Financial Results for FY2014

Ended March 31, 2015

May 11, 2015
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, promote unapproved uses in any fashion nor provide medical advice of any kind.

Financial Results for FY2014 (Core Basis)

FY2014: From Apr. 2014 through Mar. 2015

(Billion YEN)

	FY2013 Results	FY2014 Results	Change %	FY2014 Forecasts#	Achievement %
Sales	1,139.9	1,247.3	+9.4%	1,210.0	103.1%
COGs as % of sales	330.6 29.0%	333.2 26.7%	+0.8%		
SG&A expenses as % of sales	397.0 34.8%	452.5 36.3%	+14.0%		
R&D expenses as % of sales	191.5 16.8%	206.6 16.6%	+7.9%	200.0 16.5%	103.3%
Amortisation of intangible assets	36.0	38.7	+7.4%		
Share of profits of associates and joint ventures	1.5	0.2	-85.1%		
Core operating profit	186.3	216.5	+16.2%	210.0	103.1%
Core profit for the year	132.8	153.2	+15.4%	154.0	99.5%

#Announced with 2Q/FY2014 financial results in October 2014

- Exchange Rates (YEN)

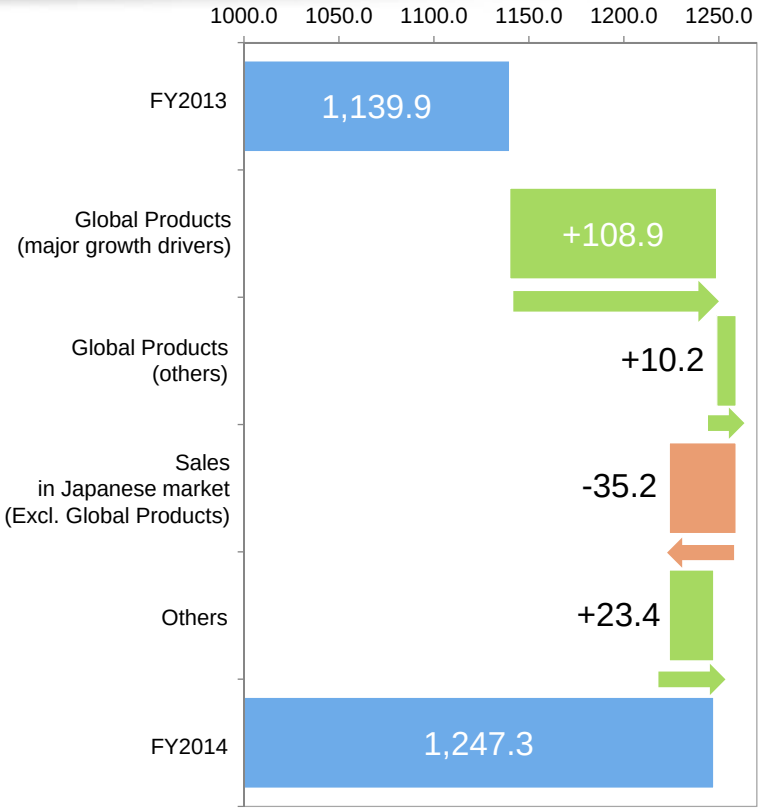
[Average for terms]	FY2013	FY2014	Change	FY2014 Forecasts
USD	100	110	10 weakening of YEN	104
EUR	134	139	4 weakening of YEN	137

[Change from beginning to end of terms]	FY2013	FY2014
USD	9 weakening of YEN	17 weakening of YEN
EUR	21 weakening of YEN	11 strengthening of YEN

Depreciation and amortisation
-FY2014: 65.5
-FY2013: 64.3

Forex impact
-Sales: +47.7
-Core operating profit: +18.0

Results of FY2014: Analysis of Change in Sales (vs. Previous Year)



Sales: +107.4

Forex impact: +47.7

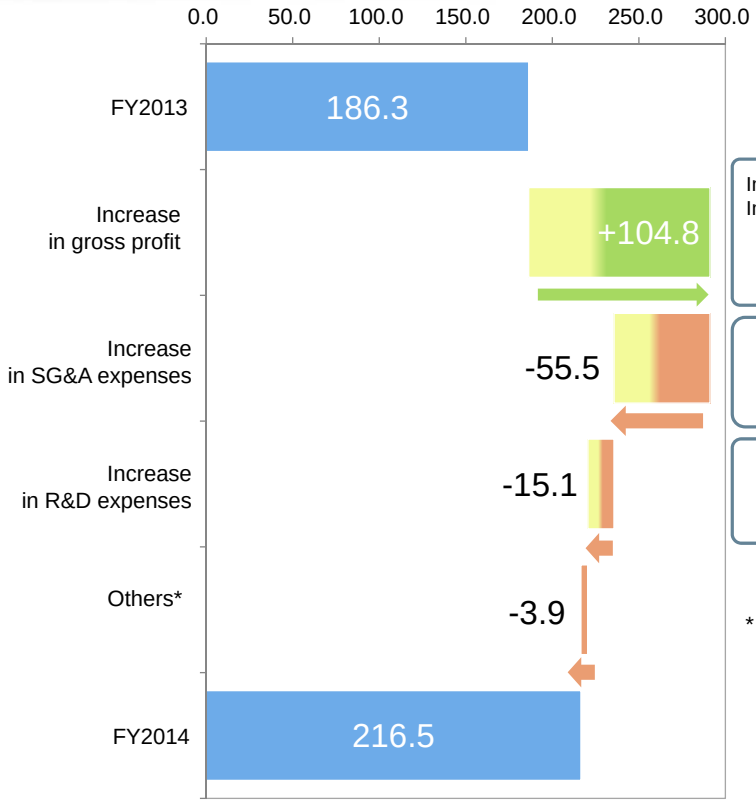
-Vesicare and Betanis/Myrbetriq/BETMIGA +26.4 / XTANDI +82.6

-Prograf +13.7 / Harnal -3.5 / Funguard/MYCAMINE +2.7 / Protopic -3.3 / Eligard +0.6

-New Products and Growing Products -0.2 / Micardis -1.8 / Lipitor -15.5 / Gaster -7.7 / Myslee -8.8 / Seroquel -7.1

-Scan +4.5 / Tarceva +4.1 / Other European products etc. +14.8

Results of FY2014: Analysis of Change in Core Operating Profit (vs. Previous Year)



(Billion YEN)

Core operating profit: +30.2

Forex impact: +18.0

Increase in sales: +107.4
Increase in COGs: -2.6
Decrease in COGs ratio: -2.3ppt (29.0%→26.7%)
-Change in product mix etc.: -1.9ppt
-Forex impact on elimination of unrealized gain: -0.4ppt

-Cost for co-promotion of XTANDI in US
-Forex impact etc.

-Cost for development project
-Forex impact etc.

* Amortisation of intangible assets and share of profits of associates and joint ventures

Financial Results for FY2014 (Full Basis)

(Billion YEN)

	FY2013 Results	FY2014 Results	Change %
Sales	1,139.9	1,247.3	+9.4%
COGs as % of sales	330.6 29.0%	333.2 26.7%	+0.8%
SG&A expenses as % of sales	397.0 34.8%	452.5 36.3%	+14.0%
R&D expenses as % of sales	191.5 16.8%	206.6 16.6%	+7.9%
Amortisation of intangible assets	36.0	38.7	+7.4%
Share of profits of associates and joint ventures	1.5	0.2	-85.1%
Other income	11.6	12.5	+8.0%
Other expense	81.0	43.3	-46.5%
Operating profit	116.8	185.7	+59.0%
Profit before tax	122.0	189.7	+55.5%
Profit for the year	90.9	135.9	+49.5%

Other income: 12.5
-Gain on sales of property, plant and equipment: 1.4

Other expense: 43.3
-Restructuring costs: 11.5
Premium severance benefit in early retirement incentive program: 9.9 (2Q/FY2014)
-Impairment losses: 10.3
-Litigation costs: 16.2

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Sales by Region (Local Currency Basis)

Calculated based on the location of the seller

Continuous sales increase in Americas, Europe and Asia/Oceania while decrease in Japan

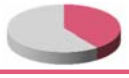
Japan

(Billion YEN)

530.6 → 498.7 (-6.0% YonY)



Sales in Japanese market:
481.7 bn YEN (-6.6% YonY)
-Sales decrease due to NHI drug price reduction, generic impact and temporary fluctuations in supply and demand conditions before and after the consumption tax hike

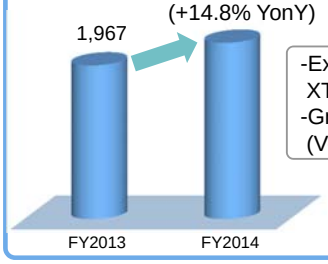


Europe

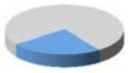
Incl. Middle East / Africa

(EUR million)

1,967 → 2,258 (+14.8% YonY)



-Expansion of new product XTANDI
-Growth of OAB treatments (Vesicare and BETMIGA)



Americas

(USD million)

2,863 → 3,284 (+14.7% YonY)



-Expansion of new product XTANDI
-Growth of OAB treatments (VESIcare and Myrbetriq)

