</b>	<b>35.5</b>
<b>Prograf</b>	<b>24.6</b>	<b>28.5</b>	<b>34.8</b>
<b>Myslee</b>	<b>21.5</b>	<b>25.7</b>	<b>27.8</b>
<b>Seroquel</b>	<b>19.2</b>	<b>21.0</b>	<b>22.9</b>
<b>Vesicare</b>	<b>13.5</b>	<b>19.0</b>	<b>22.8</b>
<b>Celecox</b>	<b>3.7</b>	<b>10.4</b>	<b>15.0</b>
<b>Geninax</b>	<b>3.7</b>	<b>6.4</b>	<b>11.3</b>
<b>Irribow</b>	<b>-</b>	<b>1.6</b>	<b>3.0</b>

**No. 2 Share  
(7.2%)**

**Rich Product  
Lineup**

**MR Customer  
Satisfaction  
Ranking: No. 1<sup>\*\*</sup>**

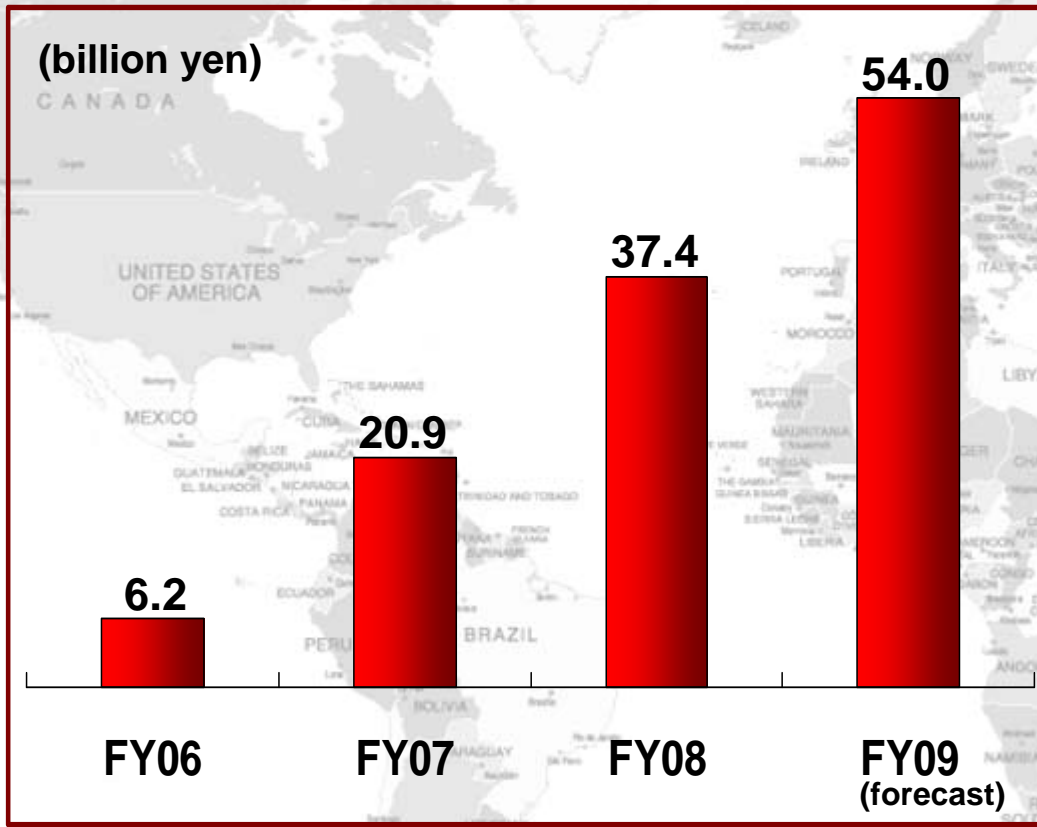
\*Forecasts \*\*Company Image Survey by Nikkei Medical

# To Be the No. 1 Company

Japan

## Sales Target of 100 Billion Yen for New Products

Vesicare, Celecox, Geninax, Iribow, Bonoteo



### Growth Drivers

Continuous Expansion of Main Products  
Rich New Product Lineup

Bonoteo: Sales in Apr. 0.6 bil. yen

Micombi\*: Hypertension (Combo)

