Financial Results for FY2012

Year ended March 31, 2013

May 14, 2013
Yoshihiko Hatanaka
President and 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.

Financial Results for FY2012

Fiscal year: From April through March

(Billion YEN)

	FY2011	FY2012	Change	FY2012 Forecasts*
Net sales	969.3	1,005.6	+3.7%	972.0
COGs as % of sales	318.6 32.9%	324.1 32.2%	-	
R&D Expenses as % of sales	189.8 19.6%	181.9 18.1%	-4.2%	184.0
Other SG&A	329.3	345.6	+4.9%	
Operating Income	131.5	153.8	+17.0%	147.0
Ordinary income	135.1	157.1	+16.3%	149.0
Net Income	78.2	82.8	+5.9%	98.0

Depreciation and amortization
Billion YEN
-FY2011: 53.6
-FY2012: 47.4

Amortization of goodwill
Billion YEN
-FY2011: 11.7
-FY2012: 10.3

-Special gains and losses (net): -32.4 billion YEN
-Decrease in income tax burden rate (38.4%→33.5%)

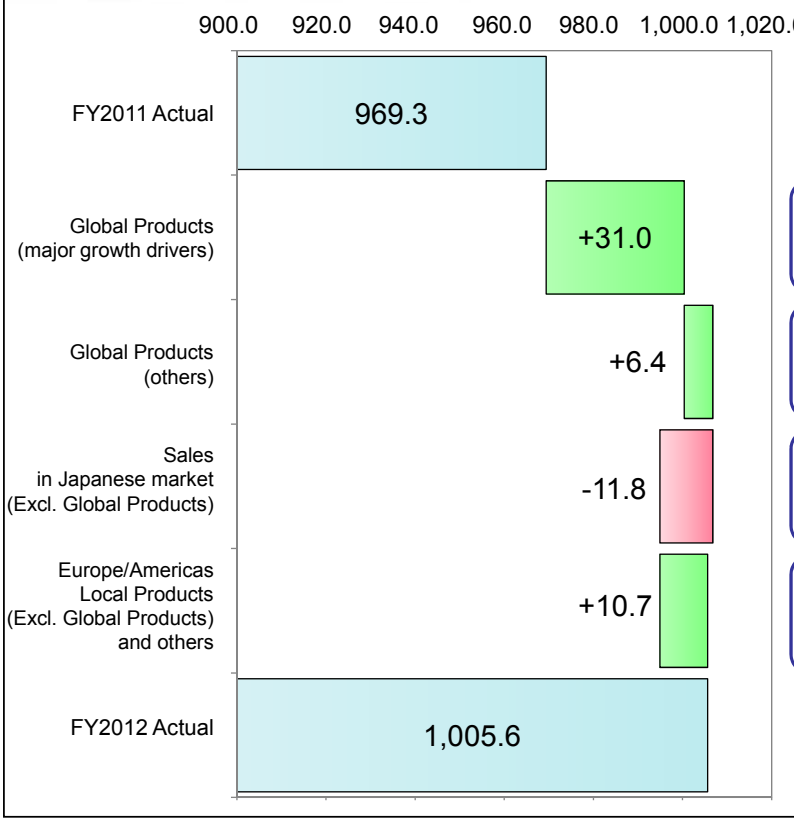
*Revised forecasts disclosed at 2Q/FY2012 financial announcement in November 2012

◆ Exchange Rates (YEN)

[Average for terms]	FY2011	FY2012	Change	FY2012 Forecasts
USD	79	83	4 weakening of YEN	80
EUR	109	107	2 strengthening of YEN	100

[Change from beginning to end of terms]	FY2011	FY2012
USD	1 strengthening of YEN	12 weakening of YEN
EUR	8 strengthening of YEN	11 weakening of YEN

Results of FY2012: Analysis of Change in Sales (vs. Previous Year)



Breakdown of sales increase by 36.2 billion YEN

1) Global Products (major growth drivers): +31.0
Vesicare +12.7/Mirabegron +6.0/XTANDI +12.2

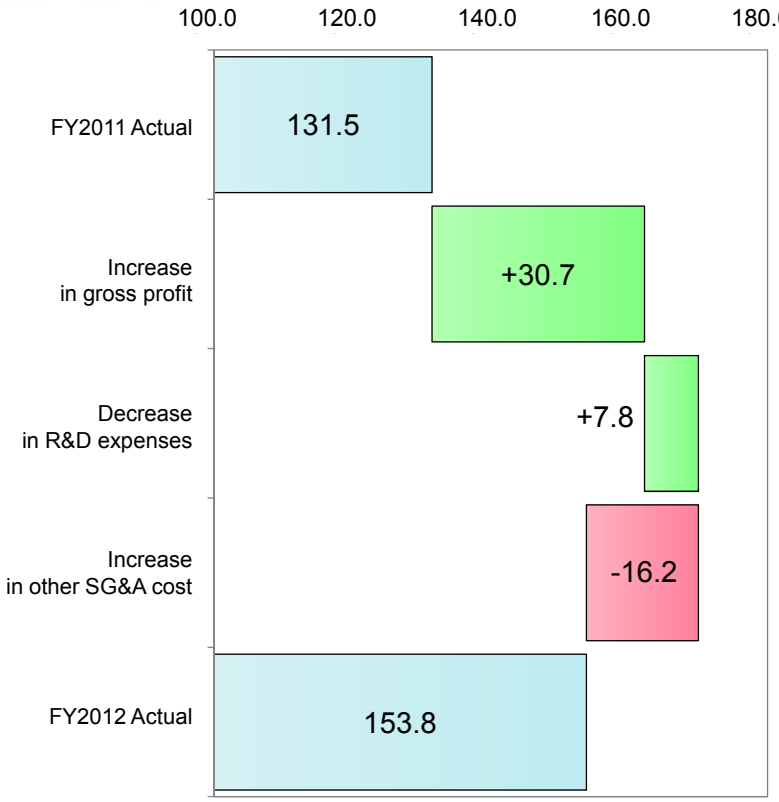
2) Global Products (others): +6.4
Prograf +6.8/Harnal -6.8/Funguard +4.4/
Protopic +0.9/Eligard +1.0

3) Sales in Japanese market (Excl. Global Products): -11.8
New Products and Growing Products +25.3/
Micardis +4.2/Lipitor -25.7/Gaster -7.3/
Transferred products -10.7

4) Europe/Americas Local Products (Excl. Global Products) and others: +10.7
Bendamustin and other European products Approx. +7.0/
Scan +4.0/Tarceva +2.8

-Impact of NHI drug price reduction in Japan: -26.7 billion YEN
-Forex impact: +9.0 billion YEN

Results of FY2012: Analysis of Change in Operating Income (vs. Previous Year)



Impact on operating income

Increase in sales: +36.2
Increase in COGs: -5.4
} Increase in gross profit: +30.7

Decrease in COGs ratio -0.6ppt (32.9%→32.2%)
-Change in product mix etc. -1.4ppt
-Forex impact on elimination of unrealized gain +0.8ppt

Decrease in R&D expenses: +7.8
-Decrease from change in depreciation method Approx. 5.5

Increase in other SG&A cost: -16.2
- Cost for oncology business in the US
- Cost for strengthening sales force in emerging markets
- Cost for product launches

-Forex impact: -7.5 billion YEN

4

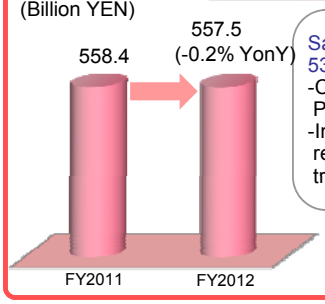
Sales by Region (Local Currency Basis)

*Calculated based on the location of the seller

Increases in Americas, Europe and Asia, remaining at almost the same level in Japan

Japan

(Billion YEN)



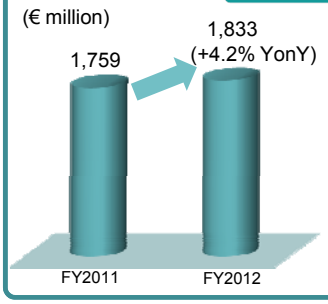
Sales in Japanese market: 535.7 bn YEN (-0.8%)
-Contribution of major Growing Products and New Products
-Impact of NHI drug price reduction and generic products/ transferred products



Europe

*Incl. Middle and Near East and Africa

(€ million)

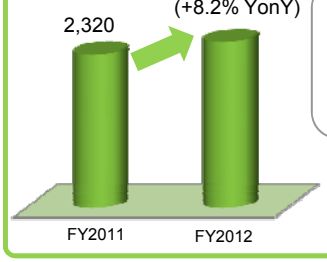


-Growth of Vesicare, Mycamine and Eligard
-Increase in bendamustin and other European product group
€547M (+15%)



Americas

($ million)



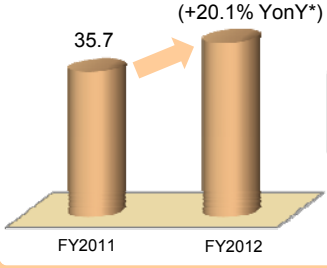
-Contribution of new products, XTANDI and Myrbetriq
-Growth of Vesicare, Scan and Tarceva



Asia

*Incl. Oceania

(Billion YEN)



