# Financial Results for FY 2009 Ending March 31, 2010

May 13, 2010

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Astellas Pharma Inc.

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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.

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# Summary of Financial Results for FY2009

(billion yen)

| | FY2008 | FY2009 | Change | 2Q/09 Forecasts for FY09 | Difference | Factors (Changes from FY2008) |
|---|---|---|---|---|---|---|
| Net sales | 965.6 | 974.8 | +9.1 | 976.0 | -1.2 | FX impact by -39.3 |
| COG<br>COG ratio | 264.4<br>27.4% | 289.2<br>29.7% | +24.8<br>+2.3ppt | | | Product mix +1.5ppt<br>FX impact on elimination of unrealized gain by +0.6ppt |
| SGA | 291.8 | 303.6 | +11.8 | | | Increase in expenses related to launches of new products |
| R&D<br>R&D ratio | 159.0<br>16.5% | 195.5<br>20.1% | +36.5<br>+3.6ppt | 179.0 | +16.5 | Increase in in-licensing fee<br>Increase in clinical development costs<br>Increase in depreciation of research facilities in Tsukuba |
| Operating income | 250.3 | 186.4 | -63.9 | 200.0 | -13.6 | FX impact by -17.2 |
| Ordinary income | 271.4 | 190.9 | -80.4 | 200.5 | -9.6 | Decline in interest income<br>Decline in currency exchange gain |
| Net income | 170.9 | 122.2 | -48.7 | 125.0 | -2.8 | |

| FX | FY2008 | FY2009 | Change | FY2009 Forecasts |
|---|---|---|---|---|
| USD | 101 yen | 93 yen | -8 | 93 yen |
| EUR | 143 yen | 131 yen | -12 | 132 yen |

# Sales by Geographical Area

## -Sales increase in all areas on a local currency basis-

### Japan

(billion yen)


**Factors**

- Lipitor +4.6
- Micardis/Micombi +7.2
- Prograf +5.2
- Vesicare +3.9
- Celecox +7.3
- Vaccines +7.9
- Gaster -3.1
- Irribow -1.4

### Europe

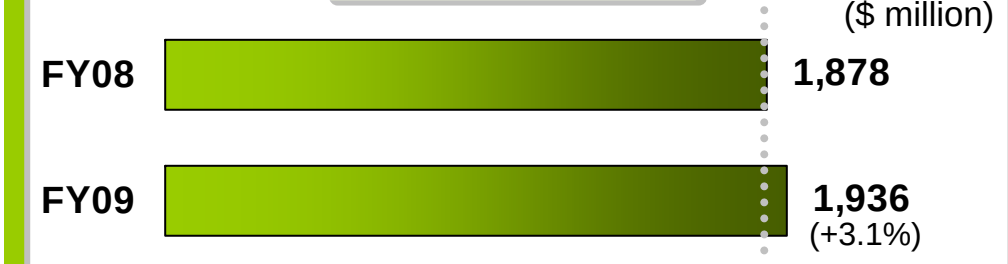
(€ million)


**Factors**

- Prograf/Advagraf +43 (export sales included)
- Harnal +5
- Harnal Bulk & Royalty +23
- Vesicare +31
- Protopic +5
- Mycamine +8
- Eligard +20

### North America

($ million)

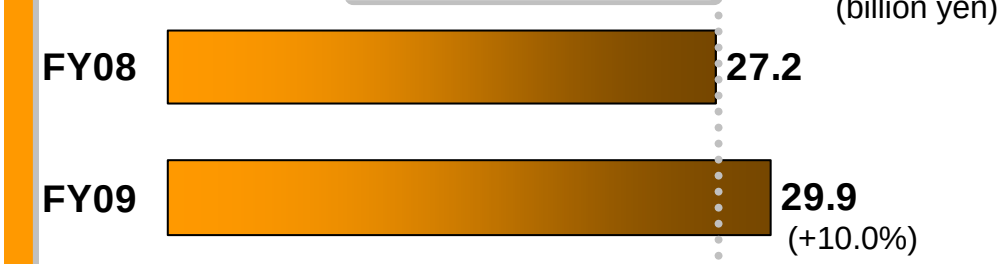



**Factors**

- Prograf -149
- Scan +105
- VESIcare +69
- Mycamine +30
- AmBisome +5

### Asia

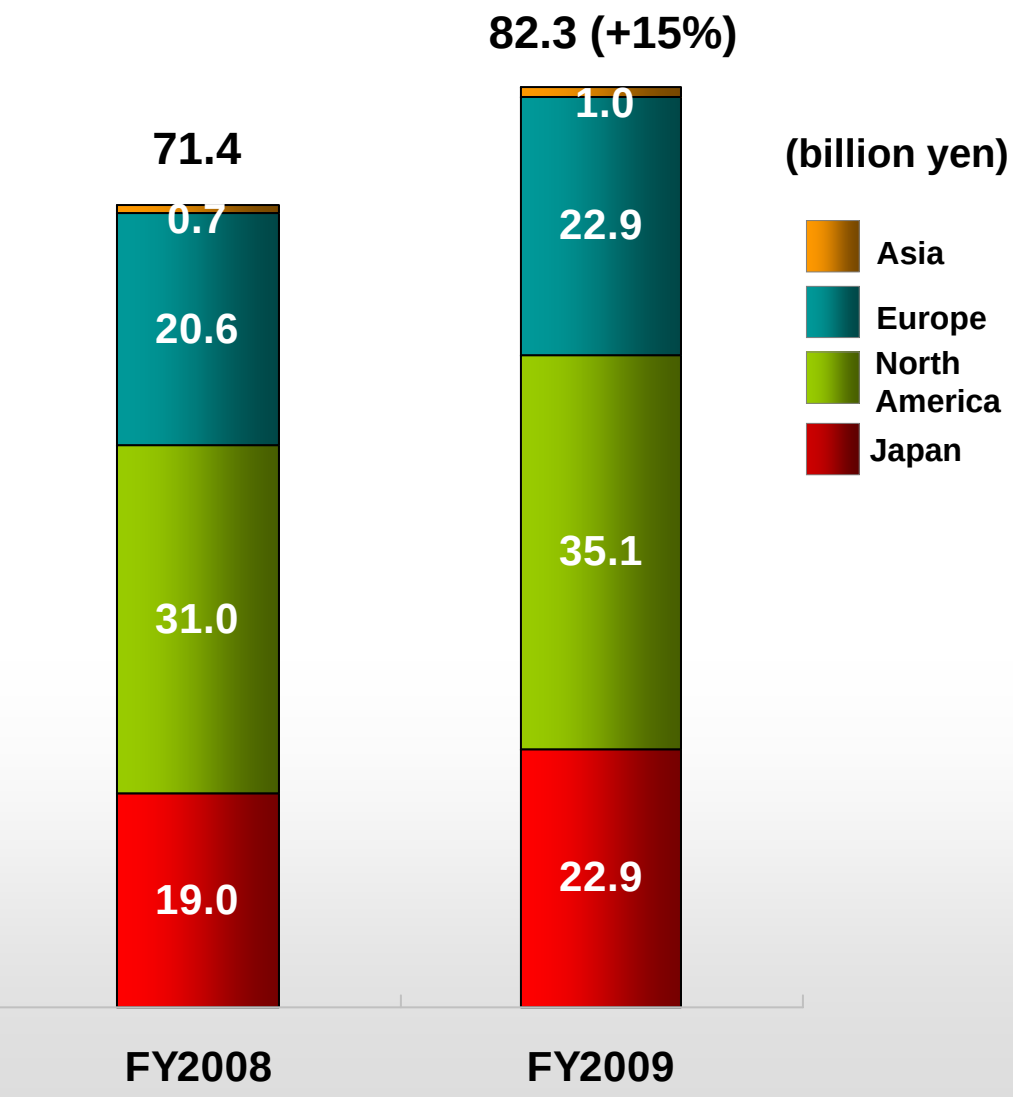
(billion yen)




**Factors**

- Prograf +1.5
- Vesicare +0.3
- Mycamine +0.4
- Harnal +0.4
- FX impact –2.7

# Vesicare




## FY09 Growth Rate

- Japan: +21%
- North America: +23% (USD)
- Europe: +22% (EUR)
- Asia: +64% (excl. FX impact)

## Market Share

- Japan : 50% (Mar 2010, NHI Drug price basis)
- US : 18% (TRx, Week of April 23, 2010)
- Europe : 35% (Feb 2010, cash basis)