Celecox: Lower back pain\*\*

Prograf: Ulcerative colitis\*\*

Myasthenia gravis (all)\*\*

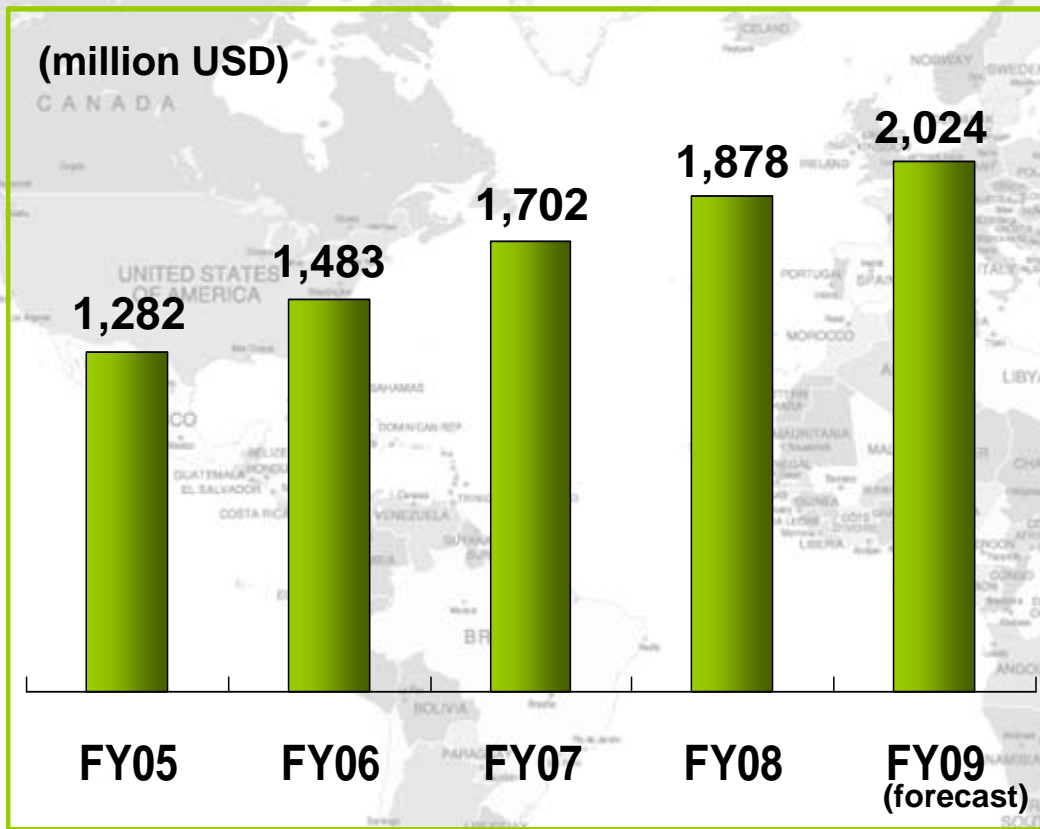
\*Launch expected in FY2009 (new product)

\*\*Launch expected in FY2009 (additional indication)

# Our Specialty Business Shows High Growth

North America

## Robust Topline Growth



### Growth Drivers

Products Following Prograf  
Expansion of Urology & Hospital Business

Vesicare FY09 Forecast: \$384M

Adenoscan and Lexiscan FY09  
Forecasts: \$500M

Portfolio Growth and Expansion in AI  
Franchise\*: Mycamine, AmBisome,  
telavancin\*\*

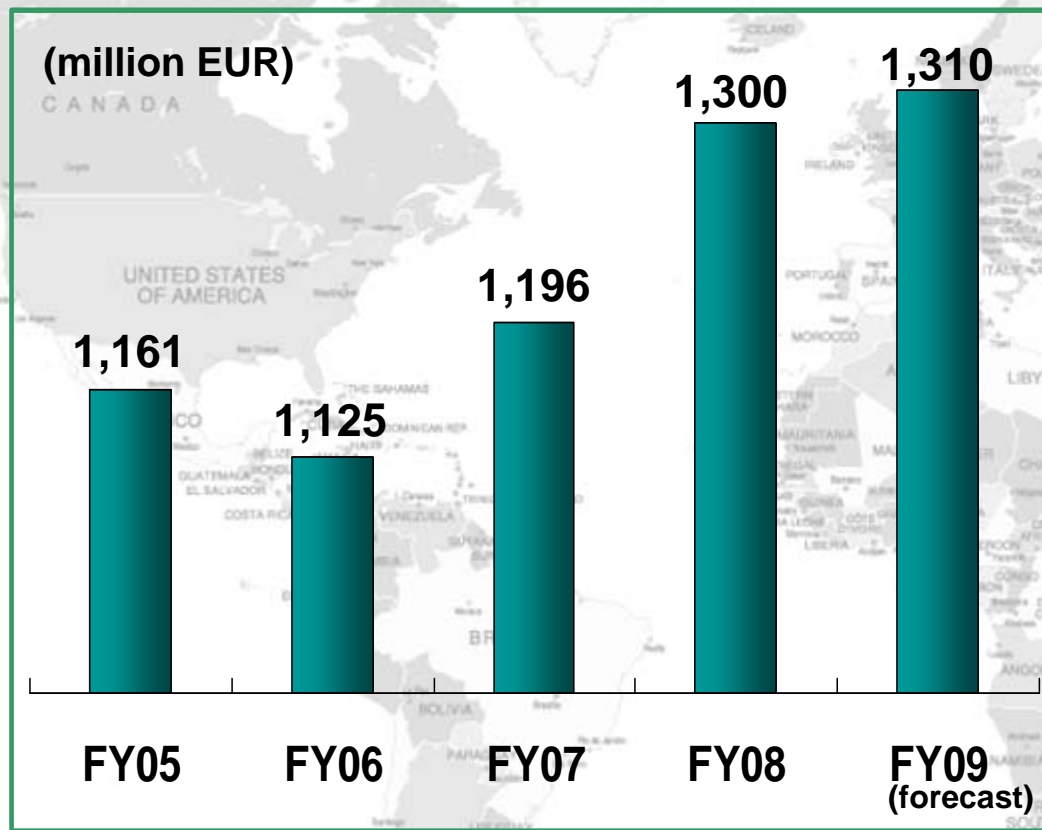
\*Anti-Infective

\*\*Launch expected in FY2009

# Expanding of Product Lineup and Sales Presence

Europe

## Sales Expansion in Both Product and Geographical Areas\*



### Growth Drivers

Reinforcement of Urology and AI\*\*  
Business Expansion of Spain, Russian,  
and Turkey Business

