FY2015 Financial Results

Ended March 31, 2016

May 11, 2016
Yoshihiko Hatanaka
President and CEO
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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Agenda

I. Full Year FY2015 Highlights

II. Financial Results & Forecasts

III. R&D Pipeline

IV. Initiatives to Build Resilience for Sustainable Growth

V. Appendix

Full Year FY2015 Highlights

Financial Update

- Net sales and earnings increased Y-on-Y
  - Net sales increased 10% to 1,372.7 billion yen
  - Core operating profit increased 24% to 267.5 billion yen
  - Core profit for the year increased 30% to 198.8 billion yen
  - Core EPS increased 33% to 92.12 yen
- Continued sales expansion in Oncology and OAB franchises
  - XTANDI sales expanded 84% to 252.1 billion yen
  - OAB sales expanded 15% to 217.4 billion yen

OAB: Overactive Bladder

R&D Pipeline Progress

- Achieved many important milestones in clinical development
  - Approval
    - Repatha (in Japan)
    - Kiklin, Cimzia and Irribow (label expansion in Japan)
  - Filing
    - Linaclotide (in Japan)
  - Phase 3 data readout
    - Romosozumab (FRAME and BRIDGE study)
    - EB178 (SYNERGY study)
  - Phase 3 entry
    - ASP8273
    - Gilteritinib

Strategic Initiatives

- Maximize the Product Value
  - Grew no. of countries/areas where the following have been launched
    - XTANDI: Approx. 60
    - Betanis/Myrbetriq/BETMIGA: Approx. 50
- Create Innovation
  - Acquisition of Ocata Therapeutics, Inc.
  - New exclusive license for next-generation vaccines from Immunomic Therapeutics, Inc.
- Pursue Operational Excellence
  - Transfer of global dermatology business to LEO Pharma A/S

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FY2015 Financial Results (Core Basis)

(billion yen)

	FY2014	FY2015	Change	FY15FCST*	Achievement
Net sales	**1,247.3**	**1,372.7**	**+10.1%**	**1,384.0**	**99.2%**
Cost of sales as % of sales	333.2 26.7%	335.6 24.4%	+0.7% -2.3 ppt		
SG&A expenses as % of sales	452.5 36.3%	500.4 36.5%	+10.6% +0.2 ppt		
R&D expenses as % of sales	206.6 16.6%	225.7 16.4%	+9.2% -0.1 ppt	238.0 17.2%	94.8%
Amortisation of intangibles	38.7	42.4	+9.6%		
Share of profits of associates/JVs	0.2	-1.2	-		
Core operating profit	**216.5**	**267.5**	**+23.5%**	**244.0**	**109.6%**
Core profit for the year	**153.2**	**198.8**	**+29.7%**	**175.0**	**113.6%**

<Exchange rate (yen)>	FY2014	FY2015	Change	FY15FCST
USD: Average	110	120	+10	121
EUR: Average	139	133	-6	133
USD: Year-end rate vs PY end	+17	-7		
EUR: Year-end rate vs PY end	-11	-3		