## Launched: 66 countries/areas

- China (launched in Dec 2009)

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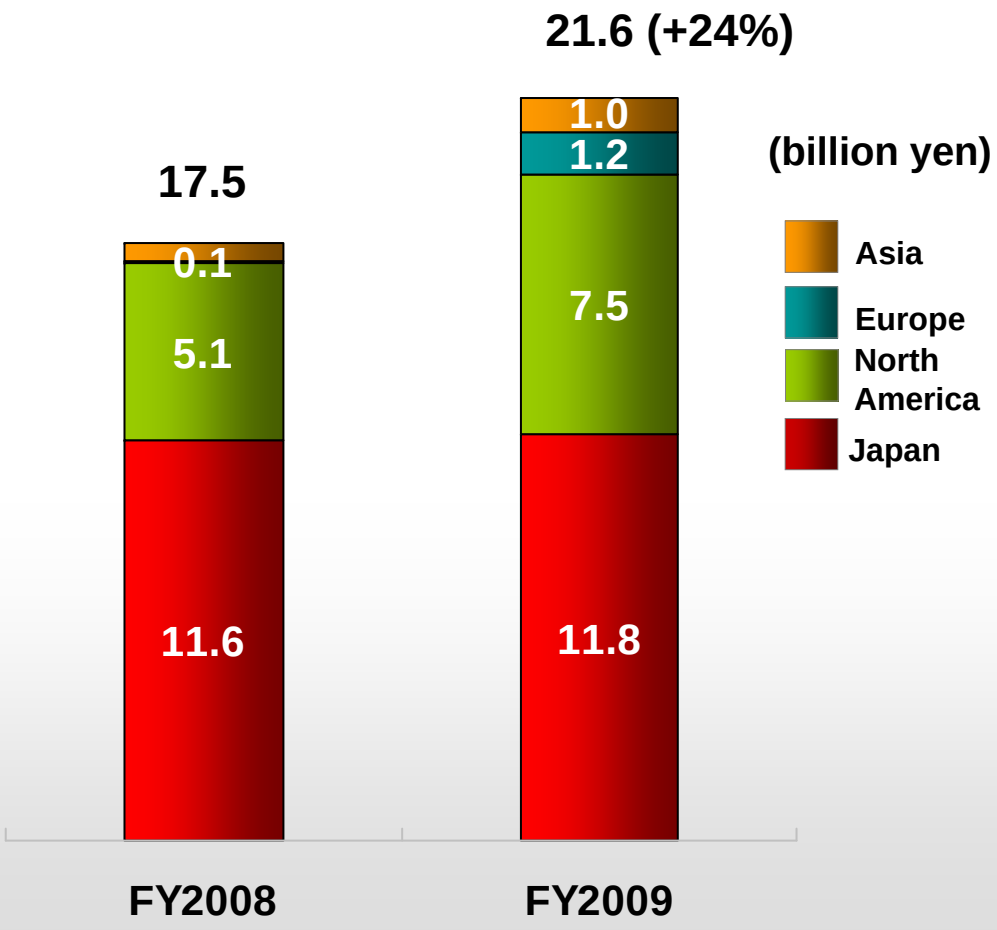
# Fungard/Mycamine




## FY09 Growth Rate

- Japan : +1%
- North America : +60% (USD)
- Europe: +€9 million (actual sales)
- Asia : +94% (excl. FX impact)

## Market Share

- Japan : 51%
  (Mar 2010 YTD; NHI Drug price basis*)
- US : 56%** (Feb 2010)

## Launched: More than 30 countries/areas

- Europe*** : Launched in 21 countries/areas
- Asia: Launched in 8 countries/areas
- Launched in India in Jan 2010
  (Co-promotion with GSK)
- Approved in Brazil in Apr 2010

* NHI Drug Price basis in antifungal injection market.
**Pt-days share among 3 candin agents.
***Including the Middle East and Africa.

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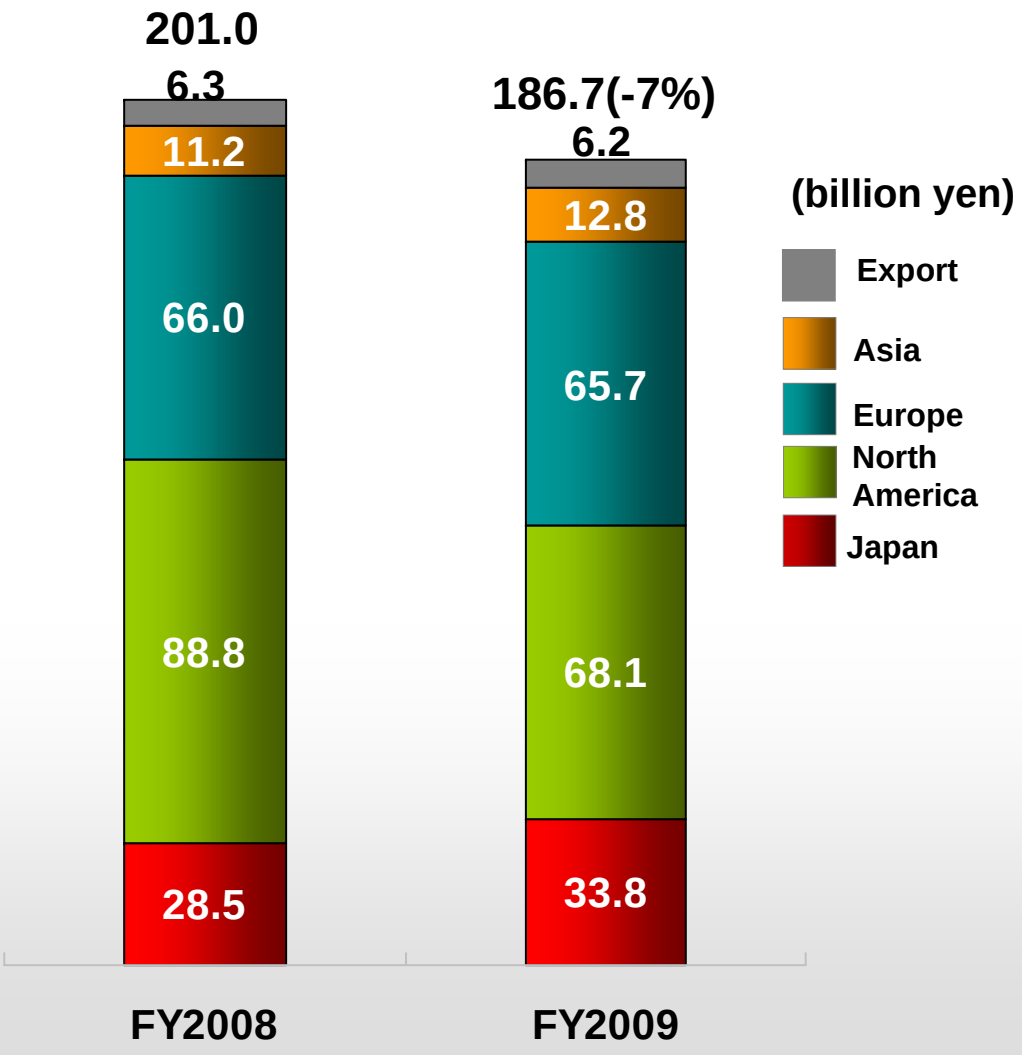
# Prograf




## FY09 Growth Rate

- Japan: +18%
- North America : -17% (USD)
- Europe : +9% (EUR)
- Asia : +24% (excl. FX impact)

## Topics

### Japan

Long period prescription of Graceptor permitted in Oct 09
Additional indication for ulcerative colitis (Jul 09)
myasthenia gravis (all) (Oct 09)

### US

Generic tacrolimus launched in Aug 09
TRx of generic tacrolimus: 43.5%
(among tacrolimus, week of Apr 23, 2010)

### EU

Sales of Advagraf: €92M
Generic tacrolimus approved in several countries,
to be launched in Germany in May 2010

### Asia

Launched in India in Mar 2010
Additional indication for lupus nephritis (Korea in Nov 09, Hong Kong in Dec 09)
Advagraf: Hong Kong, Taiwan already launched, followed by Korea (launched in Jan 2010)