*+13.7%
Excl. forex impact

-Growth in all major products

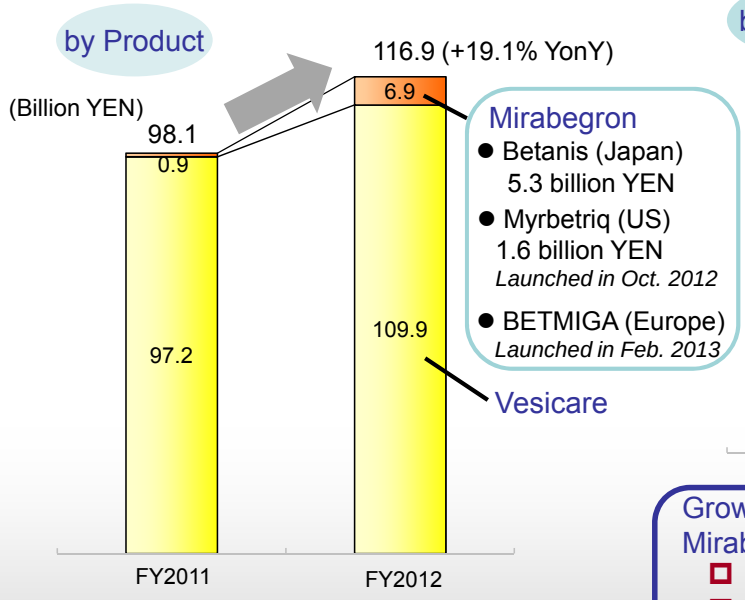


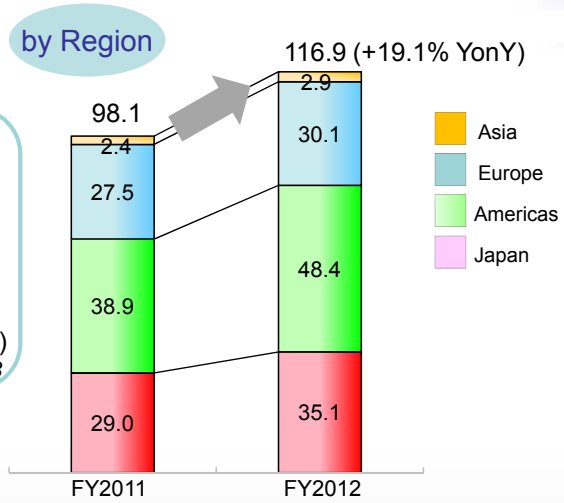
5

Overactive Bladder Franchise in Urology

Sales expansion driven by Vesicare growth and mirabegron contribution

Total sales of Vesicare and Mirabegron





Growth rate in total sales of Vesicare and Mirabegron [YonY]

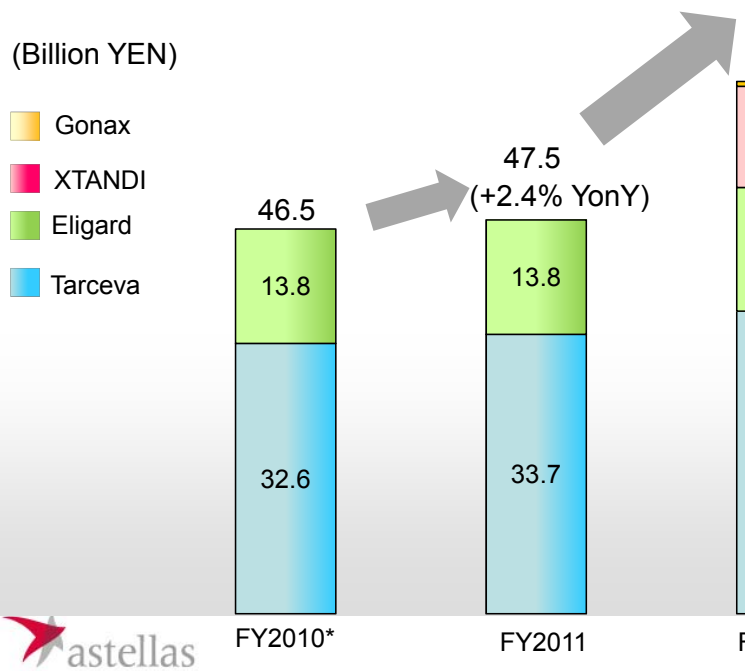
- Japan: +21%
- Americas: +18% (USD basis)
- Europe: +11% (EUR basis)
- Asia: +15% (Excl. forex impact)

6

Oncology Franchise

Expansion of oncology franchise driven by contribution of XTANDI

Total sales of XTANDI, Tarceva, Eligard and Gonax



- XTANDI
  US 146 million USD
  Launched in Sep. 2012
- Eligard
  Europe 139 million EUR
  +10% YonY (EUR basis)
- Tarceva-related revenues
  439 million USD
  +3% YonY (USD basis)

astellas
Leading Light for Life

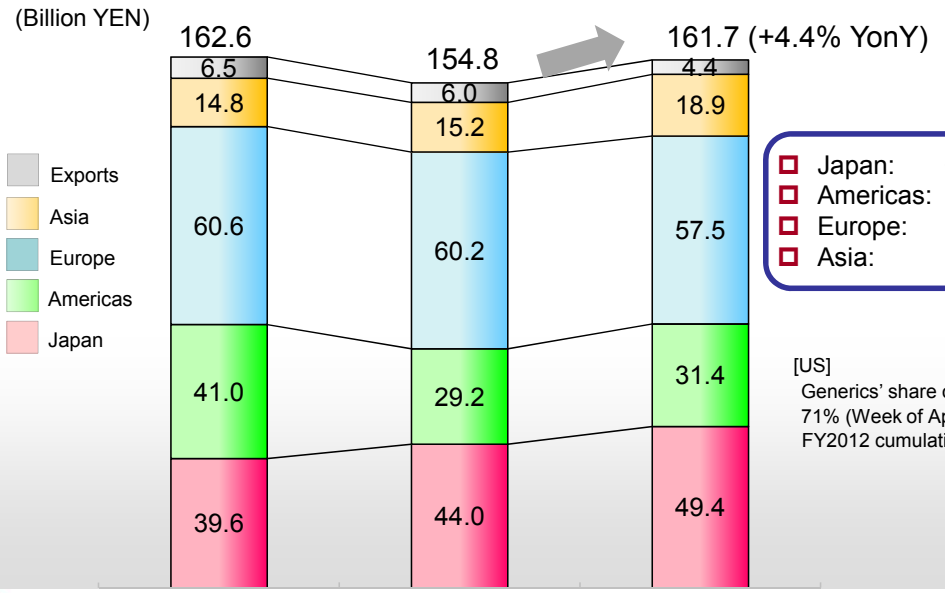
*Sales for April-June quarter calculate from OSI public information

7

Transplantation Franchise

Maintaining global sales by growth in Japan and Asia

Total sales of Prograf and Advagraf/Graceptor



- Japan: +12% [YonY]
- Americas: +2% (USD basis)
- Europe: -3% (EUR basis)
- Asia: +17% (Excl. forex impact)

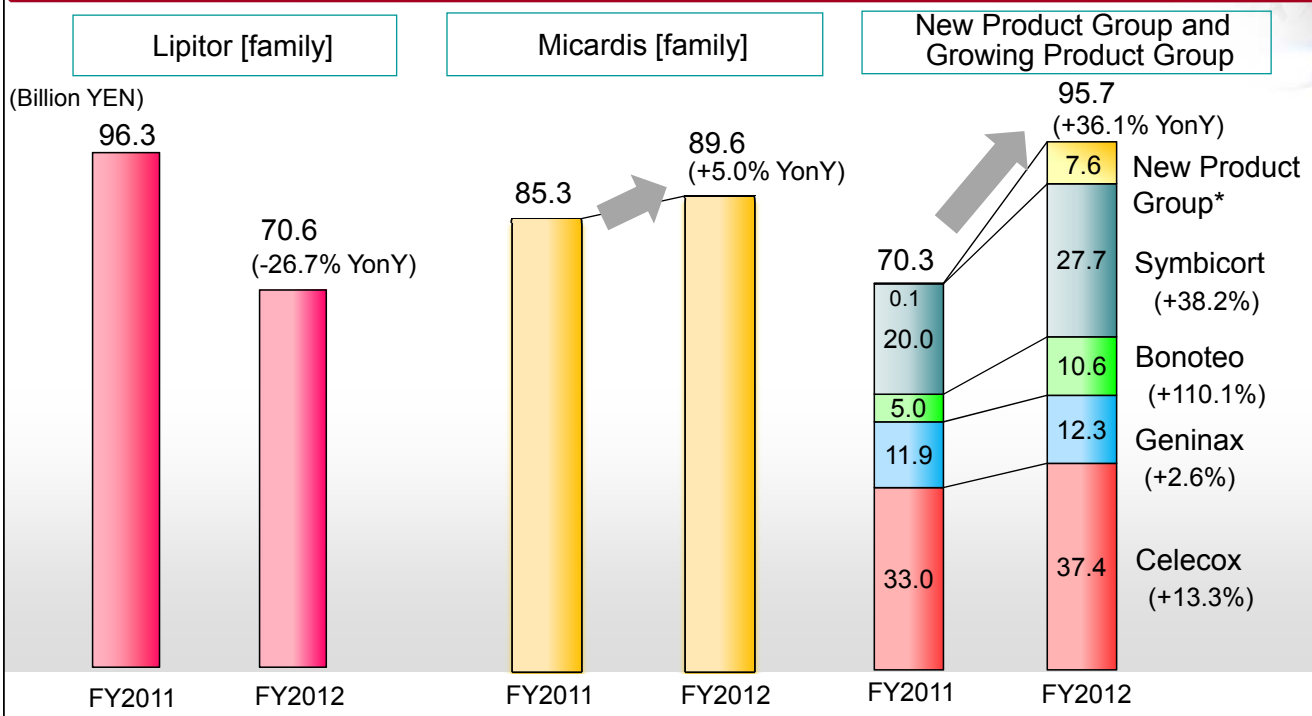
[US]
Generics' share of TRx:
71% (Week of Apr. 26, 2013)
FY2012 cumulative: 67%

astellas
Leading Light for Life

8

Major Products in Japan (Excluding Global Products)