Prograf/Advagraf

Vesicare

Omnic/Omnic OCAS

Eligard

Mycamine

Emerging  
Nations

\* Excluding European export sales from EU segment sales

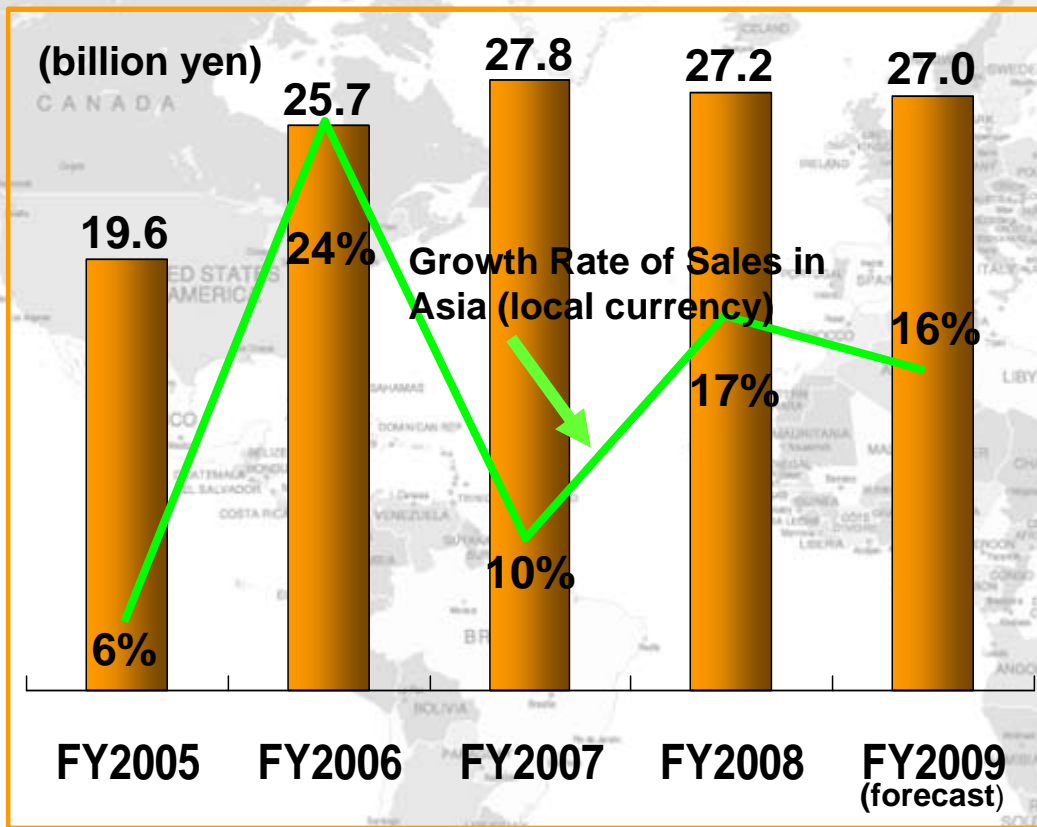
\*\* Anti-Infective

# Maximize Sales in the Higher Growth Market

Asia

## Astellas No. 1 in Sales for a Japanese Pharmaceutical Company in the Eastern Asian Market

High Growth Rate (in local currency):



### Growth Drivers

Chinese Market is Top Priority  
Development of Indian Market

Prograf

Advagraf

Harnal

Vesicare

Mycamine

Irribow

# Broaden Our Own Global Marketing Network

**Largest Global Marketing Network of a Japanese Rx Company**  
**Marketing Base: More Than 30 Countries, Number of MRs: 5,150**

## Japan

**Challenge for No. 1 Position**

**Maximization of Main and  
New Products**

## Europe

**Entered Turkey Market (2008)**

### 20 Operating Base

Germany, Spain, France, U.K., Russia, Italy, Nordic countries, Poland, The Netherlands, Belgium, Czech Republic, Ireland, Austria, Portugal, Greece, Hungary, Switzerland, South Africa, Turkey