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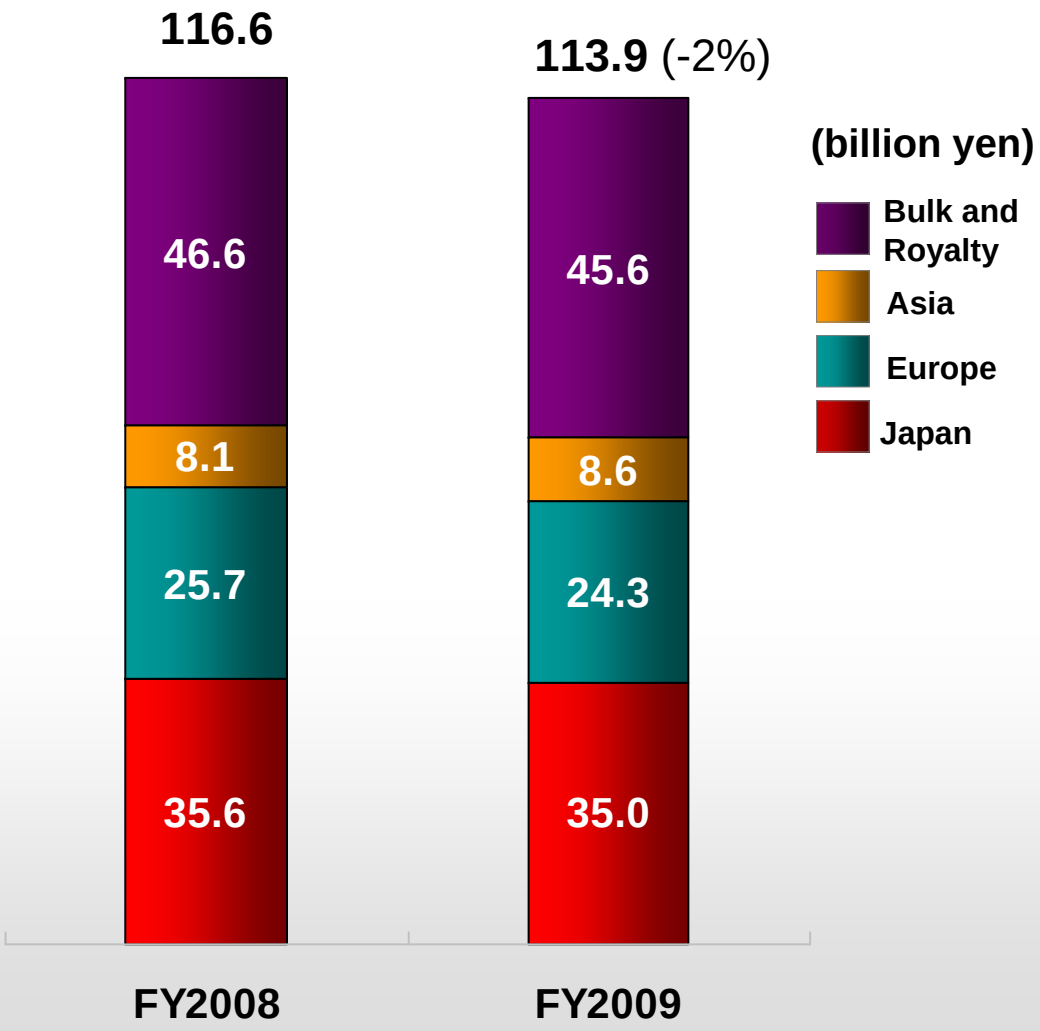
# Harnal




## FY09 Growth Rate

- Japan : -2%
- Europe : +3% (EUR)
- Asia : +14% (excl. FX impact)
- Bulk and Royalty : +7% (EUR)

## US Flomax

- Sales : $531M (Jan-Mar 2010, -5%)
- Generic tamsulosin launched in Mar 2010
  TRx of generic tamsulosin: 76%
  (among tamsulosin, week of Apr 23, 2010)

## TOCAS

- Sales in Europe : €123M (+8%)
- Europe*: Launched in 37 countries/areas
- Asia: Launched in 7 countries/areas

*Including the Middle East and Africa.

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# Japan : Sales of Major Products

Japan

(billion yen)

| | FY08 | FY09 | Change (%) |
|---|---|---|---|
| Total Rx | 491.5 | 509.8 | +4 |
| Lipitor | 95.3 | 99.9 | +5 |
| Micardis/Micombi | 64.4 | 71.6 | +11 |
| Gaster | 53.0 | 49.9 | -6 |
| Harnal | 35.6 | 35.0 | -2 |
| Prograf | 28.5 | 33.8 | +18 |
| Myslee | 25.7 | 29.1 | +13 |
| Seroquel | 21.0 | 23.6 | +12 |
| Vesicare | 19.0 | 22.9 | +21 |
| Celecox | 10.4 | 17.8 | +70 |
| Geninax | 6.4 | 8.1 | +26 |
| Symbicort | - | 1.5 | - |
| Bonoteo | - | 1.0 | - |
| Irribow | 1.6 | 0.2 | -87 |

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# North America: Sales of Major Products

North America

($ million)

| | FY08 | FY09 | Change (%) |
|---|---|---|---|
| Total Rx | 1,878 | 1,936 | +3 |
| Prograf | 884 | 734 | -17 |
| Scan (Adenoscan + Lexiscan) | 390 | 495 | +27 |
| VESIcare | 308 | 378 | +23 |
| Mycamine | 51 | 81 | +60 |
| Protopic | 75 | 78 | +4 |
| AmBisome | 61 | 67 | +9 |
| Amevive | 16 | 13 | -21 |
| Vaprisol | 7 | 10 | +49 |
| VIBATIV | - | 4 | - |

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# Europe: Sales of Major Products

Europe

(€ million)

| | FY08 | FY09 | Change(%) |
|---|---|---|---|
| Total Rx | 1,666 | 1,798 | +8 |
| Prograf | 502 | 545 | +9 |
| Harnal | 504 | 533 | +6 |
| Sales by Astellas | 179 | 185 | +3 |
| Bulk and Royalties | 324 | 348 | +7 |
| Vesicare | 143 | 175 | +22 |
| Eligard | 87 | 107 | +24 |
| Protopic | 36 | 42 | +15 |
| Mycamine | 0 | 9 | - |

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# Asia: Sales of Major Products

Asia

(billion yen)

| | FY08 | FY09 | Change (%) |
|---|---|---|---|
| **Total Rx** | **27.2** | **29.9** | **+10** |
| Prograf | 11.2 | 12.8 | +14 |
| Harnal | 8.1 | 8.6 | +5 |
| Vesicare | 0.7 | 1.0 | +49 |
| Mycamine | 0.5 | 1.0 | +79 |
| Protopic | 0.5 | 0.7 | +36 |

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# Outcome in FY09 – Reinforcement of Products' line

## Japan

- Bonoteo Launch (4/09)
- Micombi Launch(4/09)
- Celecox Additional Indication for Lumbago and others (6/09)
- Prograf Additional Indication for Ulcerative colitis (7/09)
- Prograf Additional Indication for Myasthenia gravis(All) (10/09)
- Caduet Combination Tablet Launch(12/09)
- Symbicort Launch(1/10)

## Americas

- VIBATIV Launch cSSSI* (11/09)
- Sumavel DosePro Launch(1/10)
- Brazil: Mycamine approved (10/4)

## Europe

- Modigraf Launch(2/10)
- Qutenza Launch (3/10)
- Business Area Expansion
  - HarnalTOCAS
  - Mycamine
  - Advagraf

## Asia

- Advagraf Launch
  - Taiwan (9/09)
  - Korea (1/10)
- Mycamine Launch
  - Indonesia (10/09)
  - India (1/10) (Co-Promotion with GSK)
- Vesicare
  - China (12/09)
- Prograf Additional Indication for lupus nephritis
  - Korea (11/09)
  - Hong Kong (12/09)

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cSSSI*=complicated skin and skin structure infections

# Outcome in FY09 – Alliance Activities

## Q1/FY09

Taiwan
febuxostat (May, 2009)
-Hyperuricemia with gout

Launched 3/10 EU
Qutenza (Jun,2009)
-Peripheral neuropathic pain

Joint venture with Maxygen (Sep, 2009)

## Q2/FY09

Launched 1/10 U.S.
Sumavel DosePro (Aug,2009)
-Migraine, cluster headache
- Co-Promotion

Launched 1/10 Japan
Symbicort(Aug,2009)
-Bronchial asthma

Launched 12/09 Japan
Caduet Combination Tablet (Aug, 2009)
-Hypercholesterolemia/ hypertension

## Q3/FY09

Phase3 (U.S.・EU) Worldwide
MDV3100 (Oct, 2009)
-Prostate cancer

Phase3(U.S.) Japan Asia
linaclotide (Nov, 2009)
-Irritable Bowel Syndrome with constipation and chronic constipation

Expand ADC collaboration for antibody drugs (Nov,2009)
-Seattle Genetics and Agensys

Phase2(U.S.) Worldwide
FLT3 kinase inhibitors(Incl.AC220) (Dec,2009)
-Acute myeloid leukemia

## Q4/FY09

Phase3 (U.S.・EU and others) Worldwide (except JP)
isavuconazole(Feb,2010)
- Invasive aspergillosis and Candidemia/ Invasive candidiasis

## 10/Q1

China
Hong Kong
febuxostat (Apr, 2010)
-Hyperuricemia with gout

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# Outcome in FY09
## - Broaden Global Marketing Network

**Marketing Base: More than 40 countries**

- Expanding business areas in emerging countries including BRICs.
- Coverage for all BRICs completed, with establishment of Brazilian affiliate in Jul,2009.