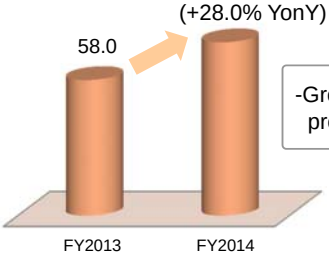


Asia/Oceania

(Billion YEN)

58.0 → 74.2 (+28.0% YonY)

+17.7% YonY (Excl. forex impact)



-Growth of all the mainstay products



Overactive Bladder Franchise in Urology

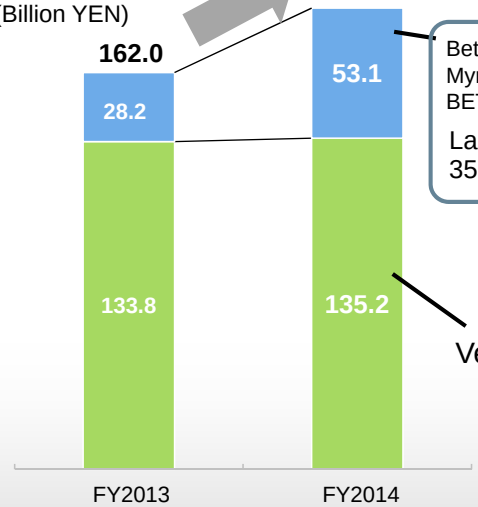
Continuous sales increase in OAB franchise (Vesicare and Betanis/Myrbetriq/BETMIGA)

Total sales of Vesicare and Betanis/Myrbetriq/BETMIGA

by Product

(Billion YEN)

162.0 → 188.4 (+16% YonY)

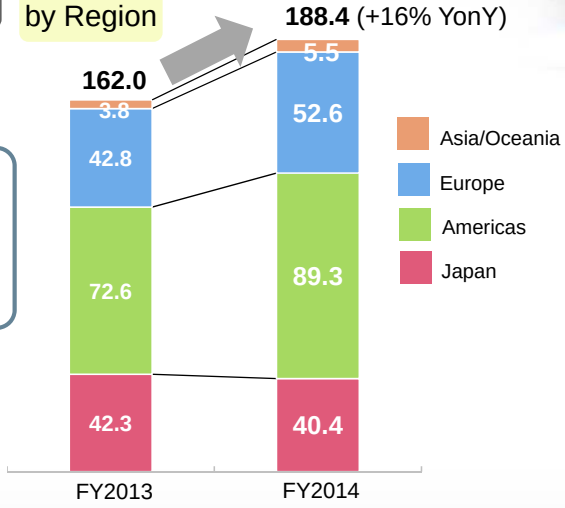


Betanis (Japan)
Myrbetriq (Americas)
BETMIGA (Europe etc.)
Launched in 35 countries/areas

Vesicare

by Region

162.0 → 188.4 (+16% YonY)



Growth rate in total sales of Vesicare and Betanis/Myrbetriq/BETMIGA [YonY]

-Japan: -5%
-Americas: +12% (USD basis)
-Europe: +19% (EUR basis)
-Asia/Oceania: +33% (Excl. forex impact)

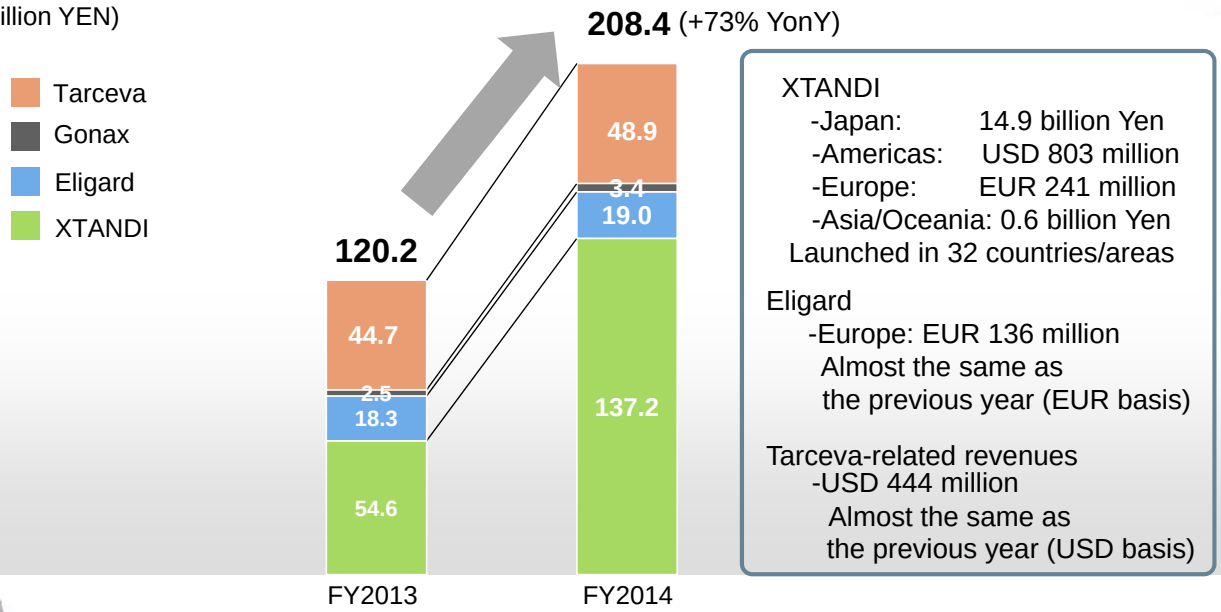
OAB: Overactive Bladder

Oncology Franchise

Expansion of oncology franchise driven by XTANDI

Total sales of XTANDI, Tarceva, Eligard and Gonax

(Billion YEN)



XTANDI
- -Japan: 14.9 billion Yen
- -Americas: USD 803 million
- -Europe: EUR 241 million
- -Asia/Oceania: 0.6 billion Yen

Launched in 32 countries/areas

Eligard
- -Europe: EUR 136 million
  Almost the same as the previous year (EUR basis)

Tarceva-related revenues
- -USD 444 million
  Almost the same as the previous year (USD basis)

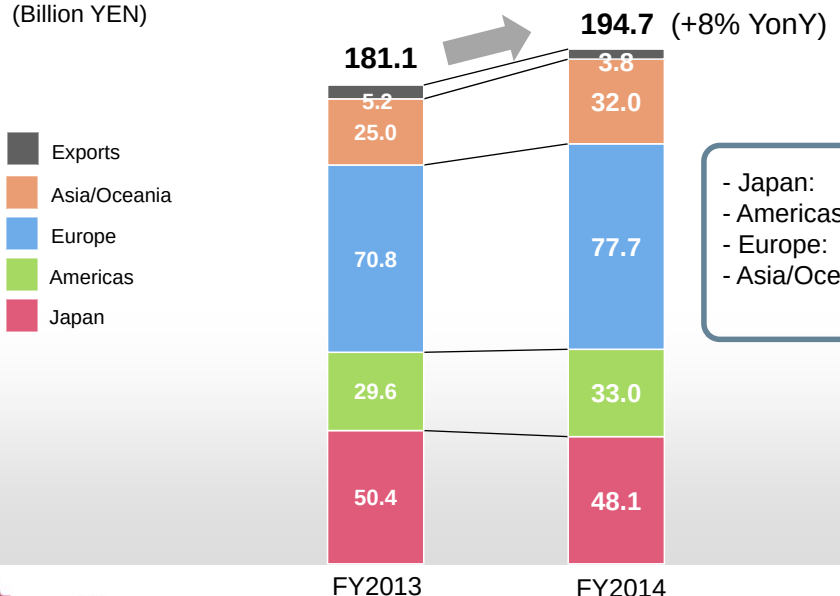
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Transplantation Franchise

Maintaining global sales

Total sales of Prograf and Advagraf/Graceptor/ASTAGRAF XL

(Billion YEN)



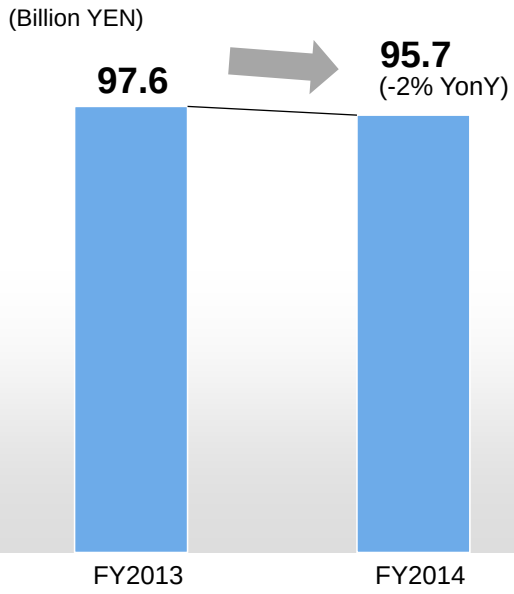
[YonY]
- Japan: -5%
- Americas: +2% (USD basis)
- Europe: +6% (EUR basis)
- Asia/Oceania: +18% (Excl. forex impact)