## Americas

**Entering Latin American Market  
(2009, under preparation)**

**U.S., Canada,  
Latin America (under preparation)**

## Asia

**Entered Indian Market (2008)**

### 8 Operating Base

China, Korea, Taiwan, Hong Kong, Indonesia, The Philippines, Thailand, India



# Global Pipeline



# Status of Astellas Pipeline



	Filed	P3	P2	P1
Urology	YM617 (LUTs, J)	YM178 (E, US, J) solifenacin/ tamsulosin (E) YM617 (Pediatric, US)	ASP3550 (J) YM905 (D tablet, J)	ASP0265 ASP3652 ASP7035
Transplant Immunology	FK506 (UC, J) FK506 (MG,J) FK506 (FK506+MMF,US) FK506 (Granule, E) YM177 (Low back pain, J)	YM177 (Acute pain, J)	ASP0485 (E, US) ASP9831 (E)	ASK8007 ASP015K ASKP1240
Anti-Infective	telavancin (US)	telavancin (E)	ASP2151 (US, J)	telavancin (J)
Diabetes Cardiology Renal	RSD1235 (US) YM086 (diabetic nephropathy, J)	YM150 (VTE, J,A) ASP1585 (J)	YM150 (VTE, E, US) YM150 (AF, E, J, A) ASP1941 (US, J) YM311 (E) ASP1517 (US, E)* YM533 (J)	YM311(J)
CNS		FK199B (J)	ASP8825 (J)	ASP2905 ASP0777
Oncology			YM155 (E, US) AGS-1C4D4 (E, US)	AGS-16M18 AGS-8M4 YM155 (J)
Others		YM443 (J) YM529 (1M, J)	YM443 (US) YM060 (E)	

\*Licensed territory: E and J etc., VTE: venous thromboembolism, AF: atrial fibrillation

# Progress in Pipeline Status from Feb. 09 (Global)

Project	Indication	Area	Stage	Memo
Protopic (ointment)	Atopic dermatitis (prevention of flares)	Europe	Approved	Approved in Feb.
telavancin	Complicated skin and skin structure infections (cSSSI)	US	Filed	Receipt of Complete Response letter from the FDA in Feb. 09 and submit the response to the FDA in Mar. 09
telavancin	Hospital-acquired pneumonia (HAP)	US	Filed	Filed in Jan. 09
solifenacin/ tamsulosin	Lower urinary tract syndrome associated with benign prostatic hyperplasia (BPH)	Europe	P3	Enter into P3
mirabegron (YM178)	Overactive bladder	Japan	P3	Enter into P3
YM150	Prevention of venous thromboembolism	Japan/Asia	P3	Entered into P3
ASP2151	Herpes zoster, genital herpes	US/Japan	P2	Suspended 28-days safety study in healthy subjects. Data evaluation underway
ASP1941	Type 2 diabetes	Japan/US	P2	Obtained P2 preliminary results in Japan and US
ASP1517	Renal anemia	US/Europe*	P2	Restarted P2
AGS-1C4D4	Pancreatic cancer	US/Europe	P2	Entered into P2

\*Licensed territory: EU, JPN etc.

# Progress in Pipeline Status from Feb. 09 (Japan)

Project	Indication	Stage	Memo
Micombi	Hypertension	Approved	Combination drug of Micardis and hydrochlorothiazide (HCTZ), Approved in Apr. 09
FK506	Ulcerative colitis	Filed	Passed Japanese Healthcare Authorities review meeting in Apr. 09
ASP1585	Hyperphosphatemia	P3	Entered into P3
ASP8825	Restless legs syndrome	P2	Obtained P2 preliminary results (Achieved primary endpoints)

# Progress in Pipeline Status from Feb. 09 (P1, etc.)

## New P1 Projects

Project	Indication	Stage	Memo
ASP7035	Nocturia	P1	Entered into P1
ASP0777	Alzheimer's disease	P1	Entered into P1

## Discontinued Projects

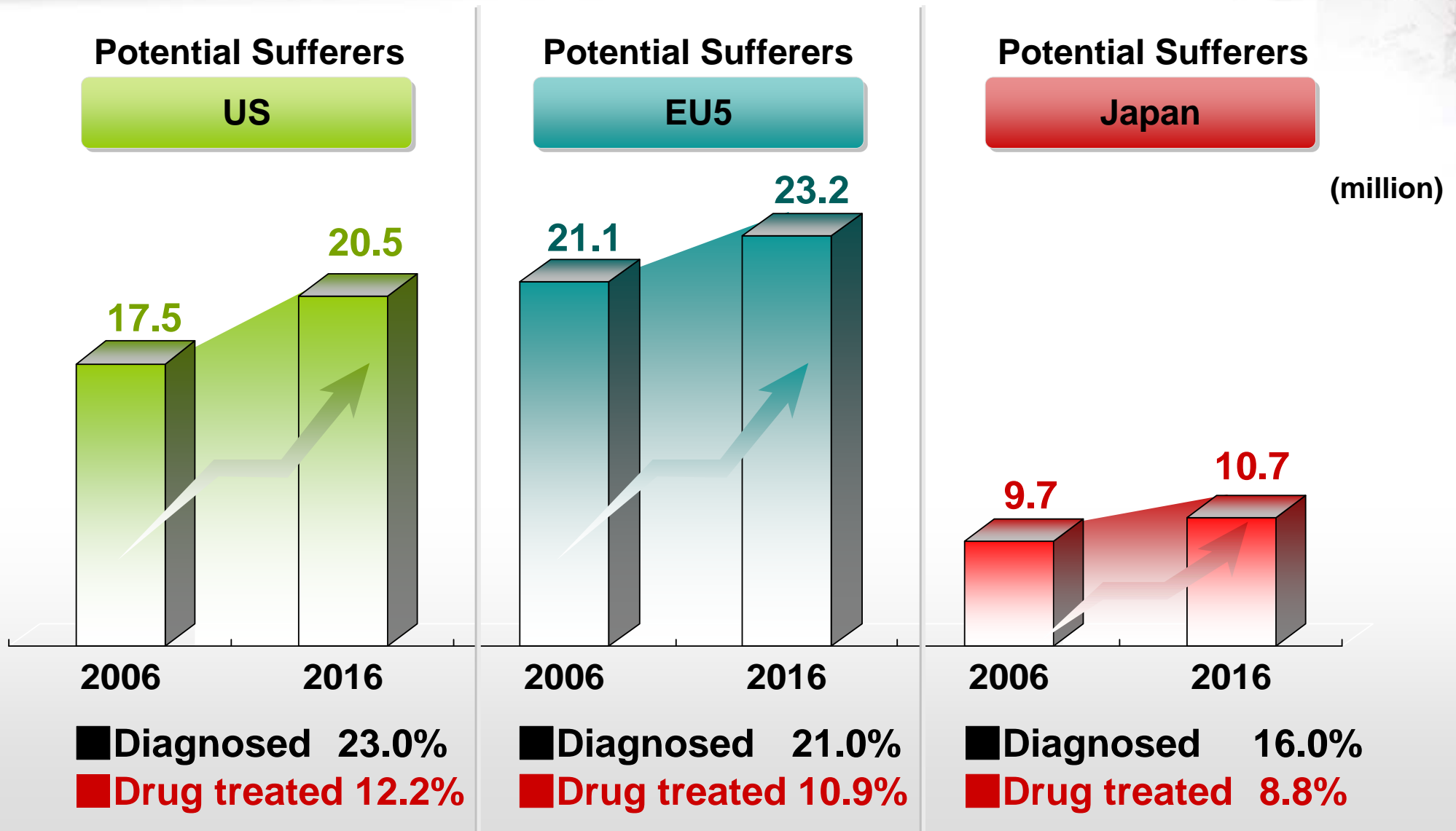
- YM543 (Type 2 diabetes)
- ASP2314 (Schizophrenia)
- ASP2535 (Alzheimer's disease, Schizophrenia)