### Americas

- **Brazil:**
  - Affiliate Established (7/09)
  - Approval of Mycamine (4/10)
  - Harnal Plan to launch (Omnic/Omnic OCAS)

### Europe

- **Rumania and Bulgaria:**
  - Legal entities for promotional activities established (9/09)
- **Russia:**
  - Sales became No.5 in EU countries

### Asia

- **India: Started Operation**
  - Mycamine launched, co-promotion with GSK (1/10)
  - Prograf launced (3/10)
- **China: Further expansion**
  - The sales in China is No.1 among Japanese pharmaceuticals

(09/4-09/12 ©2010 IMS Health MIDAS)

# Forecasts for FY2010

(billion yen)

| | FY2009 Results | FY2010 Forecasts | Change |
|---|---|---|---|
| Net sales | 974.8 | 940.0 | -34.8 |
| R&D expenses | 195.5<br>20.1% | 182.0<br>19.4% | -13.5<br>-0.7 ppt |
| Operating income | 186.4 | 152.0 | -34.4 |
| Ordinary income | 190.9 | 155.0 | -35.9 |
| Net income | 122.2 | 107.0 | -15.2 |

| FX | FY2009 Results | FY2010 Forecasts | Change |
|---|---|---|---|
| YEN/USD | 93 yen | 90 yen | -3 yen |
| YEN/EUR | 131 yen | 130 yen | -1 yen |

## Factors Behind Decrease in Sales and OP

- **Net sales -34.8 billion yen**
  - (Positive Factors)
  - Sales Growth in growing products and new products in each region: approx+60.0
    (Japan:+30.0 EU/US:+25.0 Asia:+5.0)
  - (Negative Factors)
  - Prograf in U.S. : -25.0
  - U.S. Flomax bulk& royalty: -40.0
  - NHI drug price revision in Japan: -30.0
    (incl. Impact by medical reform in the U.S. : approx -6.0)
    (incl. FX impact: approx-8.0)
- **Operating income -34.4 billion yen**
  - Decrease of gross profit (decrease of net sales, increase of COG ratio)
  - Increase of SG&A (excl. R&D expenses)
  - R&D expenses decreased

  (FX impact: approx -4.5 )

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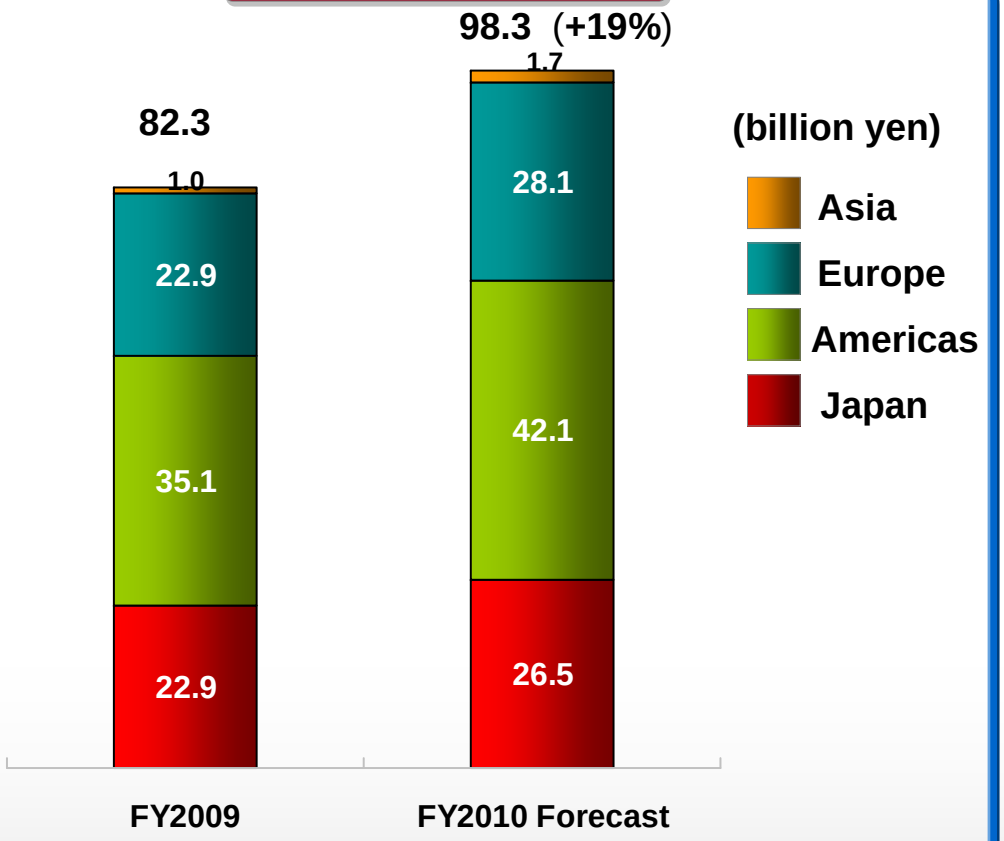
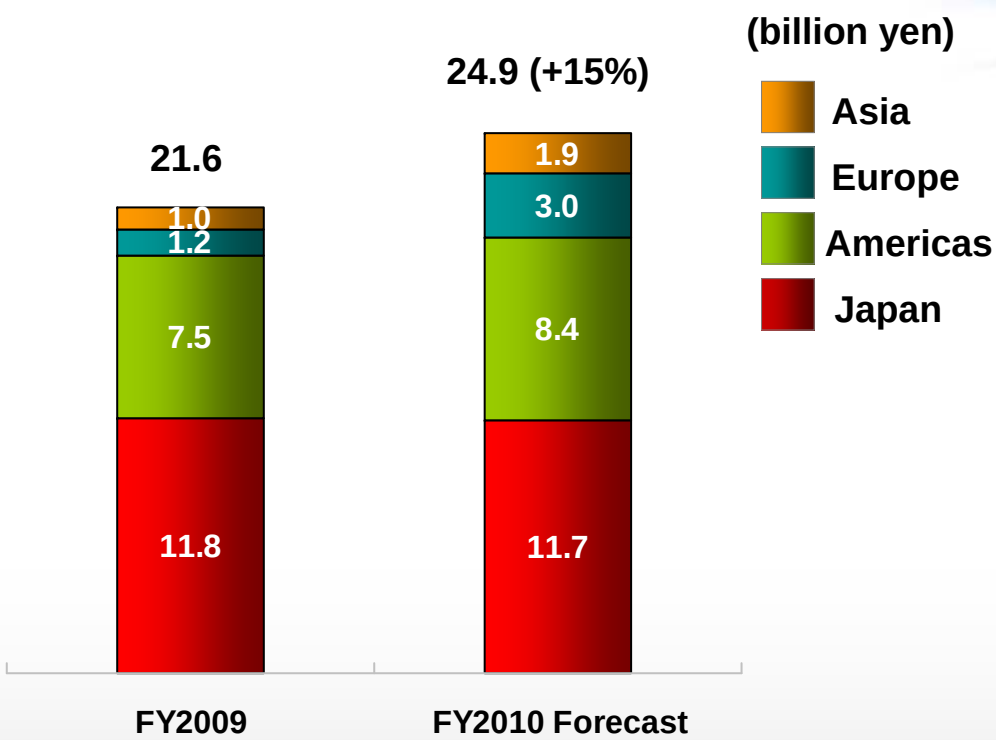
# Global Sales Forecast For FY2010