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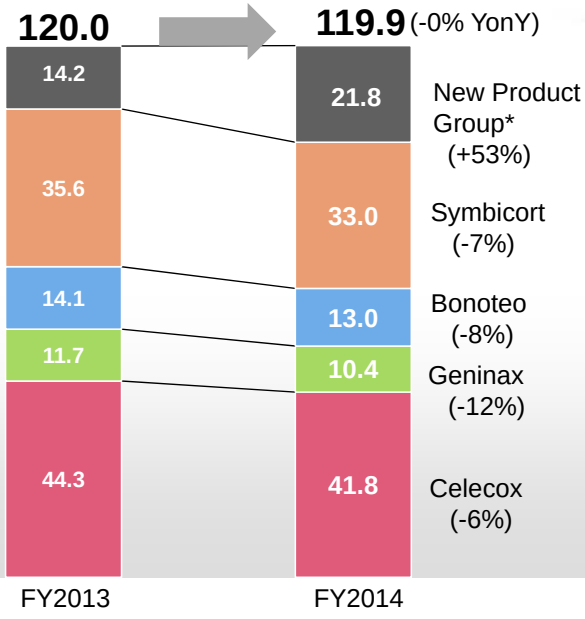
Major Products in Japan (Excluding Global Products)

Growth of New Product Group, offsetting the decrease by temporary fluctuations in supply and demand conditions before and after consumption tax hike

Micardis [family]



New Product Group and Growing Product Group



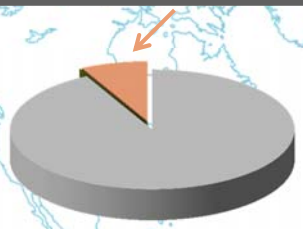
*New Product Group: Total sales of main products launched from April 2012 onward (ARGAMATE, Kiklin, Regnite, Gonax, Cimzia, Acofide and Suglat)

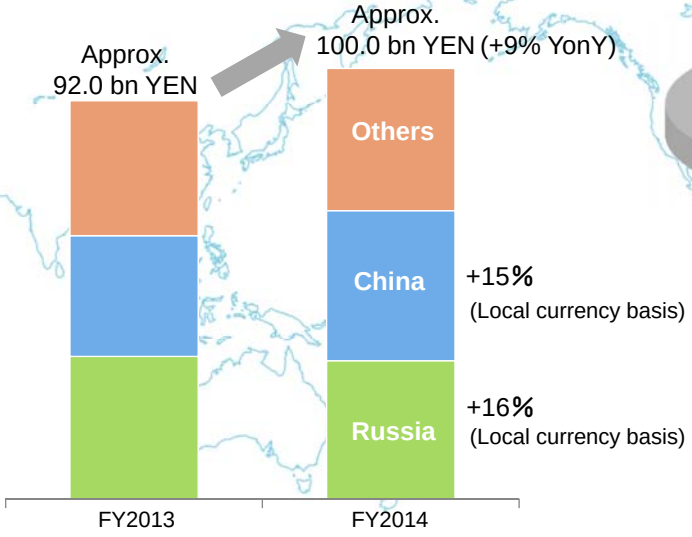
Growing Business in Emerging Markets

Continuous double-digit growth rate in China and Russia

Sales in emerging markets

Sales in emerging markets accounted for 8% of total consolidate sales





*Others:
Total sales of affiliates in countries of IMS pharma emerging definition; Brazil, India, Turkey, Thailand, Vietnam, Indonesia, Pakistan, Mexico, Argentina, Venezuela, Ukraine, Egypt, Poland, Romania and South Africa (excluding China and Russia)

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Forecasts for FY2015 (Core Basis)

FY2015: From Apr. 2015 through Mar. 2016

(Billion YEN)

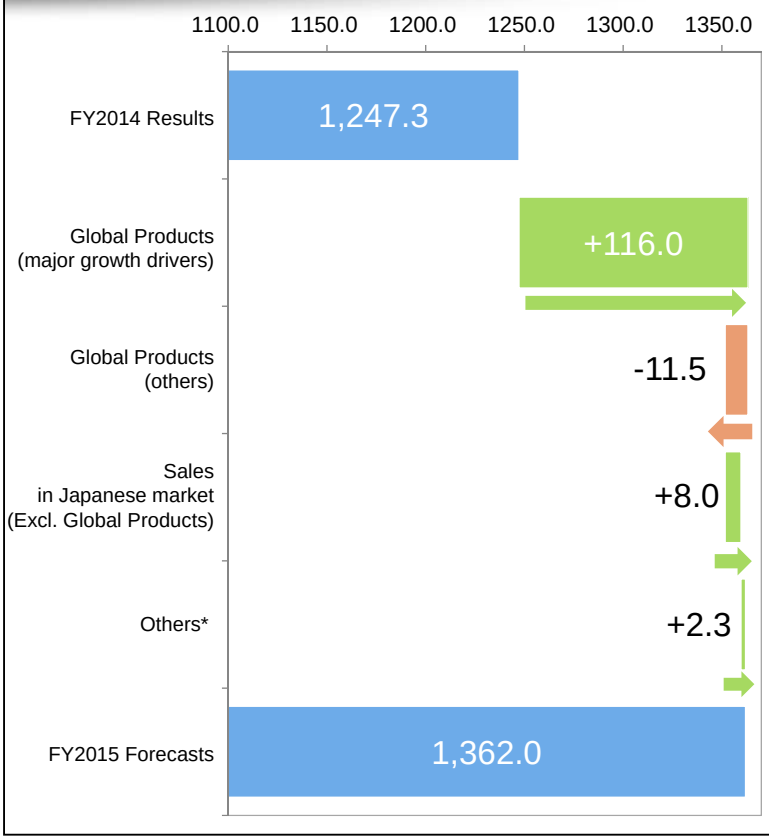
	FY2014	FY2015 Forecasts	Change
Net sales	1,247.3	1,362.0	+9.2%
R&D Expenses as % of sales	206.6 16.6%	229.0 16.8%	+10.8%
Core operating profit	216.5	238.0	+9.9%
Core profit for the year	153.2	170.0	+10.9%
Core earnings per share (YEN)	69.37	77.51	+11.7%

◆ Exchange Rate (YEN)

[Average for terms]	FY2014	FY2015 Forecasts	Change
USD	110	120	10 weakening of YEN
EUR	139	125	14 strengthening of YEN

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Forecasts for FY2015 (Core Basis): Analysis of Change in Sales (vs. Previous Year)



(Billion YEN)

Sales: +114.7

Forex impact: +9.9

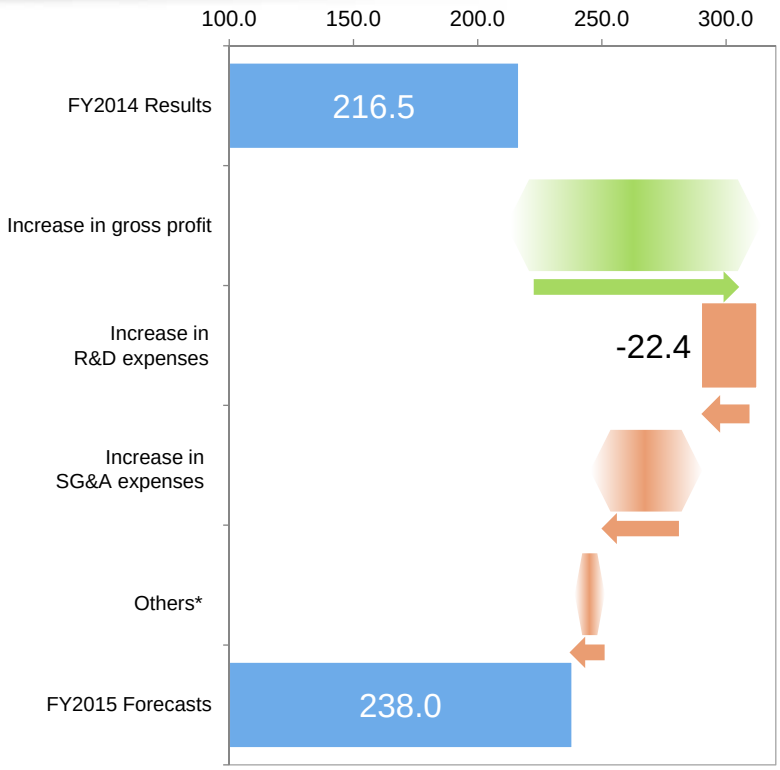
-Vesicare and Betanis/Myrbetriq/BETMIGA +23.8 / -XTANDI +92.2

-Prograf -2.1 / Harnal -2.3 / Funguard/MYCAMINE +1.8 / Protopic -8.0 / Eligard –0.9

-New Products and Growing Products +27.1 / Micardis +9.5 / Lipitor -16.3 / Gaster -2.9 / Myslee -1.2 / Seroquel -2.0

-Other European product group -5.6 / Scan +7.9

Forecasts for FY2015 (Core Basis): Analysis of Change in Operating Profit (vs. Previous Year)



Operating profit: +21.5

Forex impact: +1.9

Increase in sales
Decrease in COGs ratio
-Change in product mix

R&D expense ratio per sales: +0.2ppt
[OP decreasing factor]
-Cost for development project