Expansion of sales in growing products and New Product Group, covering Lipitor decrease

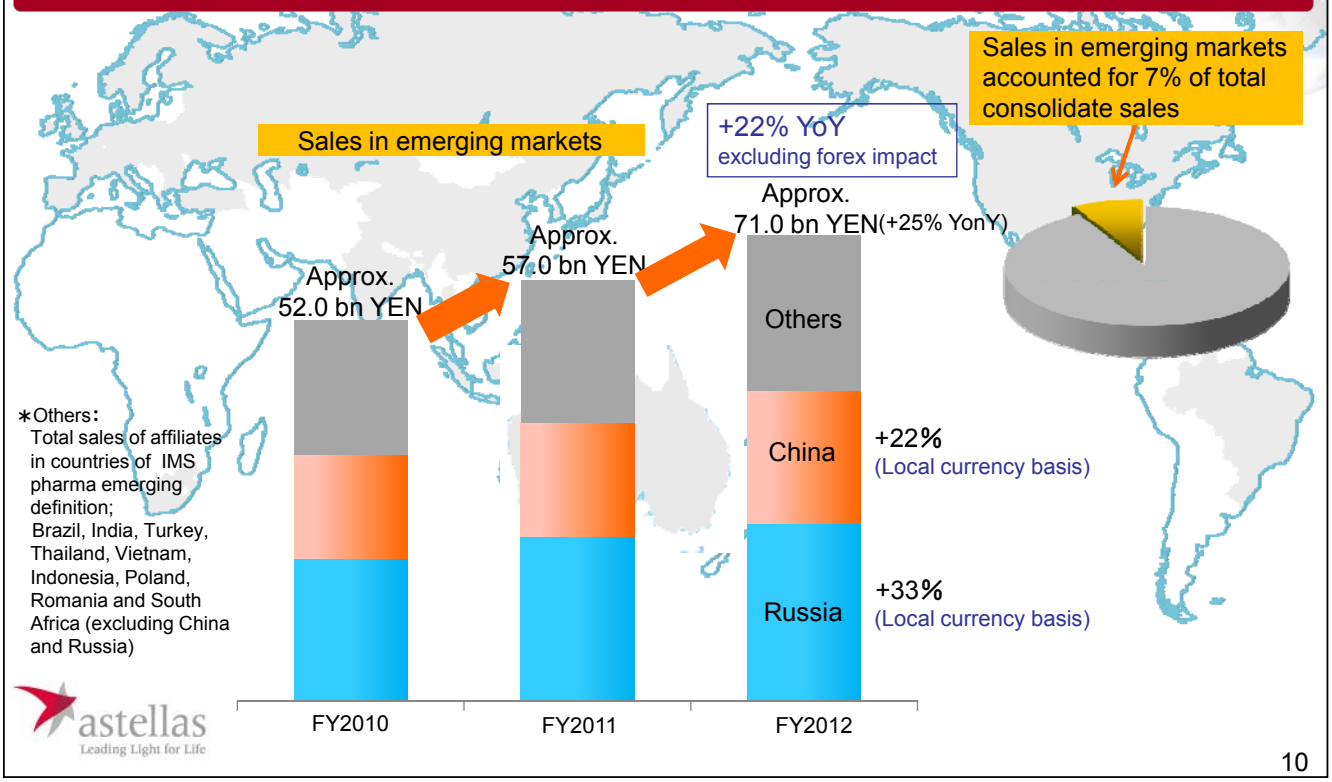


*New Product Group: Total sales of Argamate, Kiklin, Regnite, Gonax and Cimzia

9

Growing Business in Emerging Markets

Achieved high growth rate in emerging markets, led by China and Russia



∗Others:
Total sales of affiliates in countries of IMS pharma emerging definition;
Brazil, India, Turkey, Thailand, Vietnam, Indonesia, Poland, Romania and South Africa (excluding China and Russia)

astellas
Leading Light for Life

10

Launches in Europe: BETMIGA, Japan: Cimzia

BETMIGA
(Launch: Feb. 2013 in Europe)
-Beta-3 adrenoceptor agonist

[Indication]
Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder



Cimzia
(Launch: Mar. 2013 in Japan)
- TNF-alpha inhbitor

[Indication]
Treatment of rheumatoid arthritis not responding to conventional therapy (including inhibition of progression of bone structural damage)



astellas
Leading Light for Life

11

FY2012 Continuous Introduction of New Products

Continuous approval and launch of new products in each area

Achieved over 20 approvals/launches globally

Europe
- ➢May 2012
  DIFICLIR launch
  (Clostridium difficile infections)
- ➢Feb. 2013
  BETMIGA launch
  (Overactive bladder (OAB))

Americas
- ➢Sep. 2012 US
  XTANDI launch
  (mCRPC, post-chemotherapy)
- ➢Oct. US
  Myrbetriq launch (OAB)
- ➢Apr. 2013 Canada
  Myrbetriq launch (OAB)

Asia and Oceania
- ➢May 2012 Taiwan
  Feburic launch (gout)
- ➢Aug. Hong Kong
  Feburic launch (gout)
- ➢Aug. Singapore
  Advagraf launch
- ➢Oct. Hong Kong
  Eligard approval
- ➢Jan. 2013 Malaysia
  Advagraf launch
- ➢Jan. Philippines
  Harnal OCAS (new indication)
  (ureteral lithiasis)
- ➢Feb. Indonesia
  Advagraf approval
- ➢May Australia
  Mycamine approval

Japan
- ➢Jun. 2012
  Symbicort new dosage administration
  (Adult bronchial asthma, as-needed use in addition to maintenance therapy)
- ➢Jun. Kiklin launch
  (Hyperphosphatemia)
- ➢Jul. Regnite launch
  (Restless legs syndrome)
- ➢Aug. Symbicort new indication
  (Chronic obstructive pulmonary disease)
- ➢Oct. Gonax launch
  (Prostate cancer)
- ➢Oct. Launch of Quattrovac Subcutaneous Injection Syringe, Combined vaccine
- ➢Dec. Micamlo BP approval
  (Hypertension)
- ➢Jan. 2013
  ARGAMATE Granule launch
  (Hyperkalemia)
- ➢Feb. Sawacillin new indication
  (H. pylori eradication in H. pylori gastritis)
- ➢Mar. Cimzia launch
  (RA not responding to conventional therapy)
- ➢Mar. Acofide approval
  (Functional dyspepsia)

RA: Rheumatoid arthritis, mCRPC: metastatic castration-resistant prostate cancer

12

Forecasts for FY2013

(Billion YEN)

	FY2012	FY2013 Forecasts	Change
Net sales	1,005.6	1,170.0	+16.3%
R&D Expenses as % of sales	181.9 18.1%	212.0 18.1%	+16.5%
Operating Income	153.8	170.0	+10.5%
Ordinary Income	157.1	170.0	+8.2%
Net Income	82.8	110.0	+32.8%

Depreciation and amortization
Billion YEN
-FY2012: 47.4
-FY2013: 58.0

Amortization of goodwill
Billion YEN
-FY2012: 10.3
-FY2013: 5.8

Special loss associated with reshaping research framework: 11.0 billion YEN

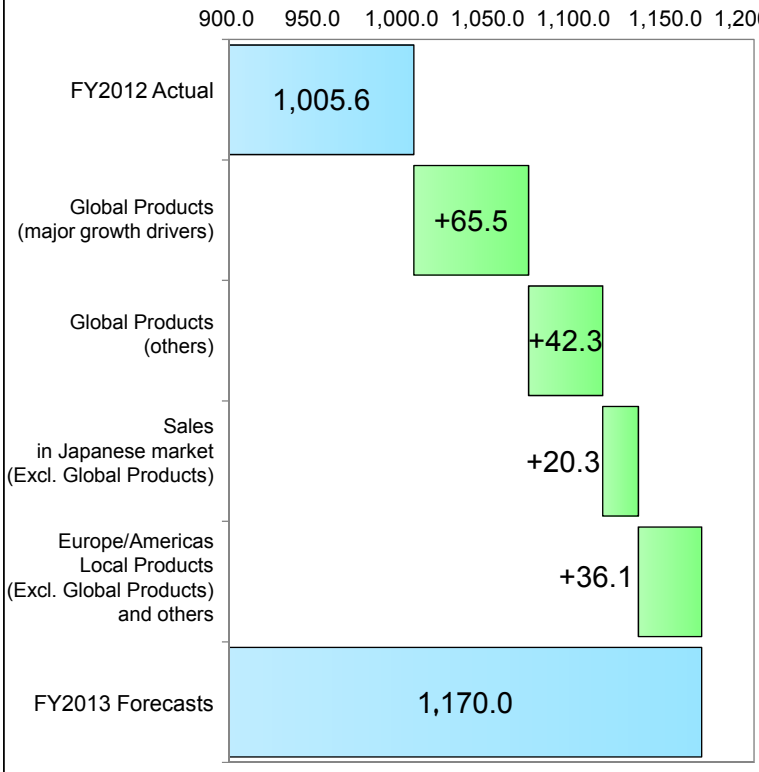
◆Exchange Rates (YEN)