## Vesicare




- Japan: +15%
- Americas: +23% (USD)
- Europe: +23% (EUR)
- Asia: +60% (excl. FX impact)

## Funguard/ Mycamine




- Japan: -1%
- Americas: +14% (USD)
- Europe: +€ 23M
- Asia: +90% (excl. FX impact)

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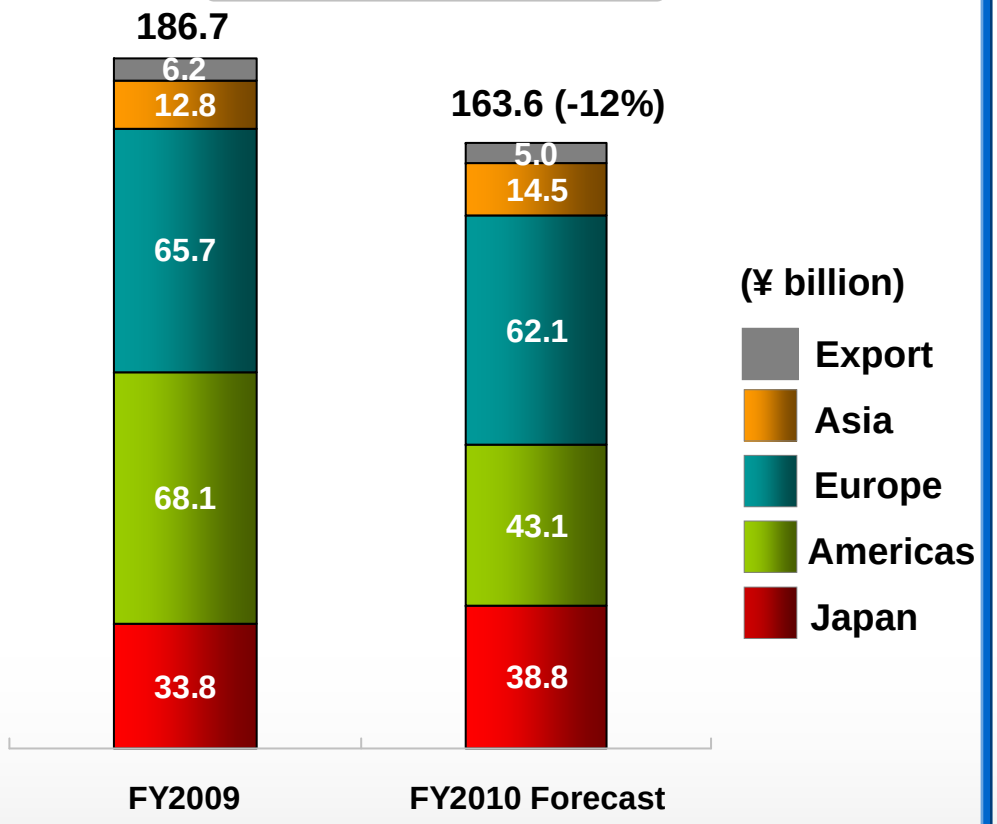
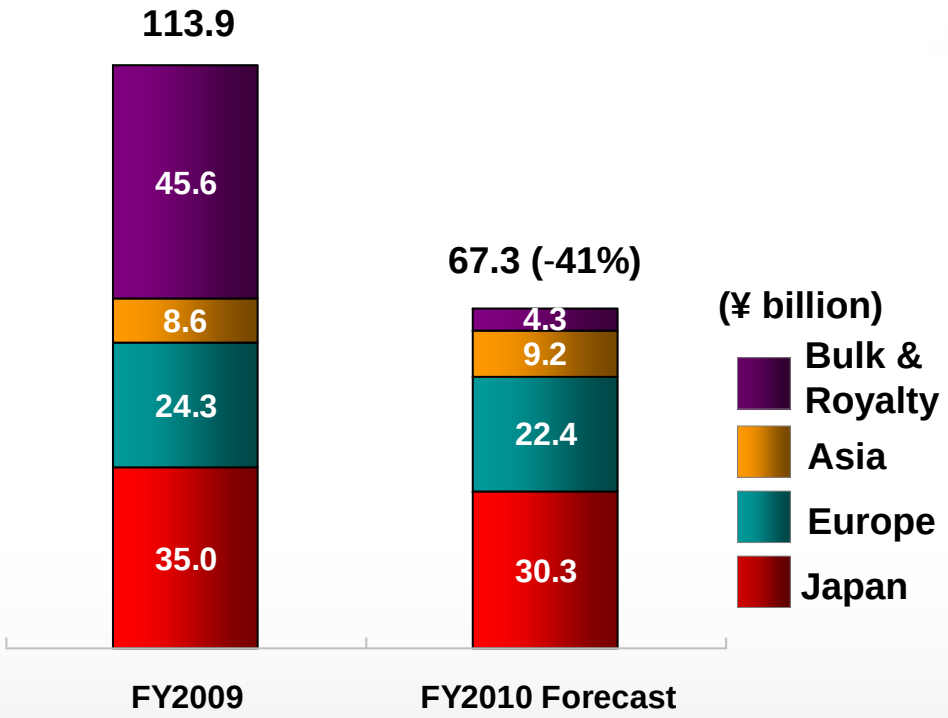
# Global Sales Forecast For FY2010

## Prograf




- Japan: +15%
- Americas: -35% (USD)
- Europe: -5% (EUR)
- Asia: +15% (excl. FX impact)

## Harnal




- Japan: -14%
- Europe: -7% (EUR)
- Asia: +0% (excl. FX impact)
- Bulk & Royalty: -91% (EUR)

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# Sales Forecast by Geographical Area

## Japan

(billion yen)

| | | |
|---|---|---|
| FY09 | 529.2 | |
| FY10 (Forecast) | 527.2 (-0.4%) | |

Rx Sales Total FY09 509.8⇒FY10 Forecast 510.9(+0.2%)

### Factors

| | | | |
|---|---|---|---|
| Celecox | +8.8 | Lipitor | -7.5 |
| Symbicort | +5.6 | Harnal | -4.7 |
| Prograf | +5.0 | Gaster | -8.5 |
| Vesicare | +3.6 | | |

## Europe

(€ million)

| | | |
|---|---|---|
| FY09 | 1,798 | |
| FY10 (Forecast) | 1,560 (-13.3%) | |

### Factors

| | | | |
|---|---|---|---|
| Vesicare | +41 | Prograf/Advagraf (Incl. Export) | -29 |
| Mycamine | +14 | Harnal | -13 |
| Eligard | +10 | HarnalBulk & Royalty | -315 |
| Protopic | +7 | | |

## Americas

($ million)

| | | |
|---|---|---|
| FY09 | 1,936 | |
| FY10 (Forecast) | 1,941 | (+0.2%) |

### Factors

| | | | |
|---|---|---|---|
| VESIcare | +89 | Prograf | -255 |
| Scan | +68 | | |
| Protopic | +18 | | |
| Mycamine | +12 | | |

## Asia

(billion yen)

| | | |
|---|---|---|
| FY09 | 29.9 | |
| FY10 (Forecast) | 35.4 (+18.1%) | |

### Factors

| | | | |
|---|---|---|---|
| Prograf | +1.7 | Fx impact | –3.4 |
| Mycamine | +0.9 | | |
| Vesicare | +0.7 | | |
| Protopic | +0.7 | | |

# Profit Distribution Policy

- Top priority on investment for growth in Rx business
- Dividends to be increased stably and continuously based on the mid and long-term growth
- Share buyback to be implemented in a flexible manner

| | FY2008 | FY2009 | FY2010 forecasts |
|---|---|---|---|
| Earnings per share | 356.11 yen | 261.84 yen | 231.69 yen |
| Dividends per share | 120 yen | 125 yen | 125 yen |
| ROE | 16.0% | 11.7% | - |
| DOE | 5.4% | 5.6% | - |
| Share buyback | 123.4 bil. yen | 26.9 bil. yen | to be implemented flexibly |

# Global Pipeline


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# Status of Astellas' Pipeline