[OP decreasing factor]
-Cost for co-promotion of XTANDI in US

* Amortisation of intangible assets and share of profits of associates and joint ventures

Forecasts for FY2015 (Full Basis)

(Billion YEN)

	FY2014	FY2015 Forecasts	Change
Net sales	1,247.3	1,362.0	+9.2%
R&D Expenses as % of sales	206.6 16.6%	229.0 16.8%	+10.8%
Operating profit	185.7	238.0	+28.2%
Profit before tax	189.7	239.0	+26.0%
Profit for the year	135.9	170.0	+25.1%
Earnings per share (YEN)	61.50	77.51	+26.0%

- Exchange Rate (YEN)

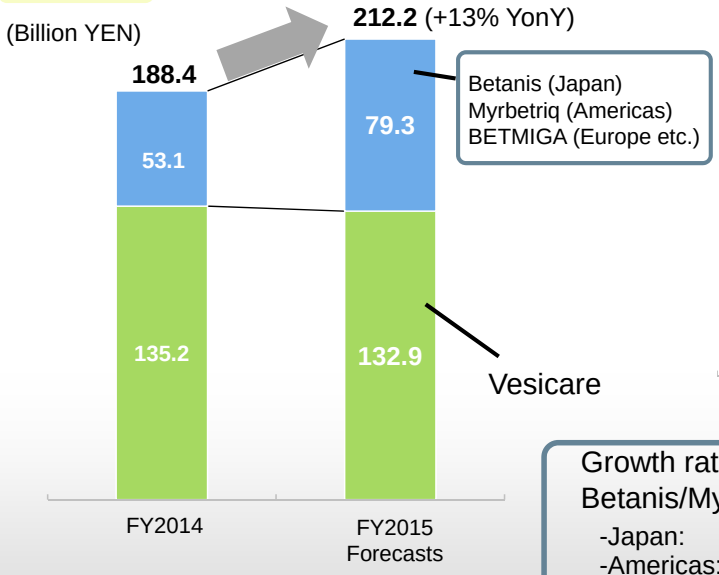
[Average for terms]	FY2014	FY2015 Forecasts	Change
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EUR	139	125	14 strengthening of YEN

OAB Franchise in Urology Forecasts for FY2015

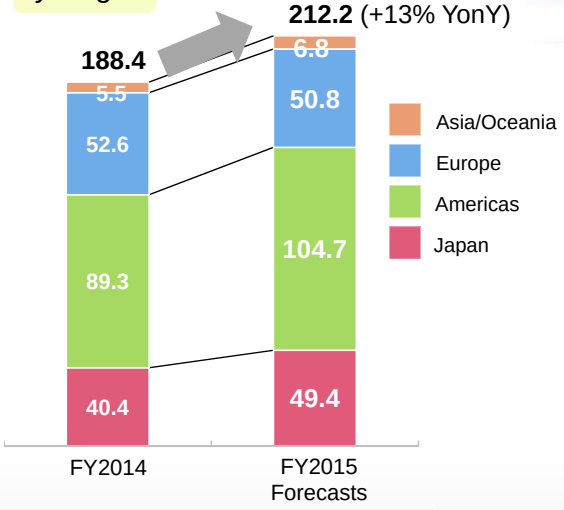
Further strengthening OAB franchise with both Vesicare and Betanis/Myrbetriq/BETMIGA

Total sales of Vesicare and Betanis/Myrbetriq/BETMIGA

by Product



by Region



Growth rate in total sales of Vesicare and Betanis/Myrbetriq/BETMIGA [YonY]

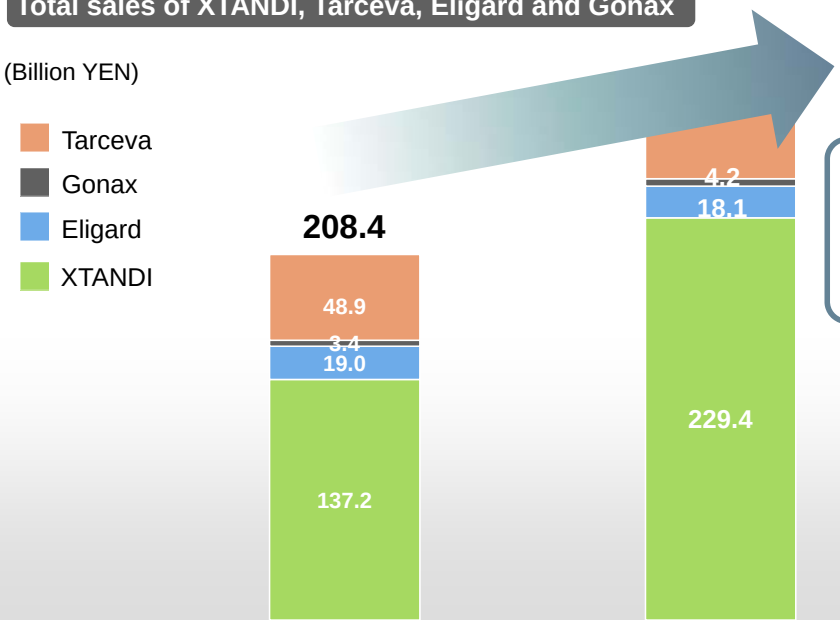
- -Japan: +22%
- -Americas: +7% (USD basis)
- -Europe: +7% (EUR basis)
- -Asia/Oceania: +18% (Excl. forex impact)

OAB: Overactive Bladder

Oncology Franchise Forecasts for FY2015

Further expansion of oncology franchise driven by XTANDI global sales

Total sales of XTANDI, Tarceva, Eligard and Gonax



XTANDI (+67% YonY)

- -Expansion of sales territory
- -Further market penetration in chemo-naive mCRPC patients*

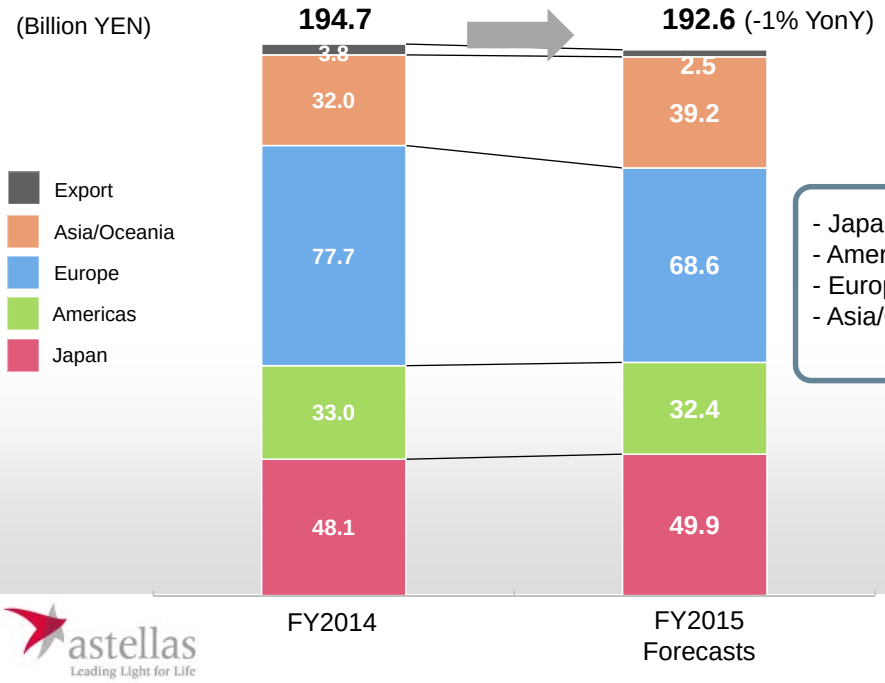
*US indication is for patients with metastatic castration-resistant prostate cancer (mCRPC). The approved indication for XTANDI may vary in different regions.