*Announced in Oct 2015

+: Yen weakening
- : Yen strengthening

Forex impacts
Sales: +26.1
Core OP: +9.5

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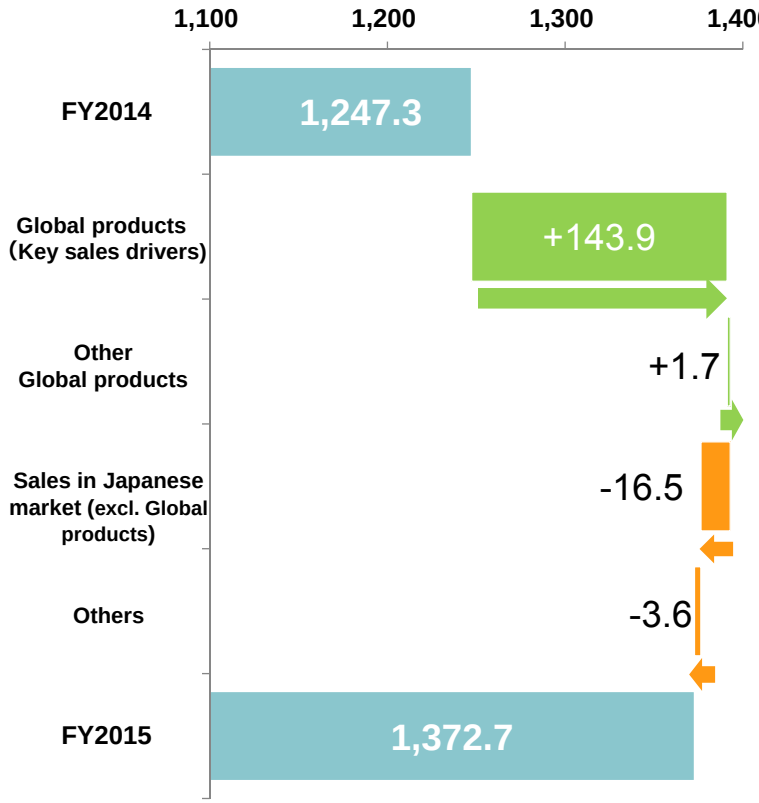
FY2015 Sales Analysis vs PY



Net sales: +125.4

Forex impact: +26.1

XTANDI +114.9
OAB products +29.0

Prograf +8.8, Funguard/MYCAMINE +2.9
Eligard -1.4, Harnal -2.6, Protopic -6.0

New & Growing products +17.1, Micardis +1.4
Lipitor -5.8, Gaster -3.3, etc.

Scan +9.9, Tarceva -2.1
EMEA other products, etc. -11.4

OAB: Overactive bladder
OAB products: Vesicare + Betanis/Myrbetriq/BETMIGA
EMEA: Europe, Middle East & Africa

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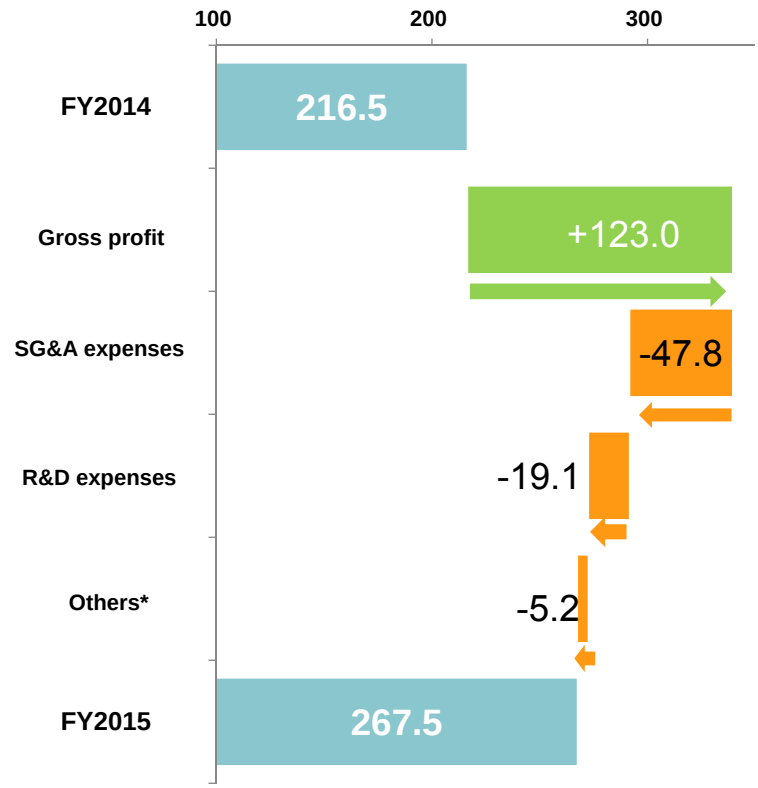
FY2015 Core OP Analysis vs PY



Core OP: +51.0

Forex impact: +9.5

Gross profit:
COGs ratio: -2.3ppt (26.7% → 24.4%)
Product Mix -1.9ppt
Fx impact on unrealized profit elim. -0.4ppt

SG&A expenses increase:
US XTANDI Co-promotion fee
Forex impact, etc.