Red: Changes from the previous announcement　: Local　: New Indication, New Formulation　: In-house Global　: Licensed-in Global

| | Filed | P3 | P2 | P1 |
|---|---|---|---|---|
| Urology | YM617(LUTs, J)<br>YM905(OAB D tablet, J) | YM178 (OAB, E, US, J)<br>solifenacin/ tamsulosin (E) | | ASP3652<br>ASP7035 |
| Transplant Immunology | | YM177 (Acute pain, J) | ASP0485 (E, US)<br>ASP9831 (E)<br>ASP015K (Transplant,US)<br>ASKP1240(Transplant,US) | ASP015K (J)<br>ASKP1240<br>ASP3291 |
| Anti-Infective | telavancin (NP,US)<br>telavancin (cSSTI/NP,E) | Isavuconazole (E,US) | ASP2151 (US, J) | telavancin (J) |
| Diabetes Cardiology Renal | RSD1235 (US) | YM150 (VTE, J, A)<br>ASP1941 (J)<br>ASP1585 (J)<br>YM533<br>(Chronic renal failure,J,A) | YM150 (VTE, E, US)<br>YM150 (AF, E, J, A)<br>YM150 (ACS, E)<br>ASP1941 (US,E)<br>YM311(US)* ASP1517(US)* | YM311 (J) *<br>ASP1517 (J) *<br>ASP4178<br>ASP5034 |
| CNS | ASP8825 (Restless legs syndrome, J) | | | ASP2905<br>ASP0777<br>FK949E |
| Oncology | | MDV3100<br>(Prostate cancer, E,US) | ASP3550(J)<br>YM155 (E, US)<br>AGS-1C4D4 (E, US)<br>ASP6183(AGS-8M4) (US)<br>AC220(E,US) | AGS-16M18<br>AGS-16M8F<br>ASG-5ME<br>YM155 (J) |
| Others | | YM443 (J)<br>YM529 (1M, J) | YM060 (E) | |

*Licensed territory: E and J etc.,
cSSTI: Complicated Skin and Soft Tissue Infections, NP:  Nosocomial Pneumonia, VTE: venous thromboembolism, AF: atrial fibrillat ACS:Acute Coronary Syndrom

# Progress in Pipeline Status from February, 2010

| Project | Indication | Area | Stage | Memo |
|---|---|---|---|---|
| YM443 | Functional dyspepsia | Japan | P3 | P3(Pivotal, long-term) last patient out |
| YM529 | Osteoporosis (Bonoteo once a month administration) | Japan | P3 | P3 last patient out |
| Isavuconazole | Invasive aspergillosis and Candidemia/ Invasive candidiasis | USA Europe | P3 | Licensed from Basilea |
| ASKP1240 | Suppression of organ rejection in organ transplant | USA | P2 | Entry into P2a in USA |

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# Progress in Pipeline Status from February, 2010 (P1, etc.)

## New P1

| Project | Indication | Stage | Memo |
|---|---|---|---|
| ASG-5ME | Cancer (ADC) | P1 | New entry into P1<br>Co-development with Seattle Genetics |
| ASP5034 | Type 2 diabetes | P1 | New entry into P1<br>New mechanism of action |

## Discontinued Projects

- YM086 (Filed, Type 2 diabetic nephropathy)
- ASP0265 (P1, Prostate cancer / Endometriosis)

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# Mirabegron (YM178) Development Progress

## NDA Filing Expected in FY2010

- **Summary results of P3 in the US and Europe have been available and NDA filing is under preparation. P3 long-term study is ongoing.**
  - **In the US and Europe: NDA filing is scheduled in the 2nd Half of FY2010.**
    - **Additional thorough-QT study is planned to be conducted before NDA.**
- **Summary results of P3 in Japan have been available and NDA filing is under preparation.**
  - **In Japan: NDA filing is expected in the 1st Half of FY2010.**
- **P3 in Asia is ongoing (China/Korea/Taiwan/India).**

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# Mirabegron (YM178) Summary Results of P3 in Japan

## Study outline

- **Study design:** Double-blind, placebo-controlled study (Tolterodine is reference drug)
- **Primary endpoint:** Mean change from baseline in number of micturitions per 24-hour
- **Treatment period:** 12 weeks
- **Number of patients in safety analysis: 1,137 patients**

## Results

- **The study met its objective by demonstrating efficacy for the primary efficacy variables compared to placebo in mirabegron treatment groups.**
- **Based on the available top-line safety results, mirabegron appears to be safe and well tolerated.**
- **The incidence of anti-cholinergic side effects with mirabegron was low and comparable to those in the placebo group.**

**The Phase 3 results appear sufficient for regulatory submission.**

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# Mirabegron (YM178) Summary Results of P3 in the US and Europe

*presented at the 2Q/FY2009 financial results announcement in November,2009*

## Study outline

- Study design: Double-blind, placebo-controlled study
- Primary endpoint: Mean change from baseline in change of number of incontinence episodes per 24-hour and number of micturitions per 24-hour
- Treatment period: 12 weeks
- Number of patients in safety analysis: [US]1,328 patients, [Europe] 1,978 patients

## Results

**The results of both P3 in the US and Europe showed as below.**

- The study met its objective by demonstrating efficacy for the co-primary efficacy variables compared to placebo in both mirabegron treatment groups.
- Based on the available top-line safety results, mirabegron appears to be safe and well tolerated.
- The incidence of anti-cholinergic side effects with mirabegron was low and comparable to those in the placebo group.

**The Phase 3 results appear sufficient for regulatory submission.**

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# Mirabegron P2b results were presented at EAU (European Association of Urology) 2010 in April (1)

## Study outline:

- **Study design:** Double-blind, placebo-controlled study
- **Primary endpoint:** Mean change from baseline to end of treatment in number of micturitions per 24-hour
- **Treatment period:** 12 weeks

## Study results:

- Mirabegron led to statistically significant and dose-dependent reductions in the mean number of mictuations per 24 hours compared with placebo.
- Mirabegron statistically significant improved the majority of secondary efficacy variables compared with placebo when administered to patients with OAB; the magnitude of these improvements was generally dose-dependent.
- All treatment were well tolerated and associated with a low incidence of drug-related AEs at each dose, including dry mouth and constipation.
- Overall, this study shows that mirabegron is an effective and well tolerated therapy for the treatment of OAB.

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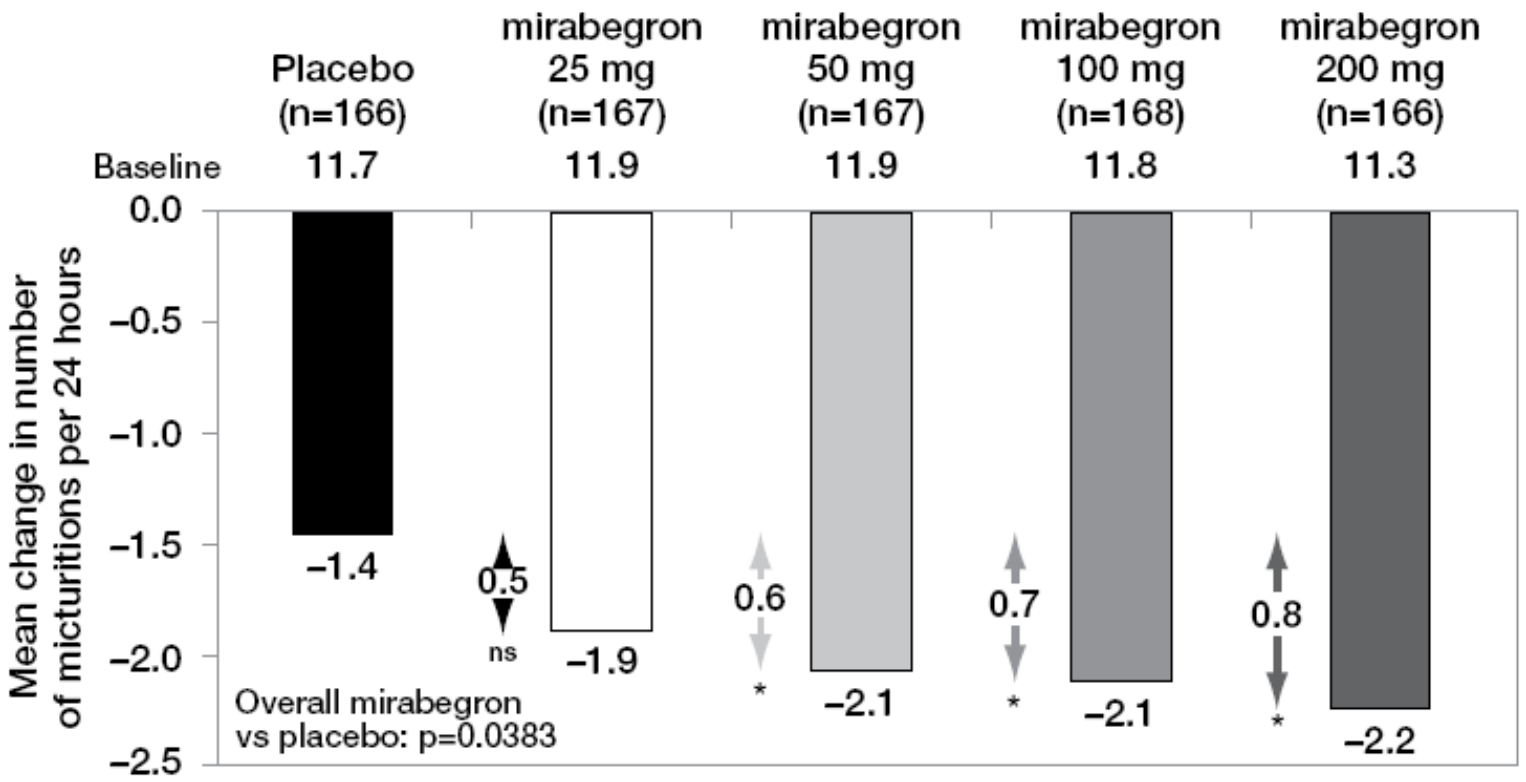
# Mirabegron P2b results were presented at EAU (European Association of Urology) 2010 in April (2)