[Average for terms]	FY2012	FY2013	Change
USD	83	100	17 weakening of YEN
EUR	107	130	23 weakening of YEN

astellas
Leading Light for Life

13

Forecasts for FY2013: Analysis of Change in Sales (vs. Previous Year)



Breakdown of sales increase by 164.3 billion YEN

1) Global Products (major growth drivers): +65.5
Vesicare +21.8/Mirabegron +15.9/XTANDI +27.7

2) Global Products (others): +42.3
Prograf +20.6/Harnal +4.6/Funguard +6.5/
Protopic +5.3/Eligard +5.1

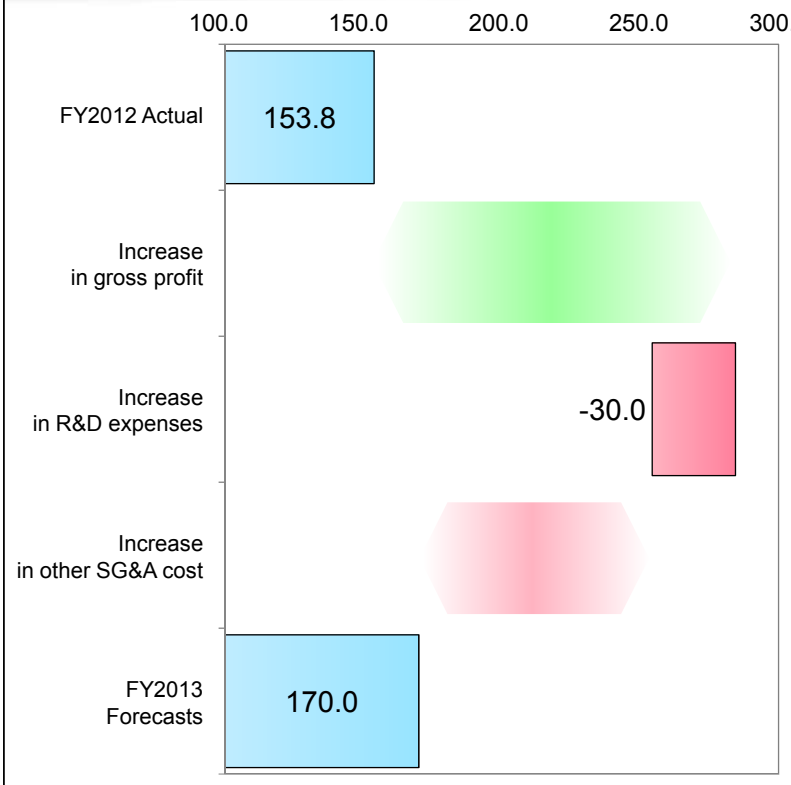
3) Sales in Japanese market (Excl.Global Products): +20.3
New Products and Growing Products +37.2/Micardis +11.0
Seroquel -5.6/Lipitor -5.4/Gaster -2.9/ Myslee -2.3

4) Europe/Americas Local Products (Excl. Global Products) and others: +36.1
Bendamustin and other European product group Approx. +28.0/
Scan -2.2

-Forex impact: +101.1 billion YEN

14

Forecasts for FY2013: Analysis of Change in Operating Income (vs. Previous Year)



Impact on operating income

Increase in sales: +164.3
Increase in COGs
Decrease in COGs ratio
} Increase in gross profit

[OP decreasing factor]
Increase in R&D expenses: -30.0

[OP decreasing factor]
Increase in other SG&A cost
- Cost for oncology business in the US
- Cost to strengthen sales force in emerging markets
- Cost for product launches

-Forex impact: +17.6 billion YEN

15

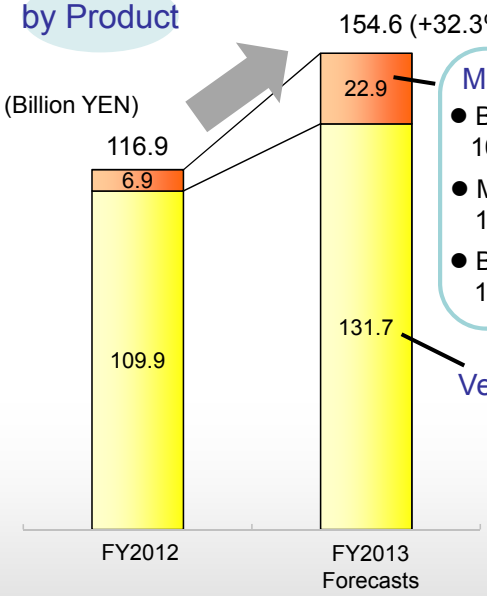
Overactive Bladder (OAB) Franchise in Urology

Forecasts for FY2013

Maximizing sales in OAB with both Vesicare and Mirabegron

Total sales of Vesicare and Mirabegron

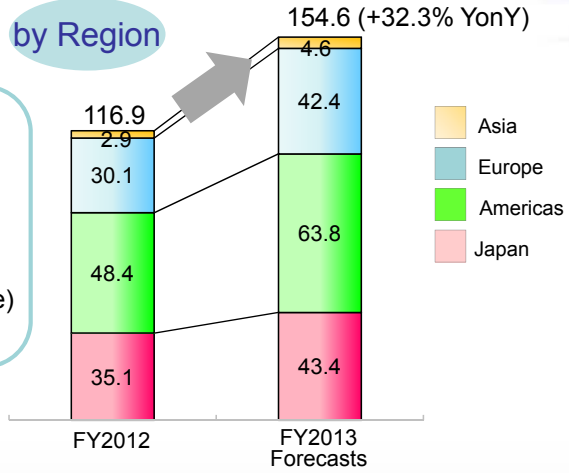
by Product



Mirabegron
- Betanis (Japan) 10.9 billion YEN
- Myrbetriq (US) 10.2 billion YEN
- BETMIGA (Europe) 1.6 billion YEN

Vesicare

by Region



Growth rate in total sales of Vesicare and Mirabegron [YonY]
- Japan: +24%
- Americas: +10% (USD basis)
- Europe: +16% (EUR basis)
- Asia: +27% (Excl. forex impact)

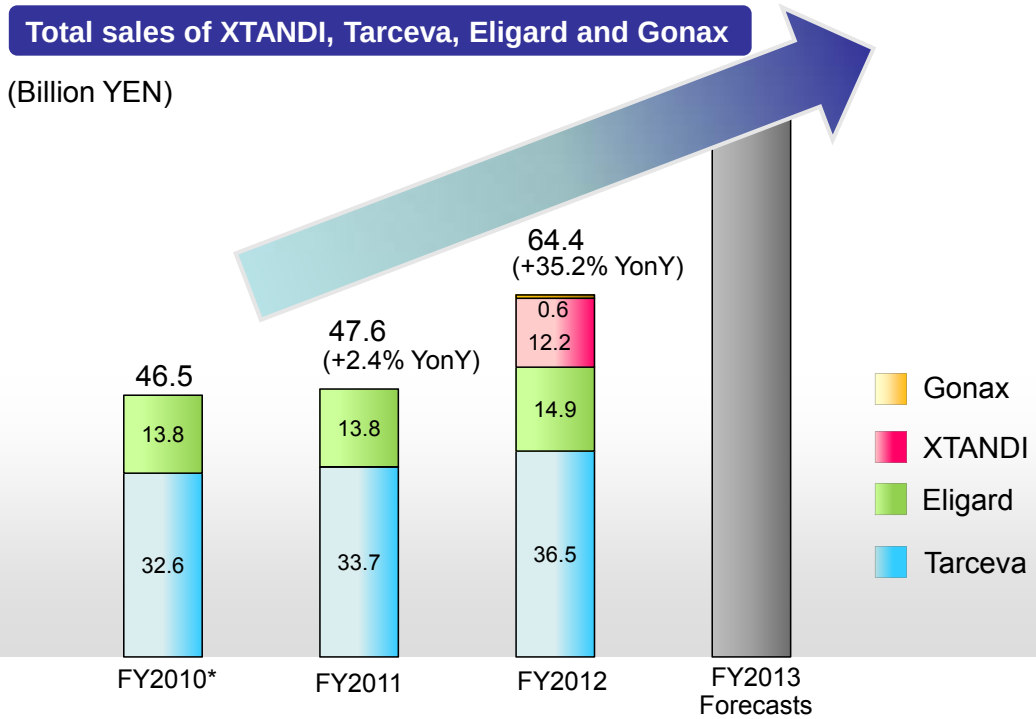
16

Oncology Franchise

Forecasts for FY2013

Continuous expansion by growth of XTANDI and Tarceva

Total sales of XTANDI, Tarceva, Eligard and Gonax



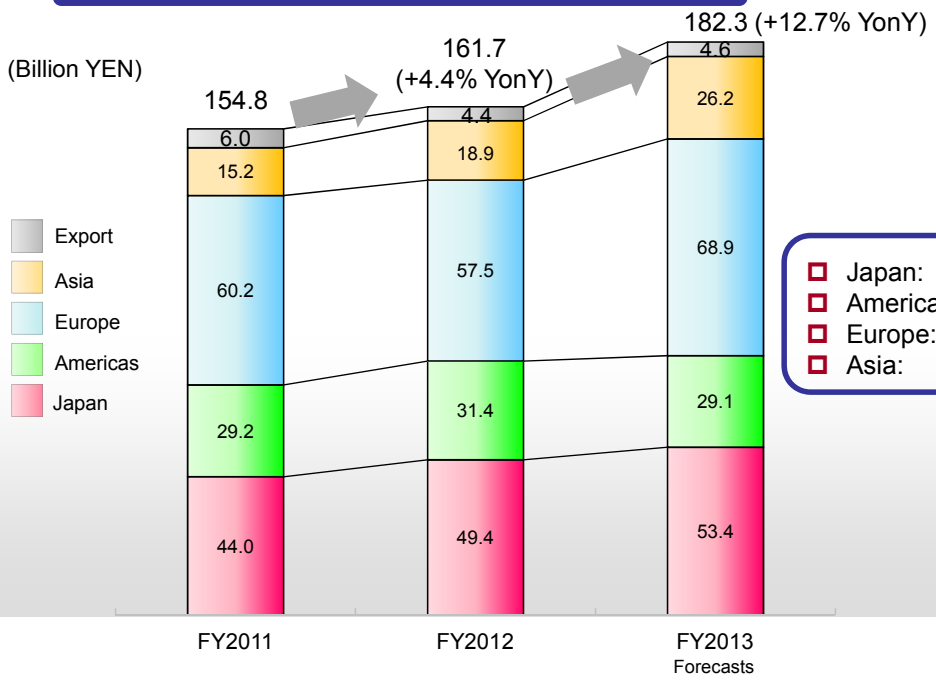
*Sales for April to June quarter calculated from OSI public information