R&D expenses increase:
Development project cost
Forex impact, etc.

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

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FY2015 Financial Results (Full Basis)

(billion yen)

	FY2014	FY2015	Change	FY2015FCST*	Achievement
Net sales	**1,247.3**	**1,372.7**	**+10.1%**	**1,384.0**	**99.2%**
Core operating profit	**216.5**	**267.5**	**+23.5%**	**244.0**	**109.6%**
Other income	12.5	1.7			
Other expenses	43.3	20.2			
Operating profit	**185.7**	**249.0**	**+34.1%**	**229.0**	**108.7%**
Financial income	7.1	14.4			
Financial loss	3.1	1.6			
Profit before tax	189.7	261.8	+38.0%	242.0	108.2%
Profit for the year	**135.9**	**193.7**	**+42.6%**	**172.0**	**112.6%**

*Announced in Oct 2015

- Other expenses in FY2015
  - Impairment loss of tangible assets: Related to Kashima office, Kiyosu plant
  - Net foreign exchange loss, etc.
- Financial income in FY2015
  - Gain on sales of available-for-sale financial assets, etc.

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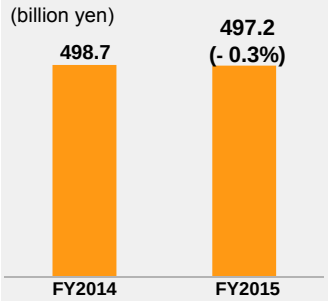
Sales by Region (Local Currency Basis)

*Based on the location of the seller

Maintain double-digit growth in Americas, EMEA and Asia/Oceania

Japan

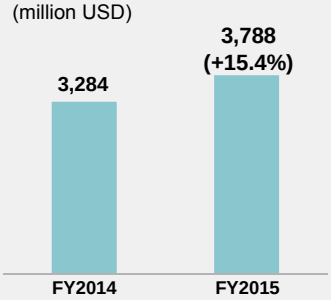
(billion yen)



- Sales in Japanese market 483.0 (+0.3%)
- New and Growing products offset generics impact

Americas

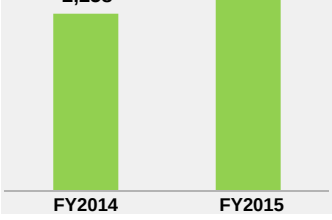
(million USD)



- Growth of XTANDI
- Expansion in OAB products
- Contribution of Scan & CRESEMBA

EMEA (Europe, Middle East and Africa)

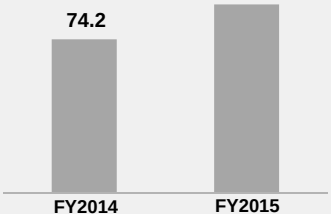
(million EUR)



- Growth of XTANDI
- Expansion in OAB products & Prograf

Asia/Oceania

(billion yen)



- 19% growth on a CER basis
- Contribution of XTANDI & OAB products
- Growth of Prograf & Harnal

CER: Constant Exchange Rate

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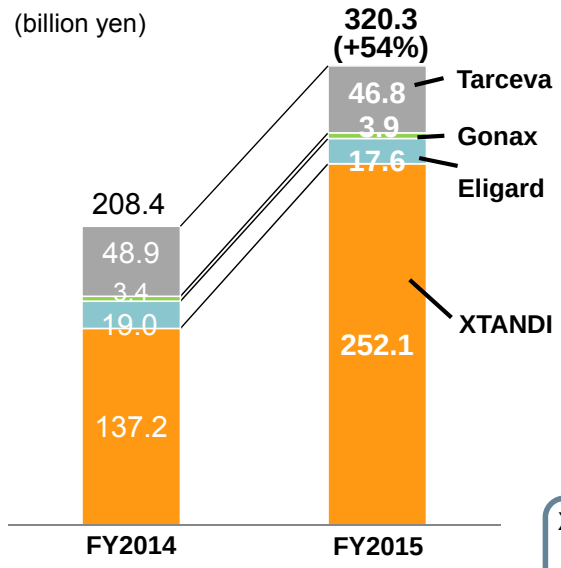
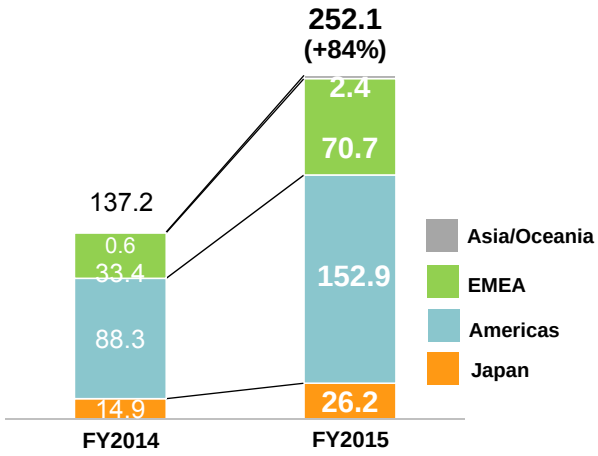
Oncology Franchise