## Primary endpoint

Figure 3A. Mean change from baseline to end of treatment in number of micturitions per 24 hours (FAS)




Least squares mean change from baseline and differences to placebo; *p<0.05 vs placebo; ns=not significant (versus placebo); FAS=full analysis set

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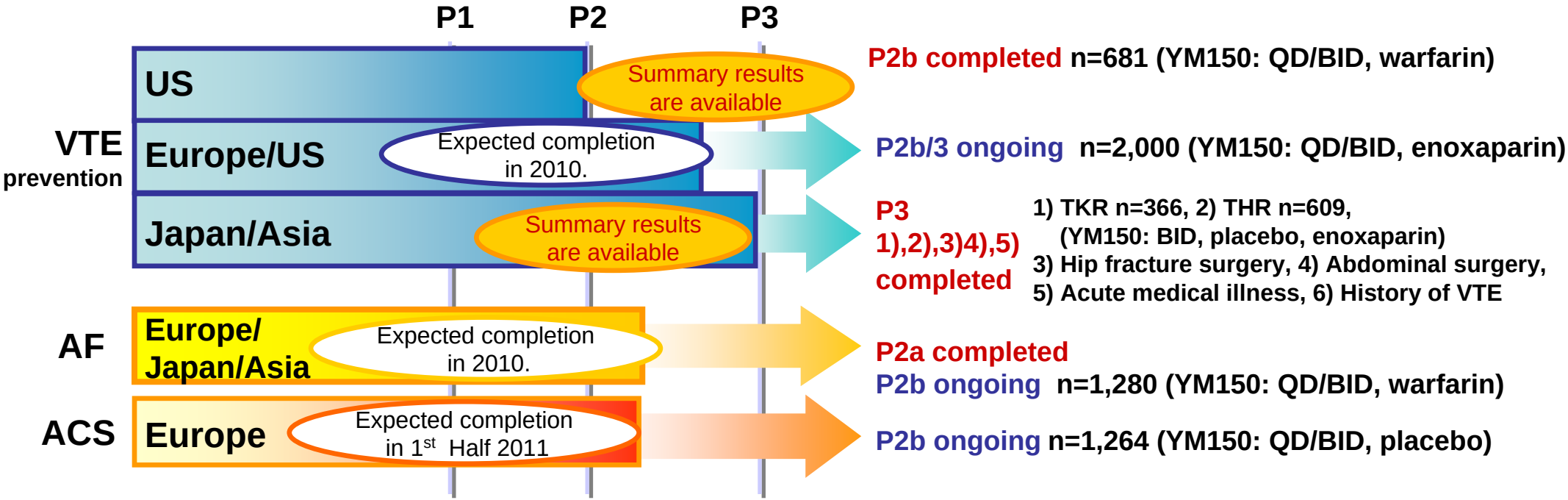
# YM150 Development Progress

## Clinical trial status

■**P2b and P3 are ongoing for VTE, AF, ACS**

- ➢Five P3 studies for VTE indications in Japan/Asia were completed.
- ➢NDA filing for VTE indications in Japan scheduled in 2010.
- ➢P2a study in AF completed. P3 study design in AF will be decided after having P2b study results in the end of 2010.




**YM150 development aims for an anticoagulant with the best risk-benefit balance.**

VTE: Venous Thromboembolism, AF: Atrial Fibrillation, ACS: Acute Coronary Syndrome,
THR: Total Hip Replacement, TKR: Total Knee Replacement

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# YM150 for VTE: P3 studies in Asia/Japan

## Two pivotal P3 studies completed

## Study outline

- **Subject:** Patients undergoing elective total knee replacement surgery
  Patients undergoing elective total hip replacement surgery
- **Study design :** Double-blind, Placebo-controlled study
- **Primary endpoint:** Incidence of venous thromboembolism
- **Treatment period:** 10-14 days
- **Number of patients:** 366 patients (Knee) / 609 patients (Hip)

## Summary results

- **Both studies demonstrated superiority of YM150 against placebo.**
- **YM150 appears to be safe and well tolerated in this population.**

**The P3 results support regulatory submission in Japan.**
**Expected NDA filing in 2010.**

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# YM150 for VTE: P2 study in North America

## Efficacy of YM150 was confirmed in North America

### Study outline

- **Subject:** Patients undergoing elective total knee replacement surgery
- **Study design :** Double-blind, Warfarin-controlled study
- **Primary endpoint:** Overall incidence of venous thromboembolism
- **Treatment period:** 10-14 days
- **Number of patients:** 681 patients

### Summary results

- **The study demonstrated dose dependent efficacy of YM150 in the primary endpoint.**
- **YM150 appears to be safe and well tolerated in this population.**

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# YM150 for AF: P2a study

## Safety of YM150 was confirmed in Atrial Fibrillation

### Study outline

- **Subject:** Patients with Atrial Fibrillation
- **Study design :** Double-blind, Warfarin-controlled study
- **Primary endpoint:** All clinically relevant bleeds during the treatment period rated as "major" or "clinically relevant non-major"
- **Treatment period:** 12 weeks
- **Number of patients:** 448 patients

### Summary results

- **The study demonstrated safety of YM150 over 12 weeks treatment.**

**→Results will be presented at the international scientific meeting in 2010.**

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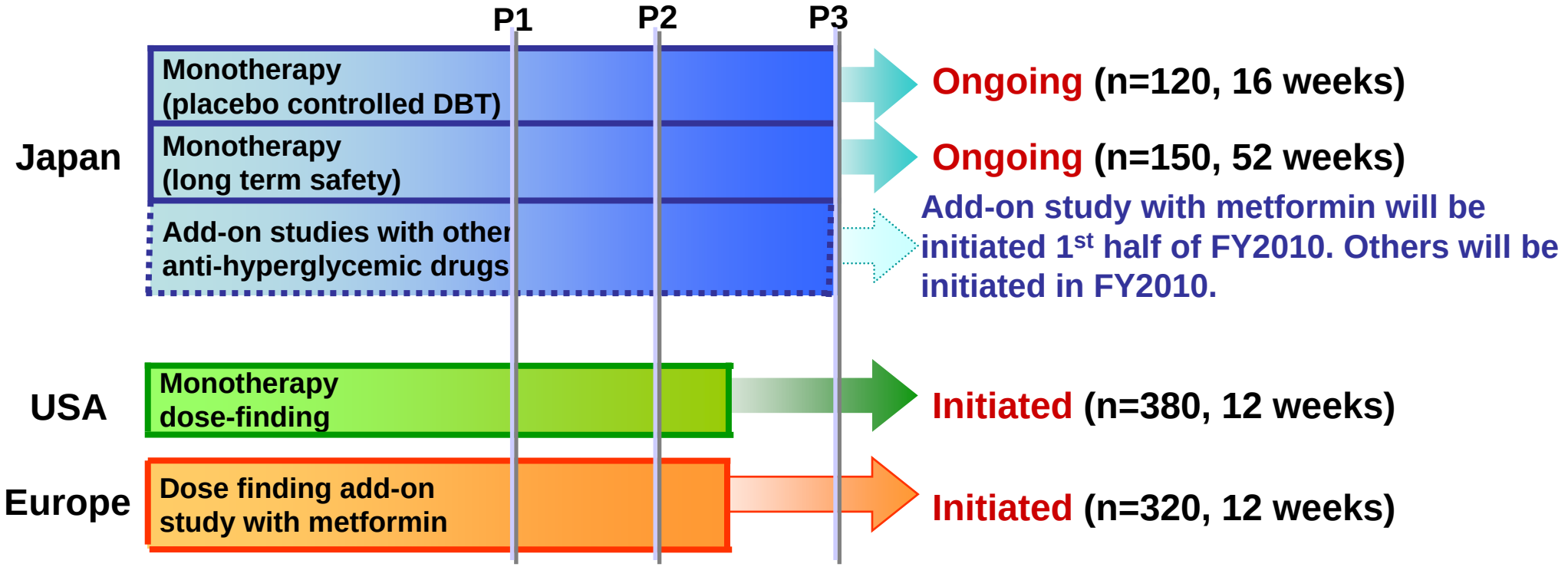
# ASP1941 (SGLT2 Inhibitor) Development Progress