# mirabegron (YM178)

## NDA Filing Expected in FY2010

- **Indication:** Urinary frequency, urinary incontinence or urgency associated with overactive bladder (OAB)
- **Mechanism of Action:** Beta 3 adrenoreceptor agonist (Novel mechanism, first-in-class)
- **Status:** Under P3 clinical trials and long-term trials in Europe and the U.S., entering into P3 in Japan
- **Dosage:** Oral, once daily
- **Expected Product Profile:**
  - Less incidence of such adverse events as dry mouth observed with anticholinergic
  - Less concern of urinary retention in male patients with lower urinary tract syndromes compared to anti-cholinergics due to no decrease of voiding pressure

# mirabegron (YM178): High Potential for OAB\* Markets

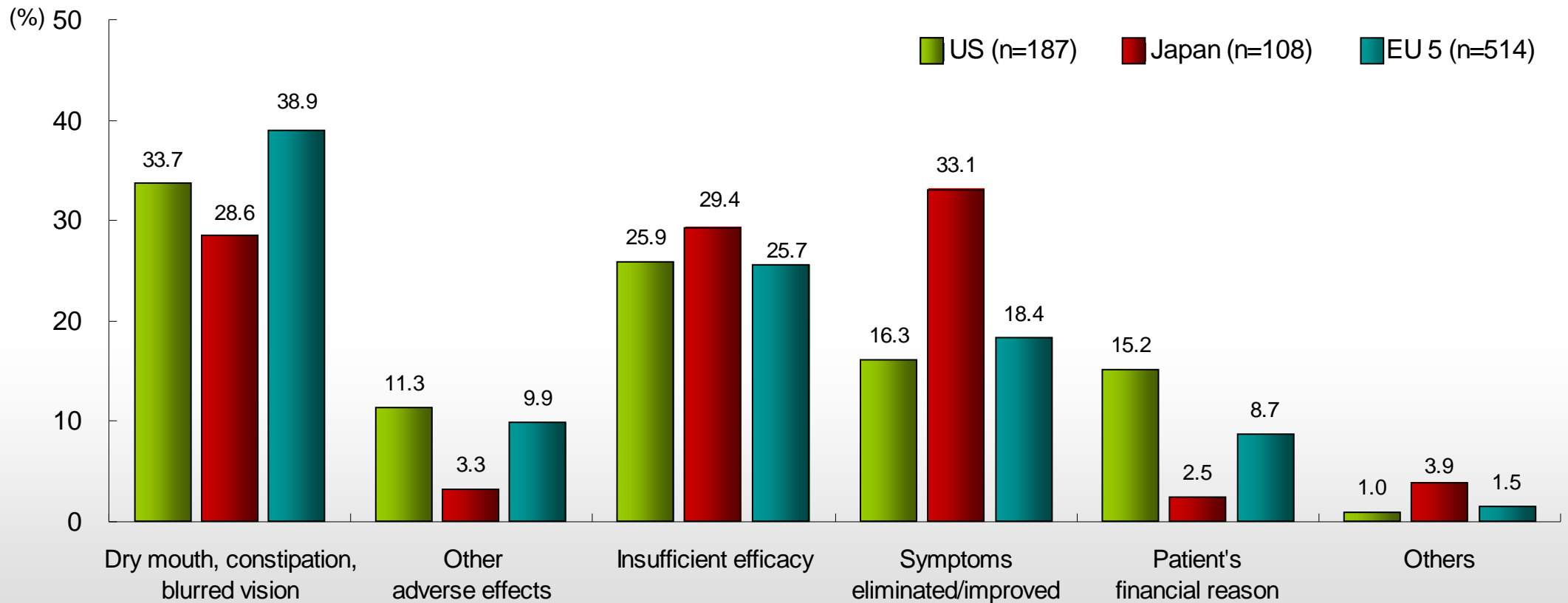


\*OAB: overactive bladder

Source: DecisionBase 2008, Decision Resources Inc.