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Transplantation Franchise Forecasts for FY2015

Continuous growth in Asia/Oceania and maintaining global sales

Total sales of Prograf and Advagraf/Graceptor/ASTAGRAF XL

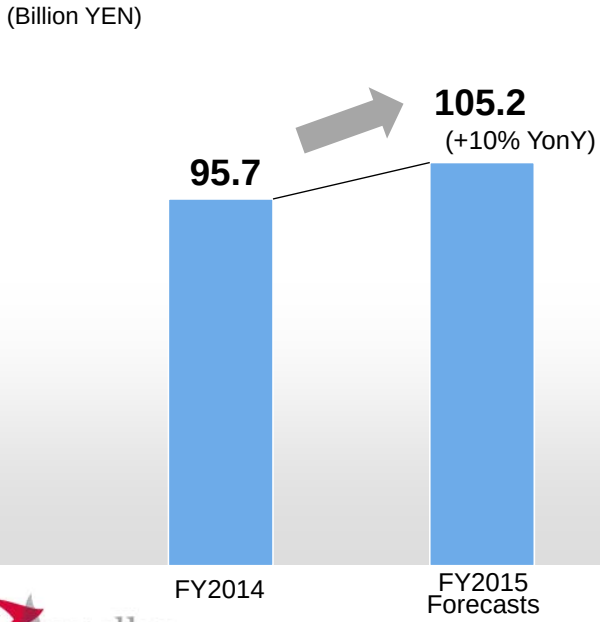


[YonY]
- Japan: +4%
- Americas: -10% (USD basis)
- Europe: -2% (EUR basis)
- Asia/Oceania: +14% (Excl. forex impact)

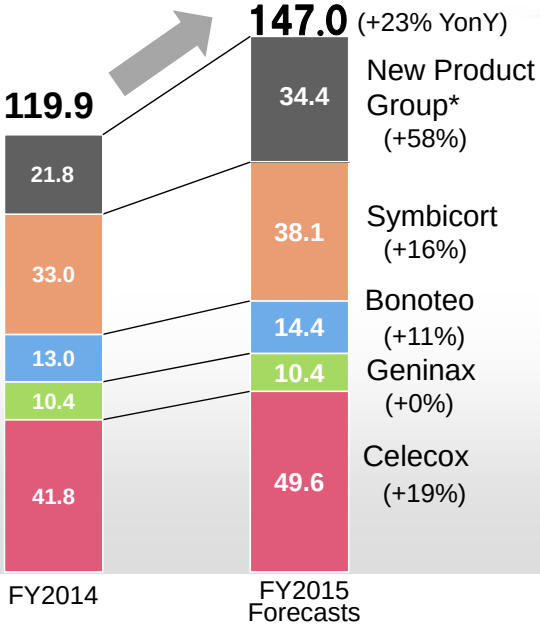
Major Products in Japan (Excluding Global Products) Forecasts for FY2015

Solid growth of Major Growing Products and New Product Group

Micardis [Family]



New Product Group and Growing Product Group



*New Product Group: Total sales of main products launched from April 2012 onward (ARGAMATE, Kiklin, Regnite, Gonax, Cimzia, Acofide and Suglat)

R&D Pipeline

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Robust Pipeline of Astellas

Phase 1

- mirabegron (Pediatric)
- ASP5633
- ASP2205
- ASP6282
- ASKP1240 (JP)
- ASP5094
- AGS-16C3F
- ASG-22ME
- ASP1707 (Prostate cancer, EU)
- ASG-15ME
- ASP5878
- ASP8273 (US)
- AGS67E
- ASP4132
- ASP2215 (NSCLC, US/JP/Asia)
- blinatumomab
- ASP3662 (Alzheimer)
- ASP7962
- ASP4345
- YM311 (JP)
- CK-2127107
- ASP6858

Phase 2

- ASP0113 (VCL-CB01) (CMV SOT, US/EU)
- ASKP1240 (Transplant, US)
- ASP7373 (Influenza H5N1, JP)
- ASP015K (Rheumatoid arthritis, US/EU)
- enzalutamide (Breast cancer, HCC, US/EU)
- ASP8273 (NSCLC, JP/Asia)
- ASP8477 (Neuropathic pain, EU)
- ASP3662 (PDPN, US)
- roxadustat (JP)
- YM311 (FG-2216) (Renal anemia, EU)
- ASP1707 (Endometriosis, EU/JP)
- linaclotide (Chronic constipation, JP)
- bixalomer (Granule formulation, JP)
- ASP8232 (Diabetic nephropathy: EU, diabetic macular edema: US)
- ipragliflozin (Type 1 diabetes, JP)

Phase 3

- solifenacin (Pediatric, US/EU)
- solifenacin/mirabegron (US/EU/Asia)
- ASP0113 (VCL-CB01) (CMV HCT, US/EU/JP)
- fidaxomicin (Infectious enteritis: JP, pediatric: EU)
- isavuconazonium sulfate (Candidemia, US)
- ASP015K (Rheumatoid arthritis, JP)
- enzalutamide (M0 CRPC, M0 BCR, US/EU/Asia)
- degarelix (3-month, JP)
- ASP2215 (AML, US/EU/JP/Asia)
- quetiapine (BPD, JP)
- roxadustat (Anemia associated with CKD, EU)
- beraprost sodium (Chronic renal failure, JP/Asia)
- romosozumab (Osteoporosis, JP)
- linaclotide (IBS-C, JP)

Filed

- ASP7374 (Seasonal influenza, JP)
- certolizumab pegol (DMARD-naive RA, JP)
- capsaicin (Peripheral neuropathic pain in diabetic patients, EU)
- ramosetron (IBS Female, JP)
- bixalomer (Not on dialysis, JP)
- evolocumab (Hypercholesterolemia, JP)

Therapeutic area:
- Urology
- Immunology (including Transplantation) and Infectious Diseases
- Oncology
- Neuroscience
- DM Complications and Kidney Diseases, Others

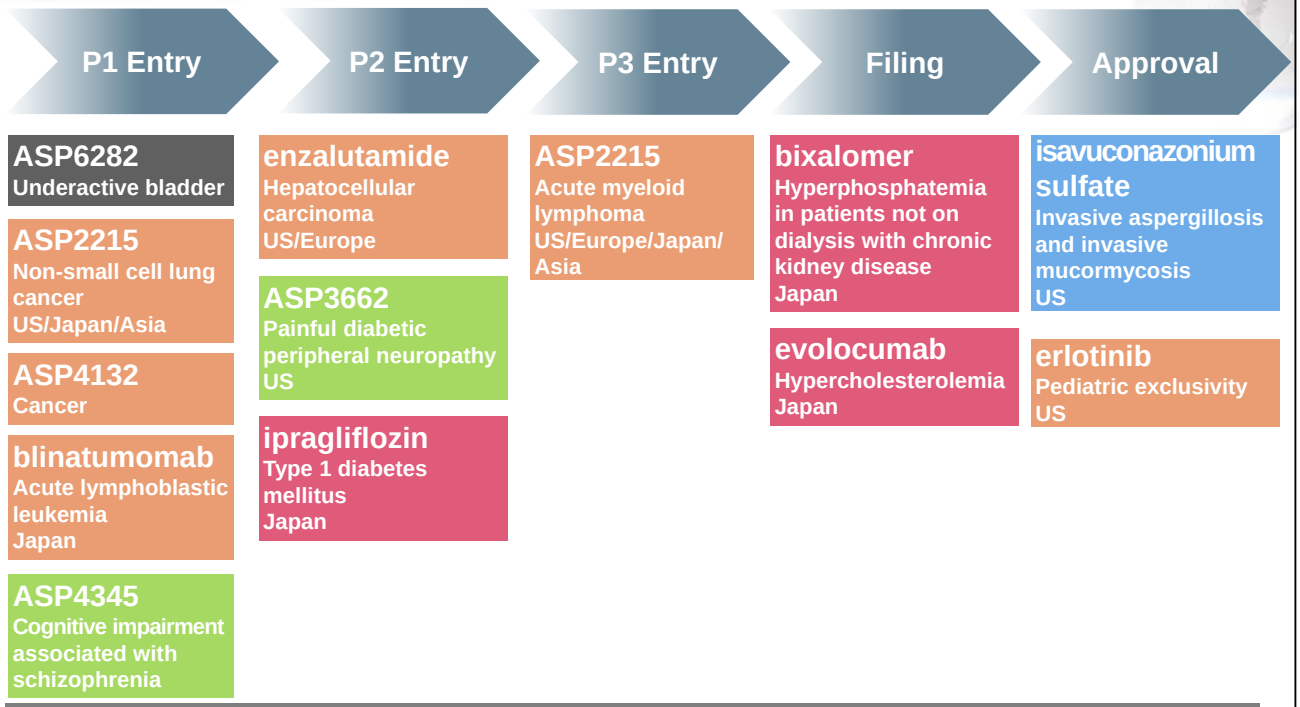
● New molecular entity

Outline of the projects are shown. Please refer to pipeline list for details including target disease.

NSCLC: Non-small cell lung cancer, CMV: Cytomegalovirus, SOT: Solid organ transplant, HCC: Hepatocellular carcinoma, PDPN: Painful diabetic peripheral neuropathy, HCT: Hematopoietic cell transplant, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, AML: Acute myeloid leukemia, BPD: Bipolar disorders, CKD: Chronic kidney disease, IBS-C: Irritable bowel syndrome with constipation, DMARD: Disease modifying anti-rheumatic drugs, RA: Rheumatoid arthritis,

Steady Progress in Development

Summary of changes from February to May



Discontinuation/Removal from pipeline list

P1 projects: ASP3700, ASP9226, ASP3325, ASP7657
P2 projects: AMG 337, ASP7991
P3 project: rilotumumab
Filed project: nateglinide

Changes in Pipeline Status Since February 2015 <Approval and Filing>

- Approval

Product Name Generic Name	Indication	Area	Changes
CRESEMBA isavuconazonium sulfate	Treatment of invasive aspergillosis and invasive mucormycosis in patients 18 years of age and older	US	Approved in March 2015

- Grant of pediatric exclusivity

Product Name Generic Name	Target Disease	Area	Changes
Tarceva erlotinib	Pediatric ependymoma*	US	The FDA determined that the submitted data met their Written Request. Pediatric exclusivity was granted. Exclusivity period has been extended to May 2019.

*Not an approved indication. The data was submitted to the FDA to fulfill Pediatric Written Request.