17

Transplantation Franchise
Forecasts for FY2013

Continuous expansion in Japan and Asia

Total sales of Prograf and Advagraf/Graceptor

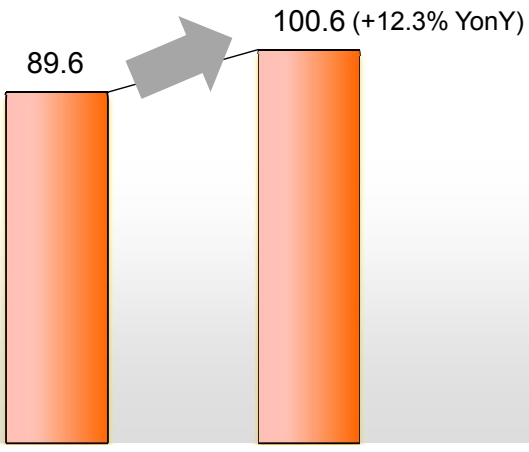


- Japan: +8% [YonY]
- Americas: -23% (USD basis)
- Europe: -1% (EUR basis)
- Asia: +14% (Excl. forex impact)

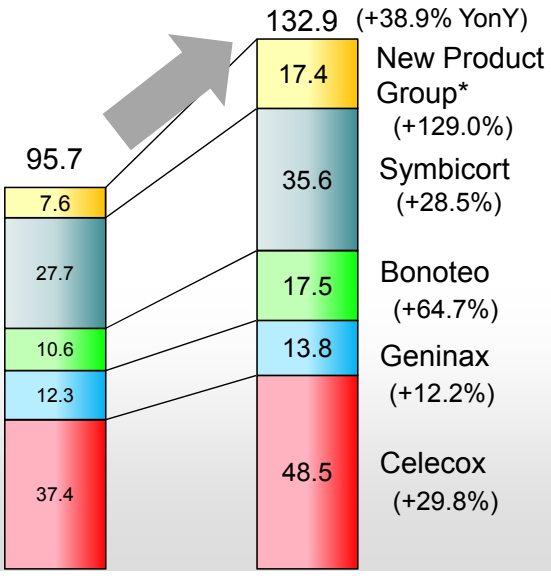
Major Products in Japan (Excluding Global Products)
Forecasts for FY2013

Growth of Major Products and New Product Group

Micardis [Family]



New Product Group and Growing Product Group



*New Product Group: Total sales of Argamate, Kiklin, Regnite, Gonax and Cimzia

R&D Pipeline

astellas
Leading Light for Life

Status of Astellas' Pipeline

:In-house, new molecular entity :In-house, additional indication or additional formulation :Licensed-in Red: Changes from the previous announcement

	Filed	P3	P2	P1
Urology	solifenacin/tamsulosin (EU)	solifenacin (Pediatric, EU/US)	solifenacin/mirabegron (EU) ASP3652 (CP/CPPS etc., EU)	ASP0306 ASP4901 (AKP-002) ASP3652 (JP), ASP6432
Immunology (including Transplantation) and Infectious Diseases	tacrolimus extended release capsules (US) micafungin (pediatric, US)	certolizumab pegol (MTX-naive RA, JP) isavuconazole (Aspergillosis, candidemia, EU/US) ASP0113 (CMV reactivation in HCT, EU/US) ASP7374 (Influenza, JP)	ASKP1240 (Transplant, US) ASP015K (RA, JP) ASP7373 (Influenza, JP) ASP0113 (SOT, EU/US, HCT, JP)	ASKP1240 (JP) ASP2408 ASP2409 fidaxomicin (JP)
Oncology	enzalutamide (PC, Post-Chemo, EU) tivozanib (RCC, US) erlotinib (1st line for NSCLC with EGFR mutation, US)	enzalutamide (PC, Pre-Chemo etc., EU/US/JP/Asia) erlotinib (NSCLC etc., US) tivozanib (RCC, EU) degarelix (3M, JP)	enzalutamide (PC, Post-Chemo, JP) linsitinib (OC, NSCLC, US) sepantronium (NHL, EU/US) tivozanib (BC, CRC, EU/US)	sepantronium (JP) AGS-16M8F/AGS-16C3F ASG-5ME, ASG-22ME ASP1707(PC, EU) ASP3026 enzalutamide (BC) ASP9853
Neuroscience	midazolam (Dentistry, JP)	quetiapine (BPD, JP) capsaicin (PDN, EU)	quetiapine (MDD, JP)	ASP0777, ASP8477 ASP9226, ASP3662
DM Complications and Kidney Diseases, Others	ipragliflozin (Diabetes, JP) ramosetron (IBS OD tablet, JP)	ASP1517 (Anemia associated with CKD, EU) beraprost (Chronic renal failure, JP/Asia) bixalomer (Hyperphosphatemia in patients not on dialysis, JP) ramosetron (IBS Female, JP) nateglinide (Diabetes, JP)	ASP1517 (Anemia associated with CKD, JP) YM311 (Renal anemia, EU) linaclotide (IBS, JP) ASP1707 (Endometriosis, EU/JP)	ASP7991 YM311 (JP) ASP8232

CP/CPPS: Chronic prostatitis/Chronic pelvic pain syndrome, MTX: Methotrexate, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant, SOT: Solid organ transplant, RA: Rheumatoid arthritis, PC: Prostate cancer, OC: Ovarian cancer, NSCLC: Non-small cell lung cancer, RCC: Renal cell carcinoma, BC: Breast cancer, NHL: Non-Hodgkin's lymphoma, CRC: Colorectal cancer, OD: Orally disintegrating, BPD: Bipolar disorders, MDD: Major depressive disorder, IBS: Irritable bowel syndrome, PDN: Peripheral diabetic neuropathy, CKD: Chronic kidney disease

21

Changes in Pipeline Status Since February 2013 <Approved>

Product Name (Generic Name)	Target Disease	Area	Stage	Changes
Sawacillin (amoxicillin)	Helicobacter pylori eradication in patients with Helicobacter pylori gastritis by triple therapy with proton pump inhibitors and either clarithromycin or metronidazole	Japan	Approved	Approved in Japan in February 2013. (New indication) *Application based on the published evidence.
Acofide (acotiamide)	Postprandial fullness, upper abdominal bloating, and early satiation associated with functional dyspepsia	Japan	Approved	Approved in Japan in March 2013.

astellas
Leading Light for Life

22

Changes in Pipeline Status Since February 2013 <Filed >

Code No. Generic Name	Target Disease	Area	Stage	Changes
midazolam	Conscious sedation in dentistry and dental surgery	Japan	Filed	NDA filed in Japan in February 2013. (New indication) *Application based on the published evidence.
ASP1941 ipragliflozin	Type 2 diabetes	Japan	Filed	NDA filed in Japan in March 2013.
MDV3100 enzalutamide	Metastatic castration-resistant prostate cancer in patients who have received docetaxel-based chemotherapy	Europe	Filed	CHMP adopted a positive opinion for XTANDI in April 2013.
FK506 tacrolimus	Prophylaxis of organ rejection in adult patients receiving kidney transplants ~~and in adult male patients receiving liver transplants~~ [Extended release capsules]	US	Filed	Application for adult male patients receiving liver transplants was withdrawn.

NDA: New drug application, CHMP: The Committee for Medicinal Products for Human Use

23

Changes in Pipeline Status Since February 2013 <Stage Up/New>

■ Stage up

Code No. Generic name	Target Disease	Area	Stage	Changes
ASP3550 degarelix	Prostate cancer (Three-month formulation)	Japan	P3	Entered into P3 in Japan. (New formulation)
ASP0113 (VCL-CB01)	Cytomegalovirus reactivation in hematopoietic cell transplant recipients	US/Europe	P3	Entered into P2 in Japan for the indication of cytomegalovirus reactivation in hematopoietic cell transplant recipients.
		Japan	P2	
	Cytomegalovirus infection or reactivation in solid organ transplant recipients	US/Europe	P2	

■ New P1

Code No.	Target Disease	Stage	Changes
ASP3662	Alzheimer's disease	P1	Entered into P1.

astellas
Leading Light for Life

24

Changes in Pipeline Status Since February 2013 <Discontinued etc.>

■ Discontinued

Code No.	Target Disease	Area	Stage	Reason for Discontinuation
OSI-027	Renal cell cancer	US	P2	We have decided to discontinue the development based on the clinical data.
ASP9603	Prostate cancer	-	P1	We have decided to discontinue the development for strategic reasons.