# Unmet Medical Needs in Current OAB Therapy

Many OAB patients stop taking the drug within 6 months mainly because of anti-cholinergic side effects or insufficient efficacy (female patients)



Source: Global market research by TNS/Astellas, 2007

# Our Target Position for the Global OAB Market

**Vesicare**

**mirabegron**

## **Market Expansion**

In addition to the current anticholinergic, Astellas delivers wide range of therapeutic options to non-responders to or patients who have discontinued the anticholinergic

**Increase Share in the OAB Market**

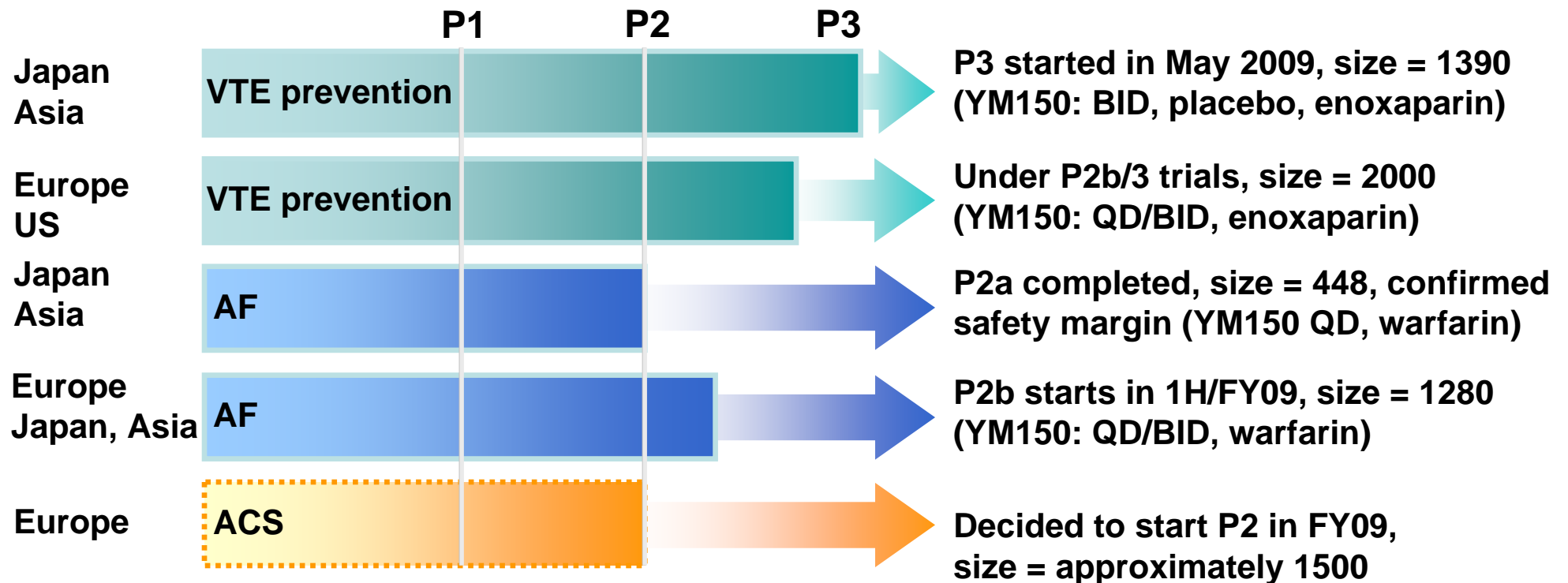
**Being the No. 1 OAB Company Worldwide**



# YM150: Development Strategy

▶ Product profile with robust balance between safety and efficacy

▶ Decide to conduct ACS clinical trials



VTE: venous thromboembolism, AF: atrial fibrillation, ACS: acute coronary syndrome

# SGLT2 Inhibitors: Type 2 Diabetes Mellitus (1)

## ASP1941 P-2 study in Japan

- Double-blind, placebo-controlled, dose-finding study (4 doses)
- Primary outcome: HbA1c
- Treatment duration: 12 weeks
- Enrollment: 361 (69–74 patients/group)

### Results

- The proof of concept was demonstrated.
- HbA1c was decreased by the treatment with ASP1941 in dose-dependent manner. Statistical significance against placebo was detected in all treatment groups.
- ASP1941 was safe and well-tolerated.
- Body weight was decreased by ASP1941 treatment

 **ASP1941 can move to the next step, Phase 3 in Japan.**

# SGLT2 Inhibitors: Type 2 Diabetes Mellitus (2)

## ▶ ASP1941 P-2a study in the US

- Double-blind, placebo-controlled safety study (4 doses)
- Treatment duration: 4 weeks
- Enrollment: 61 patients (12–13 patients/group)

### Results

- ASP1941 was safe and well-tolerated.
- Dose-dependent increases of urinary glucose excretion were observed.
- There were significant declines at the end of treatment in plasma glucose.
- Body weight reductions were also observed.