- Filing

Code No. Generic Name	Target Disease	Area	Changes
ASP1585 (AMG 223) bixalomer	Hyperphosphatemia in patients not on dialysis with chronic kidney disease	Japan	Filed in March 2015 (New indication)
AMG 145 evolocumab	Hypercholesterolemia	Japan	Filed in March 2015

Changes in Pipeline Status Since February 2015 <Progress and New P1>

- Progress of the stage

Code No. Generic name	Target Disease	Area	Stage	Change
ASP2215	Acute myeloid leukemia	US/Europe/ Japan/Asia	P3	Preparing P3 study Plan to present P1/2 study data at ASCO
	Non-small cell lung cancer	US/Japan/Asia	P1	Preparing P1b/2 study
MDV3100 enzalutamide	Hepatic cellular carcinoma	US/Europe	P2	Entered into P2
ASP3662	Painful diabetic peripheral neuropathy	US	P2	Entered into P2
ASP1941 ipragliflozin	Type 1 diabetes mellitus	Japan	P2	Entered into P2
AMG 103 blinatumomab	Acute lymphoblastic leukemia	Japan	P1	Initiated P1b/2 study

- New P1

Code No.	Target Disease	Stage	Changes
ASP4345	Cognitive impairment associated with schizophrenia	P1	Entered into P1
ASP4132	Cancer	P1	Entered into P1
ASP6282	Underactive bladder	P1	Entered into P1

ASCO: American Society of Clinical Oncology

Changes in Pipeline Status Since February 2015 <Discontinuation and Removal from Pipeline List>

- Discontinuation

Code No. Generic name	Target Disease	Area	Stage	Reason for Discontinuation
nateglinide	Type 2 diabetes Combination with DPP-4 inhibitor	Japan	Filed	Withdrew the NDA for strategic reasons and discontinued the development
AMG 102 rilotumumab	Gastric cancer	Japan	P3	Discontinued the development following study termination
ASP7991	Secondary hyperparathyroidism	Japan	P2	Discontinued the development based on P2 study results

- Discontinuation of P1 projects

Code No.	Target Disease
ASP3325	Hyperphosphatemia
ASP3700	Osteoarthritis
ASP9226	Neuropathic pain
ASP7657	Diabetic nephropathy

- Removal from the pipeline list

Code No.	Target Disease	Area	Stage	Remarks
AMG 337	Gastric cancer	Japan	P2	Removed from the pipeline list for strategic reasons based on discussion with Amgen

Oncology Pipeline

Stage in the most advanced territory

	Project	Target Cancer	Characteristics	P1	P2	P3	Filed
Small molecule	Erlotinib (Tarceva)	Pediatric ependymoma*1	HER1/EGFR tyrosine kinase inhibitor	US		Pediatric exclusivity granted	
	Enzalutamide (XTANDI)	Prostate cancer (M0 CRPC, M0 BCR), Breast cancer (BC), Hepatocellular carcinoma (HCC)	Androgen receptor inhibitor	M0 CRPC, M0 BCR			
				BC, HCC			
	Degarelix (Gonax)	Prostate cancer	1st GnRH antagonist in Japan	3-month: JP			
	ASP2215	Acute myeloid leukemia, Non-small cell lung cancer	FLT3/AXL inhibitor	AML			
				NSCLC			
	ASP8273	Non-small cell lung cancer	Mutant-selective irreversible EGFR inhibitor				
	ASP1707	Prostate cancer*2	Oral GnRH antagonist				
	ASP5878	Solid tumors	FGFR inhibitor				
	ASP4132	Advanced cancer					
Antibody	AGS-16C3F	Renal cancer	Antibody utilizing ADC (target: ENPP3)				
	ASG-22ME	Solid tumors	Antibody utilizing ADC (target: Nectin-4)				
	ASG-15ME	Bladder cancer	Antibody utilizing ADC (target: SLITRK6)				
	AGS67E	Lymphoid malignancy	Antibody utilizing ADC (target: CD37)				
	AMG 103 blinatumomab	Acute lymphoblastic leukemia	Anti-CD19 BiTE				

New clinical data presentations at ASCO 2015: enzalutamide (P2 TNBC), ASP2215 (P1/2), ASP8273 (P1 in US), AGS-16C3F (P1)

*1: Not a new indication, to fulfill Pediatric Written Request
*2: P2 for indication of endometriosis

ADC: Antibody-drug conjugate

Enzalutamide: Development Progress

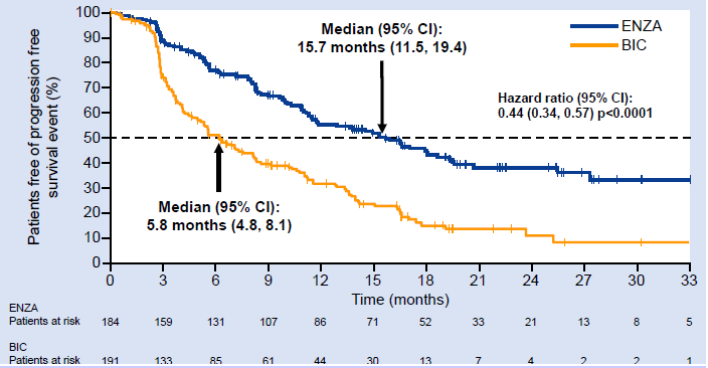
*The region where the study is performed

	Study Phase/Region*	Target	Design	P1	P2	P3	Filed
Prostate cancer	**P3** US/EU/Asia [PROSPER study]	M0 CRPC Non-metastatic CRPC	Placebo-controlled, n=1,500	First Patient In: Nov. 2013			
	P3 US/EU/Asia [EMBARK study]	M0 BCR Non-metastatic prostate cancer, biochemical recurrence	To compare with ADT and combination, n=1,860	First Patient In: Jan. 2015			
	P2 US/EU [TERRAIN study]	Pre-chemo Metastatic CRPC	To compare with bicalutamide, n=375	Presented data at EAU			
	P2 US [STRIVE study]	Pre-chemo Metastatic or non-metastatic CRPC	To compare with bicalutamide, n=400	Obtained top line results in Apr. 2015			
	P2 US	Neoadjuvant therapy Undergoing prostatectomy	Monotherapy or combo with leuprolide or dutasteride, n=50	Obtained data			
Breast cancer	**P2** US/EU	Triple-negative Advanced, androgen receptor-positive, triple-negative breast cancer	Open-label, n=118	Plan to present full data at ASCO			
	P2 US/EU	ER/PgR positive Advanced breast cancer that is ER positive or PgR positive and HER2 normal	Placebo-controlled, in combination with exemestane, n=240	Last Patient In: Mar. 2015			
	P2 US/EU	HER2 positive Advanced, androgen receptor-positive, HER2 positive/ER negative breast cancer	Open-label, n=80	First Patient In: Sep. 2014			
HCC	**P2** US/EU	Hepatocellular carcinoma	-	In preparation			

ADT: Androgen-deprivation therapy, ER: Estrogen receptor, PgR: Progesterone receptor, HER2: Human epidermal growth factor receptor 2

Enzalutamide: Positive Results Obtained from TERRAIN and STRIVE

Progression free survival (PFS) in TERRAIN presented at EAU



Heindreich A *et al*, EAU2015

Results of STRIVE to be presented at AUA

- Statistically significant increase in PFS compared to bicalutamide (Hazard Ratio=0.24; 95% CI, 0.18-0.32; p<0.0001).
- Median PFS was 19.4 months in the enzalutamide group versus 5.7 months in the bicalutamide group.
- SAEs were reported in 29.4% of enzalutamide-treated patients and 28.3% of bicalutamide-treated patients.

Design	TERRAIN	STRIVE
Population	Metastatic CRPC	Non-metastatic (35%) and metastatic (65%) CRPC
Primary endpoint	PFS -Radiographic evidence -Skeletal related events -New anti-neoplastic therapy -Deaths	PFS -Radiographic evidence -PSA progression -Deaths
Radiographic evidence	Central and local read	Local read only

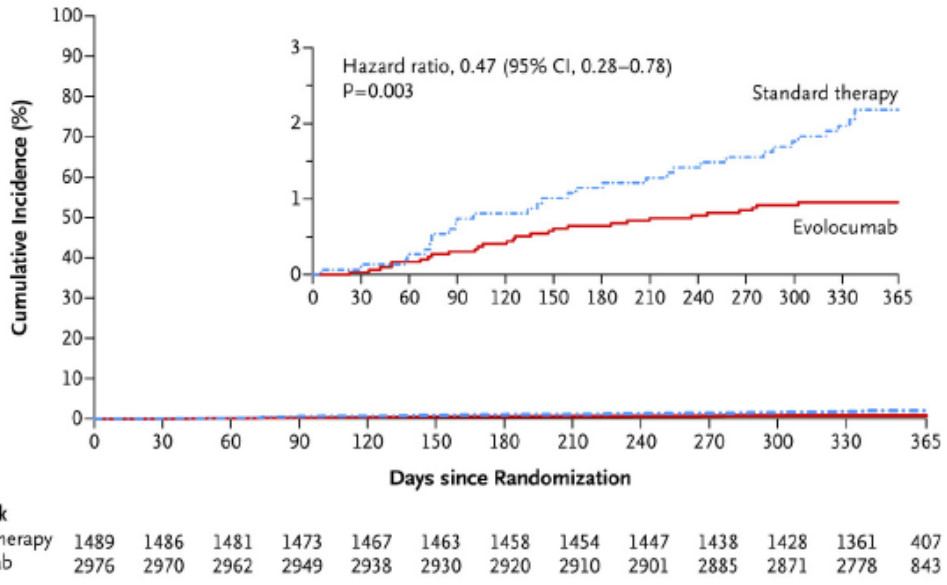
EAU: European Association of Urology, AUA: American Urological Association, SAE: Serious adverse event