■ Deleted from the pipeline list

Code No. Generic name	Target Disease	Area	Stage	Remarks
AC220 quizartinib	Acute myeloid leukemia	US/ Europe	P2	-Quizartinib was deleted from the pipeline list because we exercised our right to terminate the worldwide license agreement with Ambit for strategic reasons. The effective date of termination is September 3, 2013, at which time all right to quizartinib will revert to Ambit.
		Japan	P1	
ASP7035	Nocturia	-	P1	-ASP7035 was deleted from the pipeline list because we decided not to develop it by ourselves. Tacurion, operated by Drais, has been granted an exclusive license of ASP7035 as a part of activities of "Multi-Track R&D". -Tacurion will conduct further development. -Completed P1. Preparing for P2a. -Astellas has the option right to acquire Tacurion upon the success of P2a.

25

Oncology Pipeline

	Project	Target cancer	Characteristics	P1	P2	P3	Filed
Small molecule	Enzalutamide (XTANDI)	Prostate cancer (PC), Breast cancer (BC)	Androgen receptor inhibitor	PC: Post-chemo, EU/Japan/Asia (EU: Filed)			
				PC: Pre-chemo EU/US/Japan/Asia			
				BC:US			
	Tivozanib ASP4130	Renal cell carcinoma (RCC), Colorectal cancer (CRC), Breast cancer (BC),	Potent, selective, long half-life inhibitor of VEGF receptors 1, 2 and 3	RCC: EU/US (US: Filed)			
				CRC, BC: EU/US			
	Degarelix (Gonax)	Prostate cancer	1st GnRH antagonist in Japan	3M: JP			
	Sepantronium YM155	Non-Hodgkin's lymphoma	First-in-class survivin suppressant	EU/US/JP			
	ASP1707	Prostate cancer*	Oral GnRH antagonist				
	ASP3026	Cancer	ALK tyrosine kinase inhibitor				
	ASP9853	Cancer					
OSI	Erlotinib (Tarceva)	NSCLC (1st line for patients with EGFR mutation, adjuvant, combination with MetMab), CRC, Pediatric ependymoma	HER1/EGFR tyrosine kinase inhibitor	1st line for NSCLC with EGFR mutations: US			
				Others: US			
	Linsitinib ASP7487 (OSI-906)	Ovarian cancer, NSCLC	IGF-1R/IR tyrosine kinase inhibitor	US			
Antibody	AGS-16M8F/ AGS-16C3F	Renal cancer	Antibody utilizing ADC (target: ENPP3)				
	ASG-5ME	Prostate cancer, Pancreatic cancer	Antibody utilizing ADC (target: SLC44A4)				
	ASG-22ME	Solid tumors	Antibody utilizing ADC (target: Nectin-4)				

*P2 for indication of endometriosis NSCLC: Non-small cell lung cancer

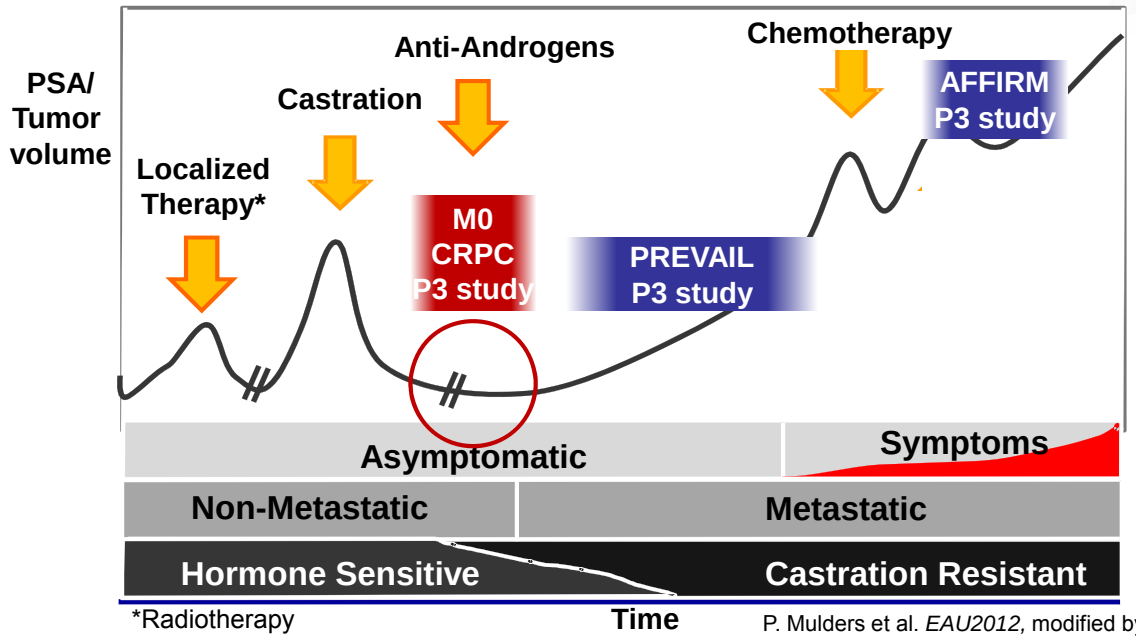
26

Enzalutamide: Development Progress

Study	Target	Design	P1	P2	P3	Filed
P3 EU/US [AFFIRM study]	Post-chemo Metastatic castration-resistant prostate cancer (CRPC)	Placebo-controlled, n=1,199	Study completed. -US Launch: Sep. 13, 2012 -EU MAA filed: June 26, 2012 CHMP positive opinion in April			
P1/2 JP	Post-chemo Metastatic CRPC	Open-label, n=46	Completed			
P3 EU/US/JP/Asia [PREVAIL study]	Pre-chemo Metastatic CRPC	Placebo-controlled, n=1,717	Completed enrollment: May 2012 Planned interim analysis: 2013			
P2 EU/US [TERRAIN study]	Pre-chemo Metastatic CRPC	To compare with bicalutamide, n=370	Ongoing			
P2 US [STRIVE study]	Pre-chemo Metastatic or non-metastatic CRPC	To compare with bicalutamide, n=400	Ongoing			
P2 US	Neoadjuvant therapy Undergoing prostatectomy	Monotherapy or combo with leuprolide or dutasteride, n=50	Completed enrollment: March 2013			
P2 EU	Hormone-naive Progressive prostate cancer	Open-label, n=67	Completed			
P1 US	Breast Cancer Hormonal therapy failure	Open-label, n=27	First Patient In: April 2012			

27

Enzalutamide: Set Out for Development in Earlier Prostate Cancer Patients



P. Mulders et al. *EAU2012,* modified by Astellas

Decided to conduct a P3 study in earlier stage prostate cancer patients: Non-metastatic CRPC (M0 CRPC)

➢Design of P3 to be determined. Planning to start in 2013.

Tivozanib: Development Progress

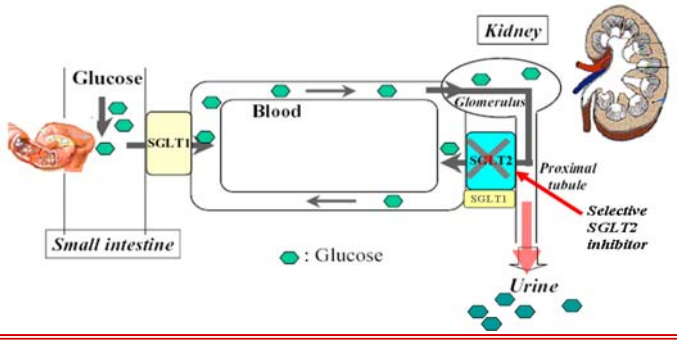
Study	Target	Design	P1	P2	P3	Filed
P3 EU/US [TIVO-1 study] Pivotal	Renal cell carcinoma (RCC) Monotherapy (Advanced RCC)	Comparing the efficacy and safety of tivozanib with sorafenib, n=517	Completed -US NDA filed: Sep. 28, 2012 ODAC meeting: May 2, 2013 PDUFA date: Jul. 28, 2013 -EU Preparing for MAA filing			
P2 EU/US [TAURUS study]	RCC Monotherapy (Metastatic RCC)	Comparing patient preference of tivozanib vs. sunitinib in a 2-way crossover design, n=160	First patient in: Sep. 2012			
P2 US [BATON-RCC study]	RCC Monotherapy (Advanced RCC)	Exploratory biomarker study, n=105	Recruitment completed			
P2 EU/US	Colorectal cancer Combo with mFOLFOX6 (versus mFOLFOX6 +bevacizumab)	Comparing the efficacy and safety of tivozanib with bevacizumab, n=252	Recruitment completed			
P2 EU/US	Breast cancer Combo with paclitaxel (Triple negative breast cancer)	Comparing the efficacy and safety of tivozanib with placebo, n=147	First patient in: Dec. 2012			

FDA Oncology Drug Advisory Committee (ODAC) voted on May 2, 2013 that the application for tivozanib did not demonstrate a favorable benefit-to-risk evaluation for the treatment of advanced RCC in an adequate and well-controlled trial (13 to 1, 0 abstentions).