## ▶ Selection: YM543 or ASP1941

**ASP1941 was selected for the next development stage.**

# Oncology: Enrich Astellas' Long-term Pipeline

## Drug Discovery

- Unique breadth of technologies
  - Medicinal chemistry, fermentation and mAbs
- Novel targets that lead to innovative NME discovery
  - Synergistic combination of Agensys' target molecules and Astellas' genomics technology (target search)

## Antibody Technology Platform

- Agensys' strong antibody research and development capabilities
- Many first-in-class antibody products for novel targets
- Cutting-edge ADC (Antibody-Drug Conjugate) technology in multiple cancer indications
- Premier fully human mAbs technology platform licensed from Regeneron

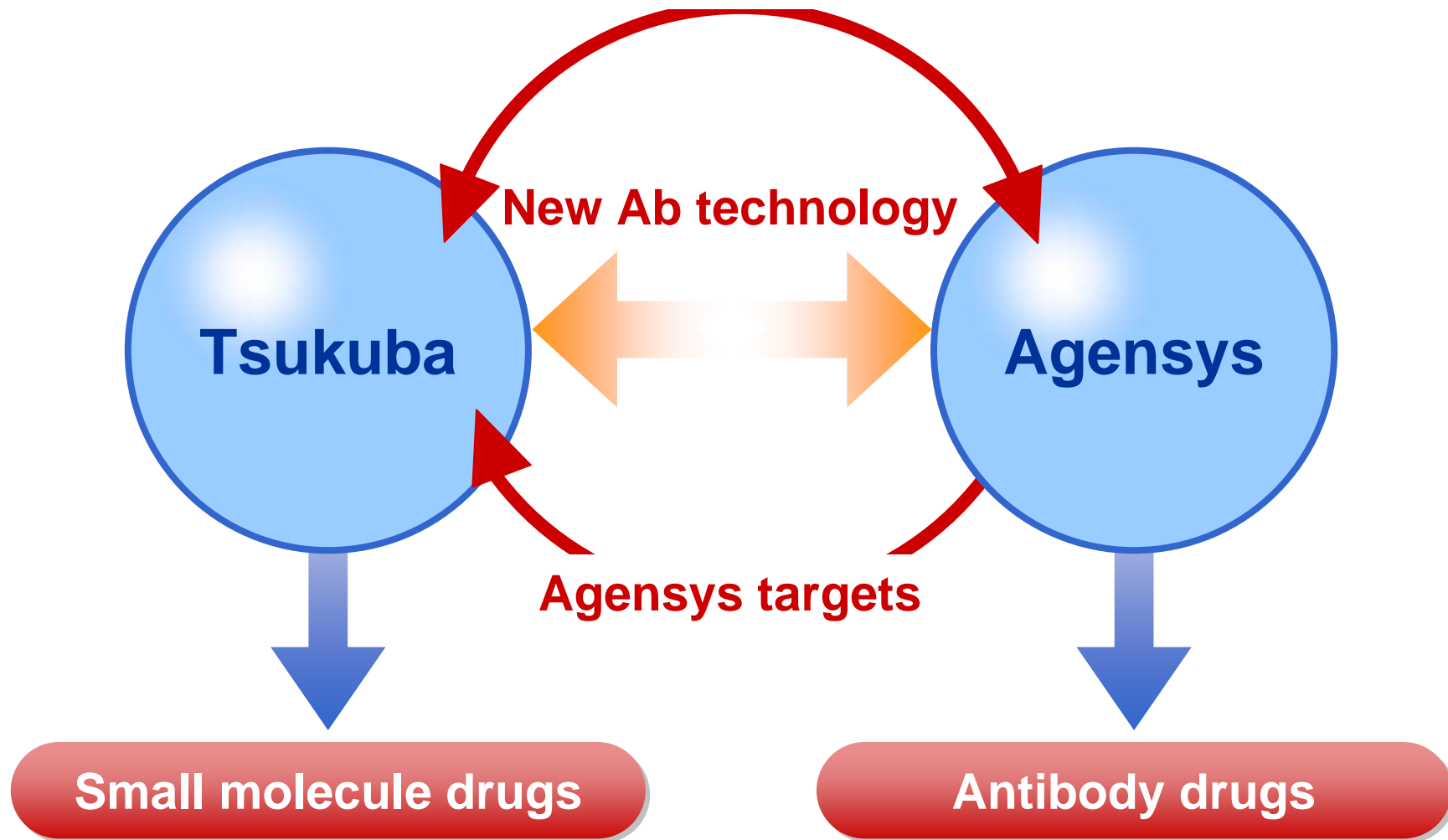
## Oncology Programs

- Antibody: Clinical 3, Preclinical 12 (naked, ADCs)
- Small molecules: Clinical 3, Preclinical 12
- Novel-target molecule: >10