Evolocumab: Exploratory Analysis of Cardiovascular Events in OSLER-1 and OSLER-2

Cumulative Incidence of Cardiovascular Events

The NEW ENGLAND JOURNAL of MEDICINE

Data from open-label extension studies with prespecified exploratory endpoints, comparing evolocumab+standard of care with standard of care



Sabatine MS *et al*. N Engl J Med 2015.
DOI: 10.1056/NEJMoa1500858

Solifenacin/Mirabegron: Development Progress

The BESIDE study delivered positive results which shall be presented at the AUA congress

- BESIDE Study

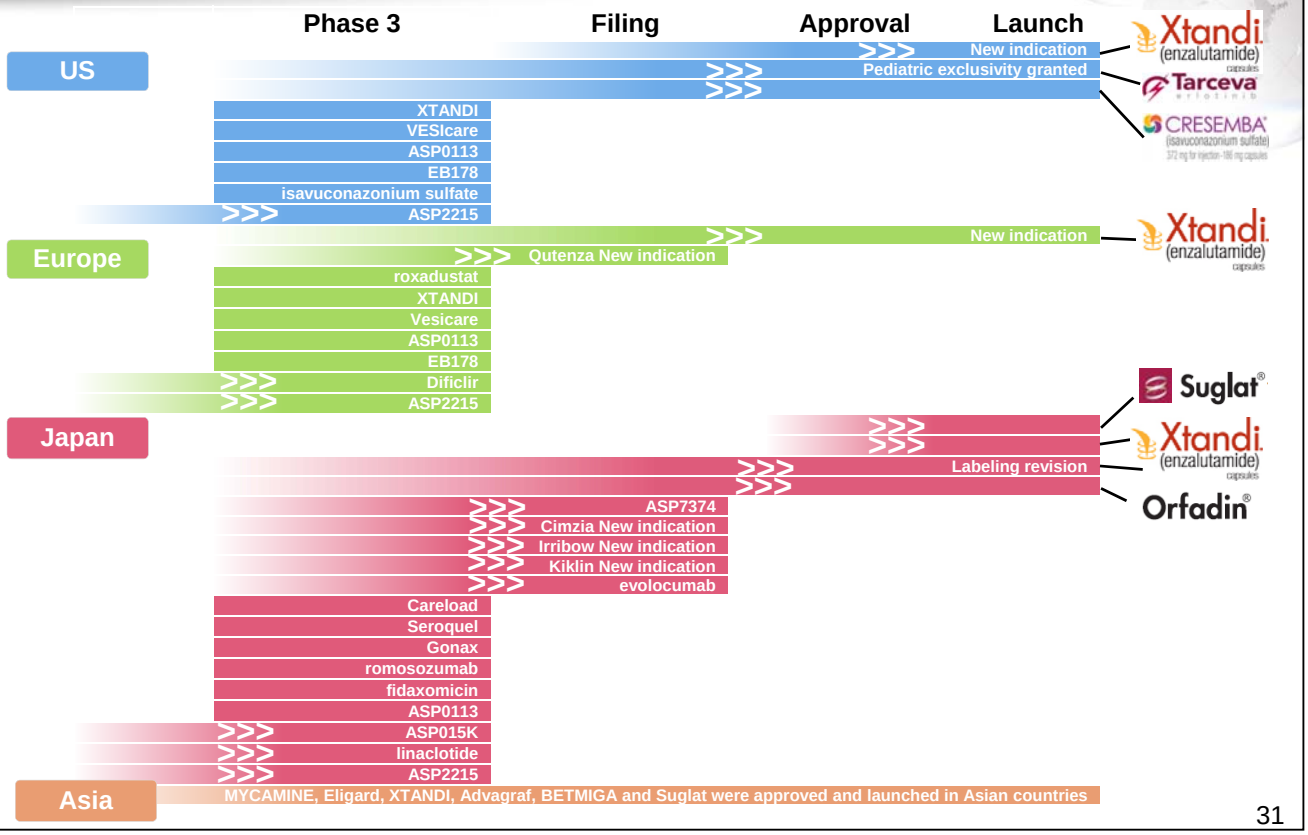
Purpose	To investigate the value of add-on therapy of mirabegron to solifenacin
Target	Incontinent OAB subjects not adequately treated with solifenacin alone (n=2,174)
Design	Double-blind placebo and active controlled, 12 week, add-on treatment
Treatment arms	3 arms -Solifenacin low dose (5 mg) -Solifenacin high dose (10 mg) -Combination of solifenacin 5 mg and mirabegron (50 mg; first 4 weeks on 25 mg)
Primary endpoint	Change from Baseline in mean number of incontinence episodes per 24 hours

- Development progress
  - SYNERGY study (Double-blind Phase 3 study): Ongoing
  - SYNERGY 2 study (Long-term Phase 3 study): Ongoing

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FY2014 Progress of Late Phase Compounds

>>>: Progress since April 2014



Initiatives to Build Resilience for Sustainable Growth

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Strategic Priorities for Sustainable Growth

Resiliently respond to changing environment and aim for sustainable growth

Growth Strategy

Maximize the Value of Products

Extension of growth drivers

- Maximize OAB franchise (extension of Vesicare+ Betanis/Myrbetriq/BETMIGA)
- Enhance oncology franchise (XTANDI sales growth, label expansion)
- New product launch in many countries

Create Innovation

Development of new therapeutic areas and novel technology platform

- Joint research chair with Osaka Univ. for next-generation cell therapies
- Option agreement with MD Anderson Cancer Center for monoclonal antibody drug targeting acute myeloid leukemia
- Exclusive research and development collaboration agreement with Potenza for immuno-oncology therapeutics

Efficiency Strategy

Pursue Operational Excellence

Response to changes of various regulations

- Make clinical trial data available to researchers through an external web site

Optimization of organizations and functions

- Strengthening of strategic function of global marketing (set position reporting directly to CEO)
- Reorganization of report line of medical affairs function
- Reorganization of global business development function
- Reorganization of report line of global IT function

Continuous Introduction of New Products

(Efforts from April 2014 onward)

Maximize the Value of Products

- Approvals and launches in 4 regions
  (Underlined items show updates from the previous announcement)

Europe

- XTANDI:
  - Launch (Hungary, Croatia, Slovenia, Rumania, Spain, Lebanon)
  - Chemo-naive indication approval
- BETMIGA:
  - Launch (Netherlands, Germany, Greece, Bulgaria, Croatia)
- VESOMNI:
  - Launch (Denmark, Belgium, Luxemburg, Czech, Portugal, Spain)

Americas

- XTANDI:
  - Launch (Argentina)
  - Chemo-naive indication approval (US, Canada)
- CRESEMBA Launch (US)

Japan

- Suglat Launch
- XTANDI Launch, Label revision*
- Orfadin Launch

Asia/Oceania

- XTANDI: Launch (Australia), Approval (Philippines, Hong Kong)
- BETMIGA: Launch (Australia, Hong Kong, Macao, Republic of Korea, Taiwan, Singapore), Approval (Thailand)
- Eligard: Launch (Philippines), Approval (Taiwan, Thailand, Singapore, Malaysia)
- Advagraf: Launch (Vietnam), Approval (Philippines)
- MYCAMINE: Launch (Singapore, Malaysia, Australia),
  Pediatric indication approval (Hong Kong, Republic of Korea)
- Suglat: Launch (Republic of Korea)

No. of countries/areas where the following have been launched:
Betanis/Myrbetriq/BETMIGA: 35
XTANDI: 32