Ipragliflozin: Development Progress

Filed in Japan in March 2013

- Applied indication: Type 2 diabetes
- Clinical Trial Data
  - -In the monotherapy P3 study, ipragliflozin demonstrated significant decrease of HbA1c and it was safe and well tolerated.
  - -In the P3 studies for a long term period used in combination with other hypoglycemic agents, effectiveness and favorable safety of ipragliflozin were confirmed.
- Mechanism of Action: Selective SGLT2 inhibitor

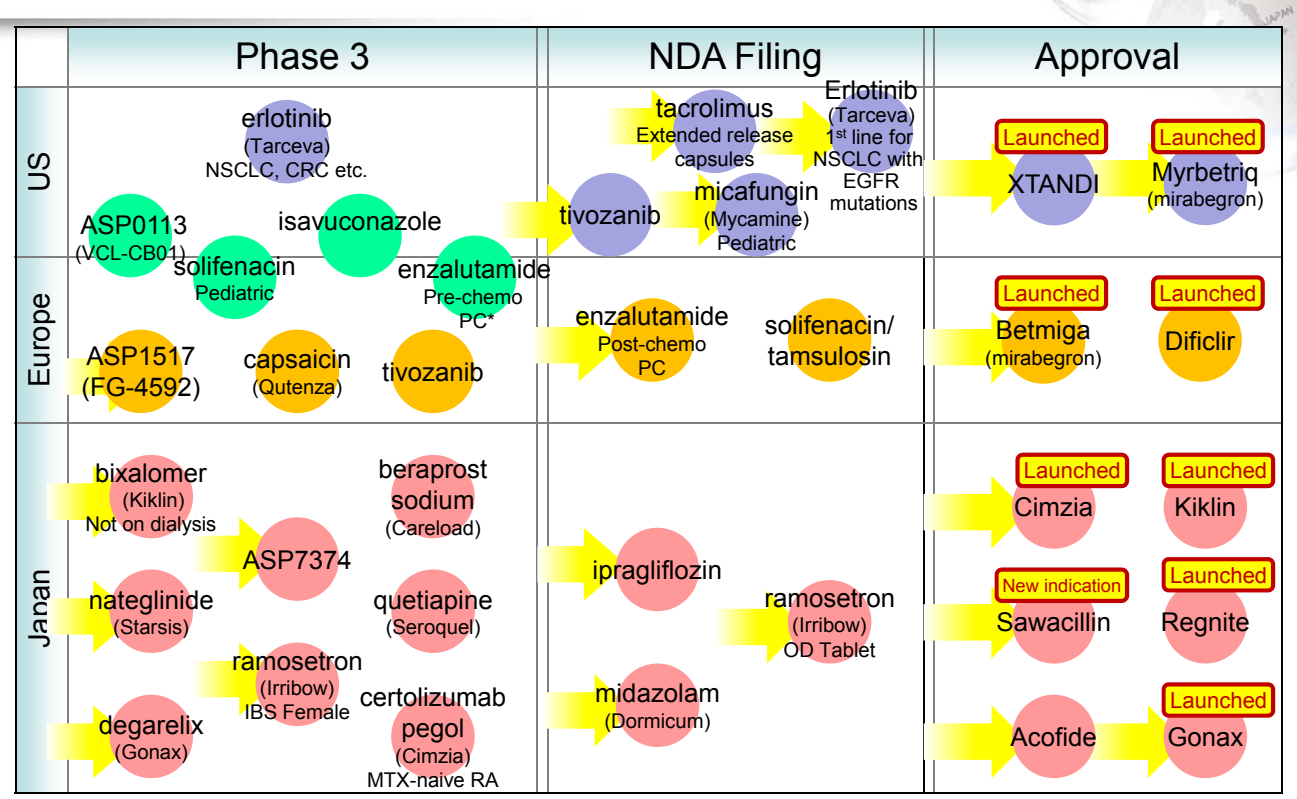


Inhibits SGLT2 selectively in the proximal tubule of the kidney
→Inhibits the reuptake of glucose
→Reduces blood glucose

Ipragliflozin is an oral hypoglycemic agent with a novel mechanism of action, which can be used as a monotherapy and in combination with a wide range of existing diabetes therapies

SGLT: Sodiumglucose co-transporter

FY2012 Progress of Many Late Phase Compounds

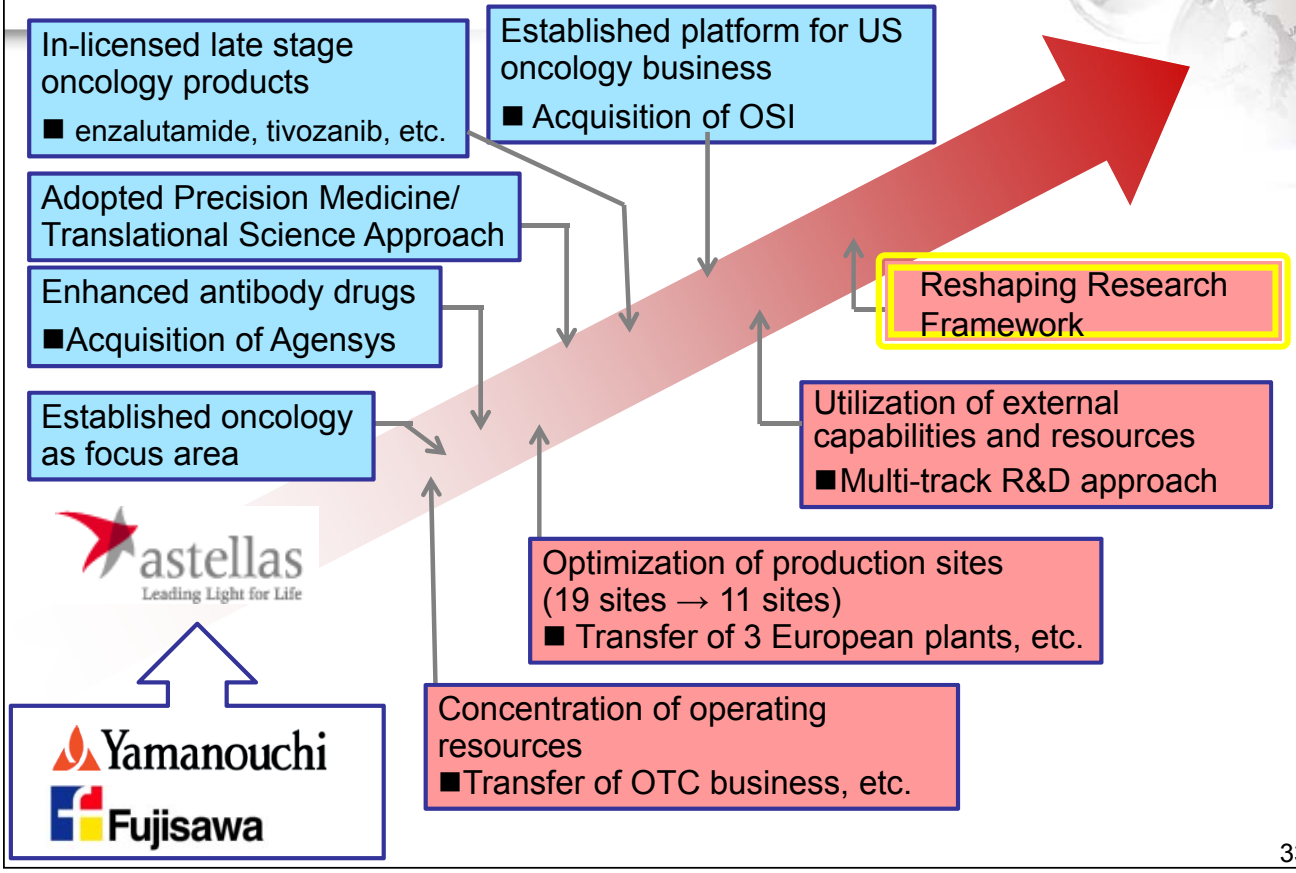


PC: Prostate cancer, NSCLC: Non-small cell lung cancer, CRC: Colorectal cancer, OD: Orally disintegrating, MTX: Methotrexate, RA: Rheumatoid arthritis *EU/US/JP

Initiatives to Build Resilience for Sustainable Growth

astellas
Leading Light for Life

Building Resilience for Sustainable Growth



33

Enhance the Ability to Generate Innovative Drugs: Current Initiatives

Enhance the ability to generate innovative drugs

Initiatives to create Innovation

- Precision Medicine Approach/Translational Science Utilization
- Open Innovation/Multi-Track R&D
- Developing New Technologies: Regenerative medicines, vaccines, etc.

Optimization of Resource Allocation

➢Thorough prioritization of PJ; utilization of external capabilities and resources; and periodic review of priority research areas.