# Agensys' Novel Targets and Genomics Technology

Target discovery and validation based on patient specimens

**Genomics Bioinformatics**



# Strength of Agensys: Antibody Development Capabilities Using ADC Technology

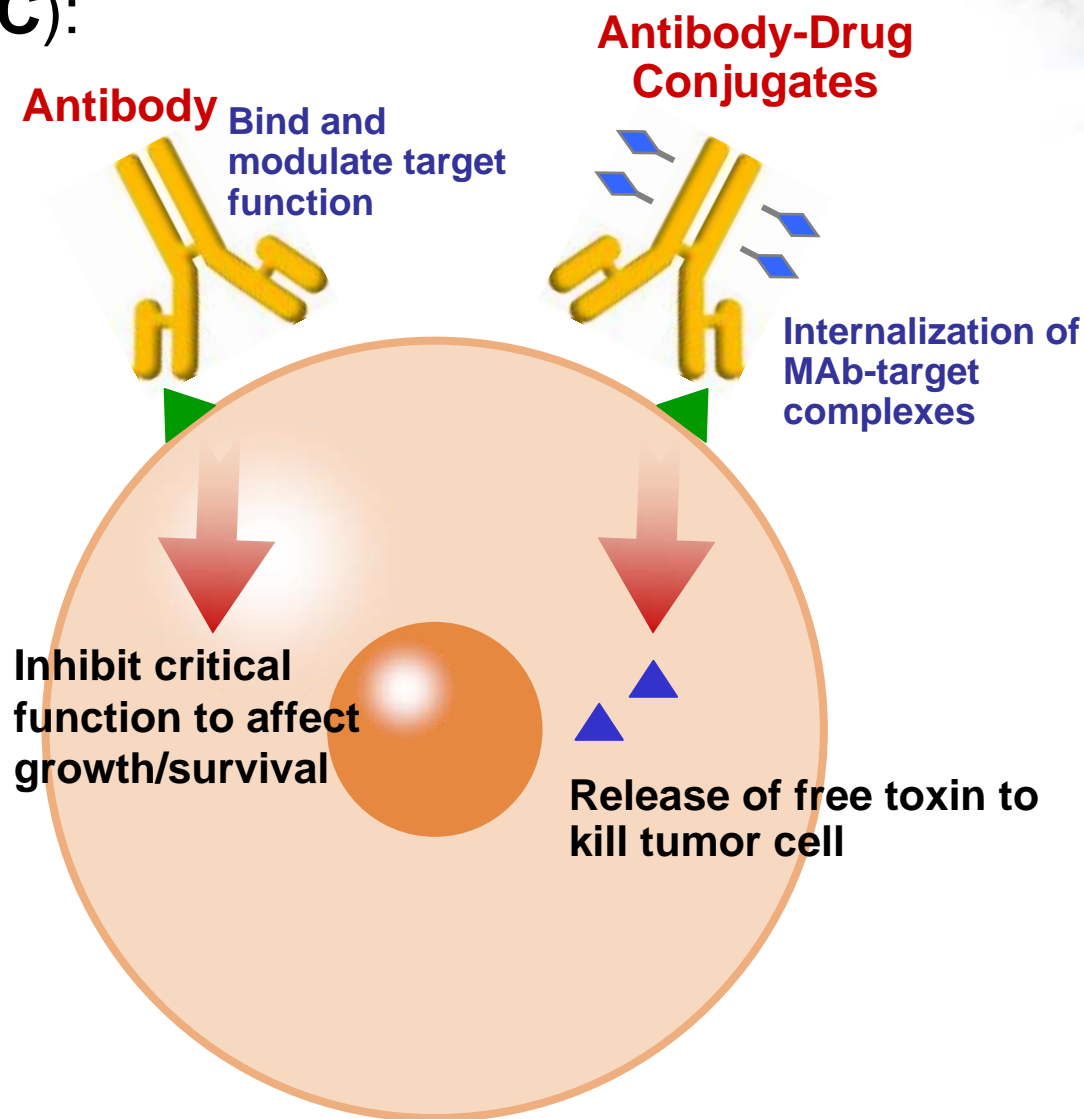
## Antibody Drug Conjugates (ADC):

Potent and tumor cell-specific therapy

- MAb utilized as a vehicle to deliver toxins to specific target-expressing tumor cells
- Applicable to any tumor target with proper expression profile (no dependency on target function)

Combining ADC technology and Agensys' novel targets

Accelerated expansion of potential antibody oncology pipeline



# Oncology Pipeline



	<b>Launch - Clinical Phase</b>	<b>Discovery - Preclinical</b>
<b>Small molecule products</b>	Eligard (EU launched) YM155 (P2) ASP3550 (P2) ASP0265 (P1)	<b>12</b>
<b>Antibody products</b>	AGS-1C4D4 (P2) AGS-16M18 (P1) AGS-8M4 (P1)	<b>12</b> (naked, ADCs)

# Astellas' Global Category Leader Aims

**1**

**Globally building a clear-cut business segment**

**2**

**Exploring specialty markets**

**3**

**Focusing on diseases with a high level of unmet medical needs**

**4**

**Sales and marketing activity capitalizing on high speciality**

**5**

**Continued delivery of in-house products to the market**

**6**

**Established links of in-house value chain integrating research, development, and sales and marketing**