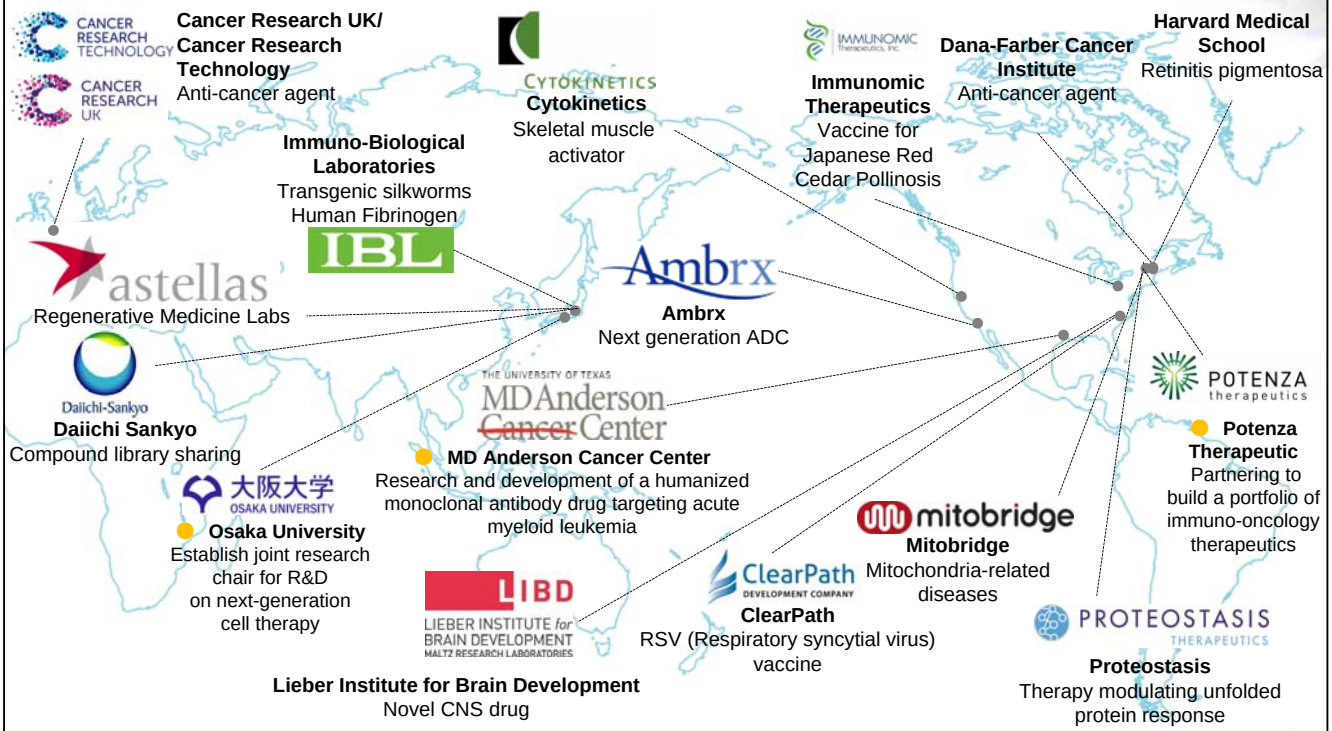
*Following description was removed in the precautions for indications; the efficacy and safety of the drug have not been established in patients with prostate cancer who have not received chemotherapy.

Develop New Therapeutic Areas and Novel Technology Platform

Create Innovation

(●: Updates from the previous announcement)

Pursue Best Science, Best Talent, Best Place with Network Research System



CNS: Central nervous system

Develop New Therapeutic Areas and Novel Technology Platform

Create Innovation

Agreement with Osaka University to establish a joint research chair with a view developing fundamental technologies for next-generation cell therapies and bringing those technologies into practical use (Dec. 2014)

- Development of technologies to make transfused/transplanted cells highly functional and to enhance their therapeutic effects through optimization of the sources of transfused/transplanted cells and the cell processing technologies, according to specific medical conditions, besides analyses and development, aimed at realizing practical utilization of allogeneic cell transplantation therapy.

大阪大学 OSAKA UNIVERSITY

Option agreement with MD Anderson Cancer Center for monoclonal antibody drug targeting acute myeloid leukemia (Apr. 2015)

- Research and development of a humanized monoclonal antibody h8F4[1)] for patients with acute myeloid leukemia led by MD Anderson Cancer Center

[1)] h8F4 targets an HLA-restricted peptide called PR1/HLA-A2, which is expressed in cancer cells and cancer stem cells, and exerts a radically novel anti-tumor activity

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

Exclusive research and development collaboration agreement with Potenza (Apr. 2015)

- Aim to build a portfolio consisting of programs with novel mechanisms of action targeting immune checkpoint pathways, co-stimulatory signals and regulatory T cells

POTENZA therapeutics

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Profit Distribution Policy

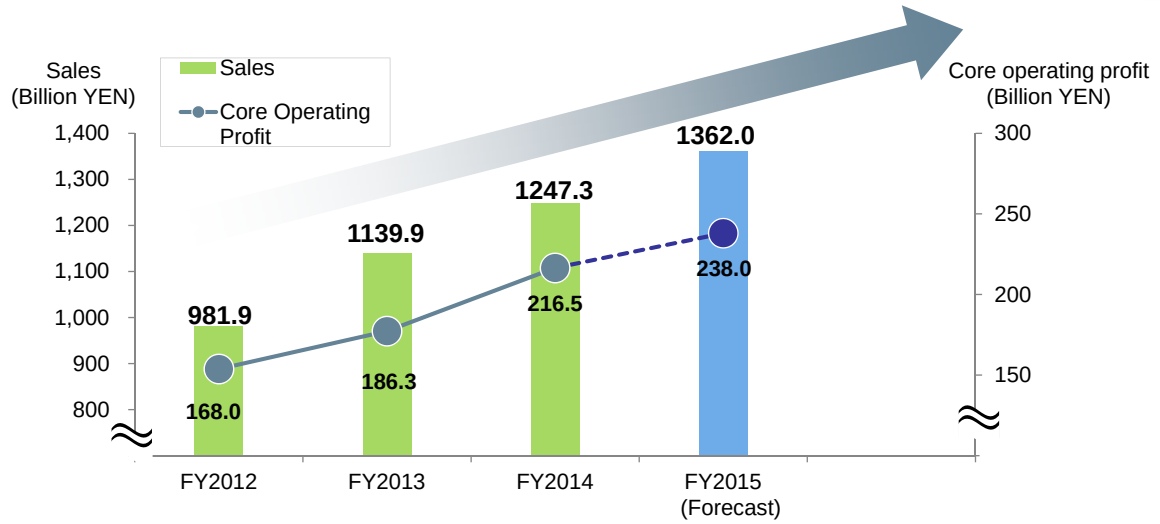
- Top priority on investment for growth of Rx business
- Dividends to be increased continuously based on mid- and long-term growth
- Share buybacks to be implemented in a flexible manner

	FY2013	FY2014	FY2015 (Forecast)
Core EPS	59.11 YEN	69.37 YEN	77.51 YEN
Dividends per Share	27 YEN	30 YEN (planned)	32 YEN
ROE	7.4%	10.5%	-
DOE	5.0%	5.1%	-
Share Buybacks	25 million shares (30.0 billion YEN)	38 million shares (58.2 billion YEN)	Implemented in a flexible manner
Cancellation of Treasury Shares	55 million shares	25 million shares	38 million shares (To be cancelled on May 29, 2015)

-Figures from FY2013 have been restated in consideration of 5-for-1 stock split on April 1, 2014 for convenience purposes

Realize Sustainable Growth

Resiliently respond to the changing environments and aim for sustainable growth



- Driven by XTANDI and Vesicare+ Betanis/Myrbetriq/BETMIGA, business will go favorably
- Will continuously work on “Maximize the Value of Products”, “Create Innovation”, and “Pursue Operational Excellence”

“Strategic Plan 2015-2017” Disclosure Schedule (Planned)

Tuesday, May 26, 2015
Press Release

Wednesday, May 27, 2015 13:30 – 15:00
Conference

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Appendix

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Definition of Core Earnings

Defined as Non-GAAP financial indicators demonstrating operating profitability from ordinary business

Full basis
Sales
Cost of Sales
Gross Profit
SG&A expenses
R&D expenses
Amortisation of intangible assets
Share of profits of associates and joint ventures
Other income
Other expense
Operating profit
Financial income
Financial expense
Profit before tax
Income tax expense
Profit for the year

"Other income" and "Other expense" to be excluded.

Impairment losses, restructuring costs, etc.

Interest income/expense, dividend income, etc.

Core operating profit

Adjusted financial income/expense (Gain/loss on sale of available-for-sale financial assets ("AFS") and impairment losses of AFS etc. to be excluded)

Core profit for the year → Core EPS

Reconciliation of Full Basis to Core Basis

Billion yen

	FY14		
Account item	Full basis	Adjustment	Core basis
Sales	**1,247.3**	**-**	**1,247.3**
Cost of sales	333.2	-	333.2
Gross profit	**914.1**	**-**	**914.1**
SG&A expenses	452.5	-	452.5
R&D expenses	206.6	-	206.6
Amortisation of intangible assets	38.7	-	38.7
Share of profits of associates and joint ventures	0.2	-	0.2
Other income *1	12.5	-12.5	-
Other expense *1	43.3	-43.3	-
Operating profit	**185.7**	**30.8**	**216.5**
Finance income *2	7.1	-5.1	1.9
Finance expense *2	3.1	-2.7	0.4
Profit before tax	**189.7**	**28.4**	**218.1**
Income tax expense	53.8	11.0	64.8
Profit for the year	**135.9**	**17.4**	**153.2**

*1. “Other income” and “Other expense” are excluded from Core results.
“Other income” and “Other expense” include gain/loss on sale and disposal of property, plant and equipment, impairment losses for other intangible assets, restructuring costs, litigation costs and net foreign exchange gains/losses, etc.

*2. Gain/loss on sale of available-for-sale (“AFS”) and impairment losses of AFS included in “Finance income” and “Finance expense” are excluded from Core results.