## Development status

- **Japan:** Two monotherapy P3 studies are ongoing. Add-on study with metformin will be initiated in 1st half of FY2010. Others will be initiated in FY2010.
- **USA/EU:** Monotherapy P2b study in USA and add-on P2b study with metformin in Europe were initiated in the first half of FY2010.




The results of P2b in Japan and P2a in USA will be presented at American Diabetes Association in June, 2010.

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# Oncology pipeline expansion

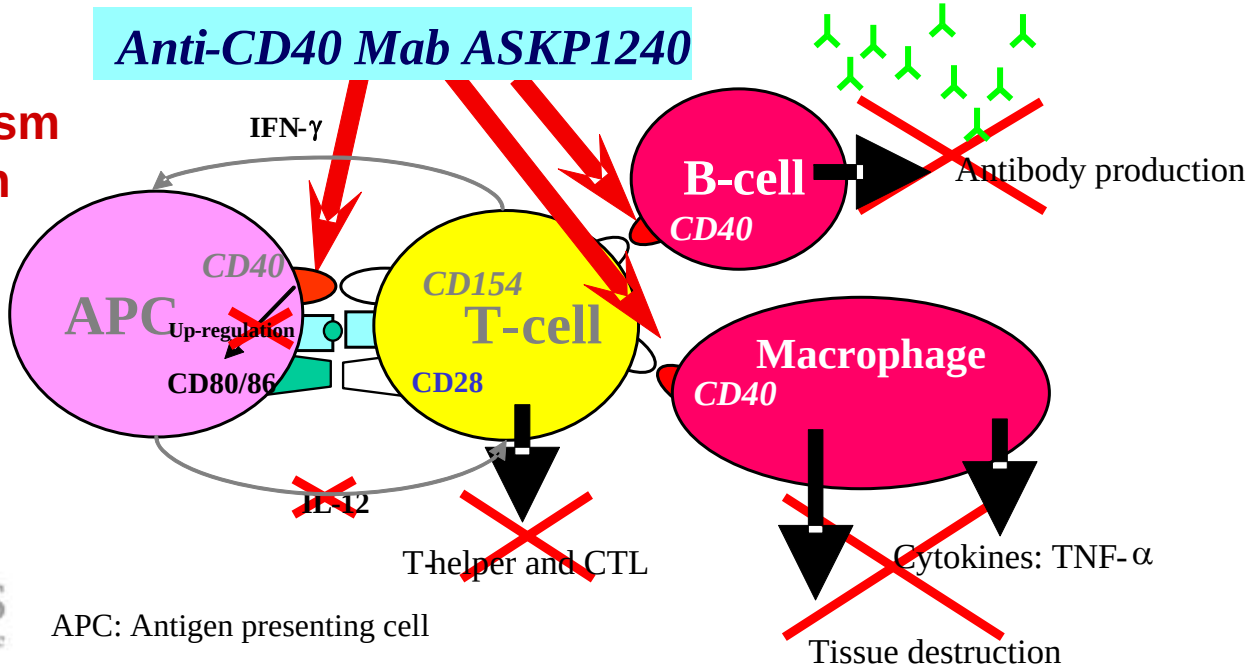
| | Project/Product name | Target cancer | Characteristics | P-1 | P-2 | P-3 | Launch |
|---|---|---|---|---|---|---|---|
| small molecule | Eligard | Prostate cancer | ➢GnRH agonist / Flexible dosing options (1, 3, 6-monthly injections) | (EU) | | | ◎ |
| | MDV3100 | Prostate cancer | ➢Second generation AR antagonist | (EU/US) | | | |
| | AC220 | Acute myeloid leukemia | ➢Potent and highly selective second generation FLT3 kinase inhibitor | (EU/US) | | | |
| | ASP3550 | Prostate cancer | ➢First GnRH antagonist in Japan | (JP) | | | |
| | YM155 | Breast cancer, Non-Hodgkin's lymphoma, Melanoma | ➢A "First-in-class" survivin suppressant | (EU/US/JP) | | | |
| antibody | AGS-1C4D4 | Pancreatic cancer | ➢Novel Antibody target (Prostate stem cell antigen) | (EU/US) | | | |
| | ASP6183 (AGS-8M4) | Ovarian cancer | ➢ A "First-in-class" antibody binds to human chondrolectin (AGS-8) | (US) | | | |
| | AGS-16M18 | | ➢Novel Antibody target | | | | |
| | AGS-16M8F | | ➢ Antibody utilizing ADC technology | | | | |
| | ASG-5ME | | ➢Antibody utilizing ADC technology | | Entry to P1 | | |

# ASKP1240: Anti-CD40 antagonist

## Tolerability was confirmed in P1 and entry into P2a

- **Indication:** Suppression of organ rejection in organ transplant
- **Mechanism of Action:** Fully human anti-CD40 antagonistic monoclonal antibody
- **Characteristic:** Immunosuppressant whose mechanism of action is considered to inhibit signal transduction between T-cell, playing main roles in immune response, and antigen-presenting cell.
- **Development status:** P2a will be initiated in USA.

**Mechanism of Action**




APC: Antigen presenting cell

Anti-CD40 Mab directly suppresses antibody production and inflammatory response by inhibiting signal transduction between T-cell and B-cell and macrophage as well as T-cell and antigen-presenting cell.

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# Isavuconazole

## Licensed from Basilea in Feb. 2010

**Indication:** **Invasive aspergillosis and Candidemia/ Invasive candidiasis**

**Compound Class:** **Novel azole antifungal agent**

**Characteristic:**
**High oral bioavailability**
**Both an intravenous infusion and oral capsules available**
**Potential for fewer drug-drug interactions**

**Development status:** **P3 is ongoing in USA and Europe etc.**

- Indication: Invasive aspergillosis and Candidemia/ Invasive candidiasis
- Primary endpoints: overall improvement rate
  (Invasive aspergillosis and Candidemia/ Invasive candidiasis)
- Expected patients number: 360 (Invasive aspergillosis), 526 (Candidemia/ Invasive candidiasis)
- Dose: intravenous infusion to oral
- Active comparator:
  Voriconazole (Invasive aspergillosis)
  Caspofungin i.v.→ Voriconazole oral (Candidemia/ Invasive candidiasis)

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# Initiative For FY2010 - Specific Measures -

## 1 Grow and Maintain Urology and Transplantation franchise

- Grow OAB franchise with continuous growth of Vesicare
- Maintain global Prograf and Harnal business

## 2 Maximize sales of growth products and new products

| | |
|---|---|
| Japan | : Micardis, Celecox, Myslee, Geninax, Bonoteo, Irribow, Symbicort |
| Americas | : Lexiscan, Mycamine, Protopic, VIBATIV, Sumavel DosePro |
| Europe | : Eligard, Mycamine,Protopic, Qutenza |
| Asia | : Mycamine, Protopic, Nasea, Dorner |

## 3 Accelerating the development of new products in pipeline

- Filed: solifenasin orally disintegrating tablet, telavancin, ASP8825 and others
- To be Filed: mirabegron (JP/ US / EU), YM150 VTE prevention (JP) and others

## 4 Actively in-license products and develop alliances

- Continue strengthening in-licensing and alliances matched to therapeutic area strategy and local franchises

## 5 Improvement of the cost efficiency

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* A new five-year mid-term management plan to begin in fiscal year 2010 ending March 31, 2011 will be announced on May 25, 2010.