Operational Excellence

34

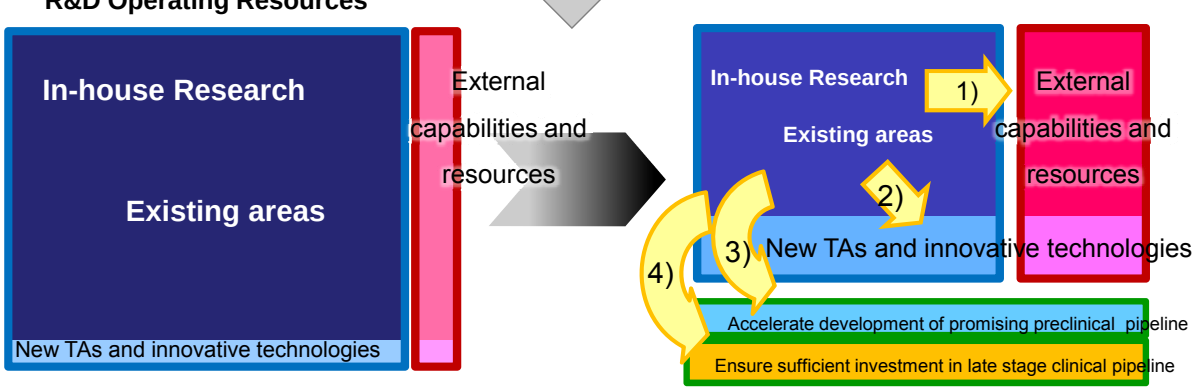
Reshaping Research Framework for a Changing Environment

- Switch to an Framework That Can "Resiliently" Respond to the Changing Environment -

1) Utilize more external capabilities and resources
2) Undertake initiatives related to new TAs and innovative technologies
3) Accelerate development of promising preclinical pipeline
4) Ensure sufficient investment in late-stage clinical pipeline

Review R&D resource allocation in order to build a agile research framework

*TA: therapeutic area



35

Reshaping Research Framework : Specific Initiatives (1)

Establish Astellas Innovation Management (AIM)

- AIM will explore external opportunities to realize innovation during the preclinical development stage
- Activities that are currently undertaken by multiple departments will be integrated into AIM

⇨ Draw more widely and systematically on innovation opportunities arising in areas ranging from bio-venture companies to academia

Enhance Research Management

- The research units for each therapeutic area will be assigned broader authority and responsibility, to promote the autonomy and agility of each unit. In addition, a closer alliance with AIM, internal and external knowledge, and other such activities will be incorporated proactively.

⇨ Carry out research to further employ cutting-edge science, including new therapeutic areas and innovative technologies

Introduce Multiple-Path Project Management

- "Fast Track": Through the focused investment of capabilities and resources on highly prioritized research projects, research and development time will be minimized
- "Ex. (External/Expedite/Exploratory) Track": Internal and external capabilities and resources will be used flexibly for unique and challenging projects.

⇨ 'Multi-Track R&D" will be expanded to preclinical-stage process

Reshaping Research Framework : Specific Initiatives(2)

Strategic Reallocation of Resources

Optimize Research Functions

- Close OSI (US)
- Close Perseid (US)
- Scale back ARIA* (US)

*Astellas Research Institute of America LLC

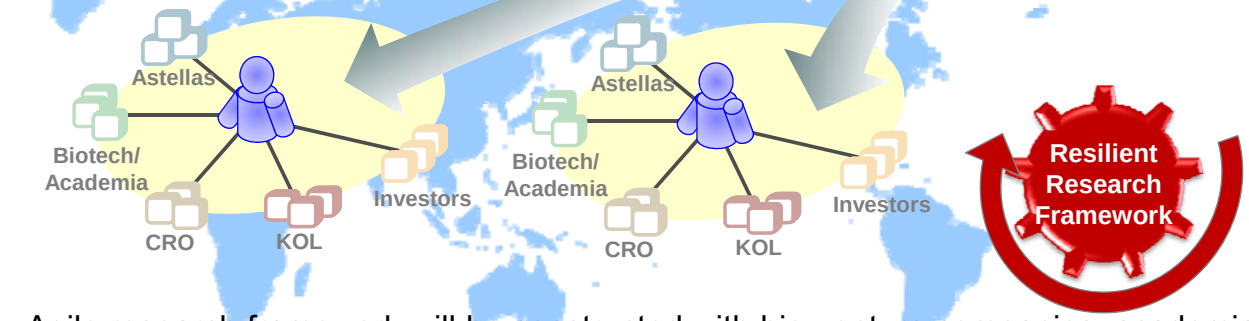
- Cease in-house fermentation drug discovery research
- Close Kashima facility (some functions will be integrated and transferred to Tsukuba etc.)

astellas
Leading Light for Life

Reshaping Research Framework : Future Astellas Research

Open Innovation Drug Discovery
- Agile research framework that uses external capabilities and resources -

AIM



Agile research framework will be constructed with bio-venture companies, academia, CROs and KOLs, etc. and open innovation drug discovery will be enhanced.

Best Science | Best Talent | Best Place

Undertake initiatives related to new therapeutic areas and innovative technologies

CRO: Clinical research organization, KOL; Key opinion leader

Meeting the Challenge of New Technology: Regenerative Medicine, Our Approach To Date

Having worked on research for regenerative drugs and applications to drug discovery of iPS cells, while incorporating external innovations proactively

Research activities at Astellas

- Regenerative drugs research (search for drugs acting on cells)
- Research with applications to drug discovery (safety studies utilizing iPS cells)

Collaboration with external parties

- Partnering with research institutions (e.g. participation in the project to accelerate iPS cell applications to medical care [based in the Special Districts for Structural Reform])
- Access to new technology by investment in venture businesses (strategic investments in Cytori Therapeutics and Fate Therapeutics)

astellas
Leading Light for Life

Meeting the Challenge of New Technology: Regenerative Medicine, Our Approach From Here

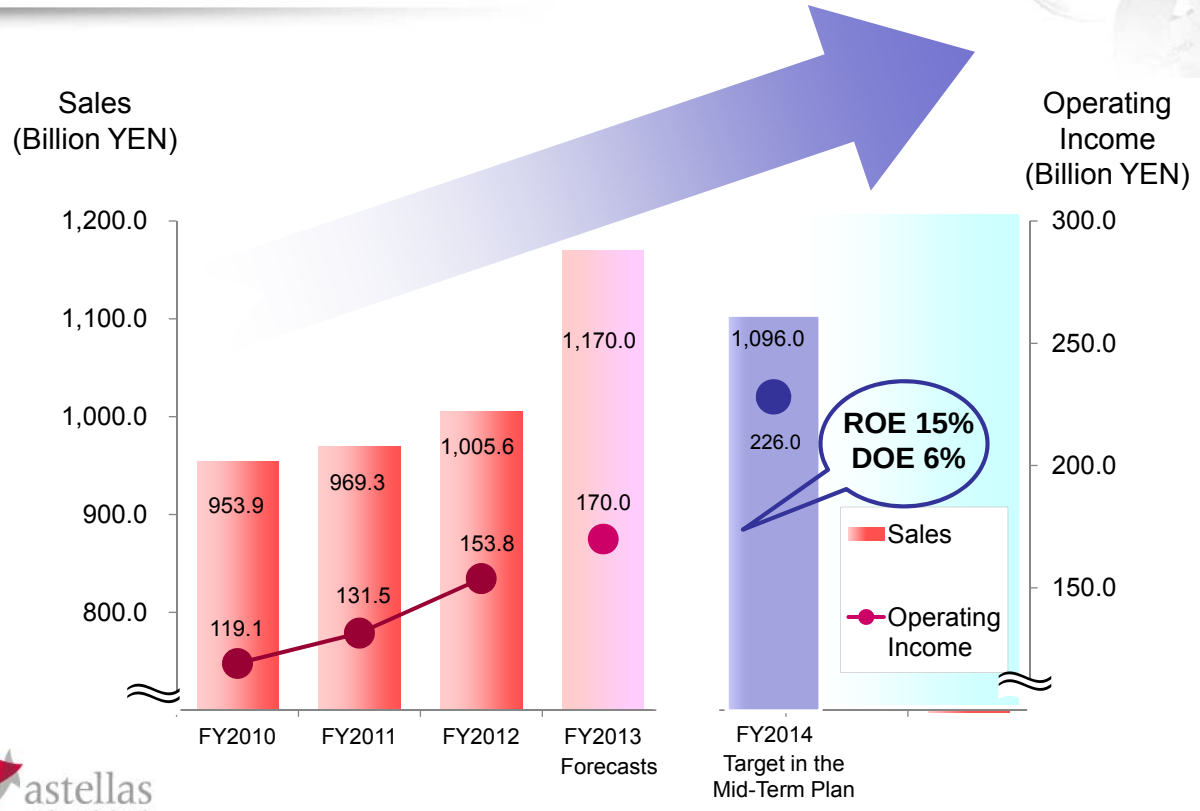
Expand our commitment to regenerative medicine and make full commitment to cell therapy over and above the regenerative drugs R&D conducted to date

- Cell therapy to enable recovery of body function by transfusion or transplantation of human cells.
  Aim to capture high therapeutic efficacy not possible with existing drug therapy by exploiting the multi-functional properties of cells
- Work on research with technology associated with somatic stem cells and iPS cells
- Target functions and diseases allowing us to aim for competitive edge
- Appropriately mix in-house research and partnering with external resources

astellas
Leading Light for Life

40

Resiliently Respond to the Changing Environment and Aim for Sustainable Growth



astellas
Leading Light for Life

41

Specific Initiatives for FY2013

Further promoting optimization of resource allocation and increasing operational excellence

Enhance ability to generate innovative drugs

- Reshaping research framework
- Steady progress of projects in late phase development

Maximize product sales

- Maximize values of enzalutamide and mirabegron
- Further expand New Products and Growing Products in each area, including emerging markets

Strengthen Management Structure

- Establish new position of Chief Medical Officer and strengthen the assessment of benefit-to-risk of medicines
- Further enhance global phamacovigilance

astellas
Leading Light for Life

Profit Distribution Policy

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

	FY2011	FY2012	FY2013 (Forecasts)
EPS	169.38 YEN	180.40 YEN	243.81 YEN
Dividends per Share	125 YEN	130 YEN (Plan)	135 YEN
ROE	7.7%	8.0%	-
DOE	5.7%	5.7% (Plan)	-
Share Buybacks	-	10.8 million shares (49.3 billion YEN)	Implemented in a flexible manner
Cancellation of Treasury Stock	-	-	11 million shares (plan)

astellas
Leading Light for Life



Changing tomorrow

astellas

Leading Light for Life