XTANDI: Adding to growth in Americas, sales doubled in other regions

Sales by product



XTAND sales by region



Oncology Franchise:
XTANDI, Tarceva, Eligard and Gonax

XTANDI Year-on-Year sales growth

- Japan: +76%
- Americas: +58% (USD basis)
- EMEA: +121% (EUR basis)
- Asia/Oceania: +309% (CER basis)

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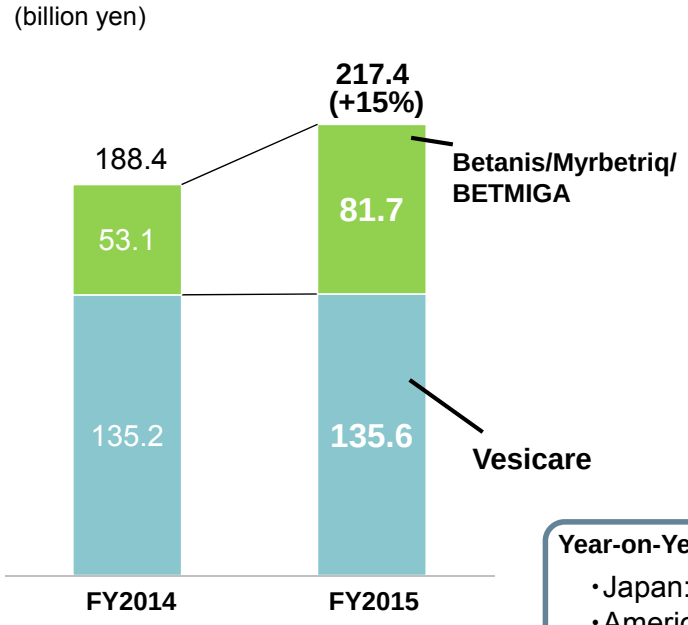
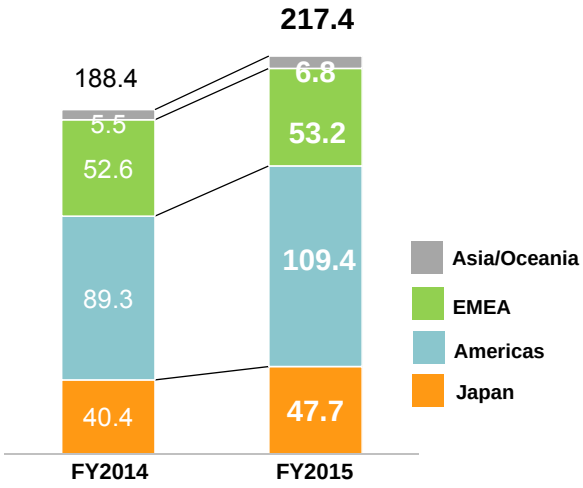
OAB Franchise in Urology

Growth in all regions enhanced the leading position in the OAB market

Sales by product



Sales by region



Year-on-Year sales growth

- Japan: +18%
- Americas: +12% (USD basis)
- EMEA: +6% (EUR basis)
- Asia/Oceania: +23% (CER basis)

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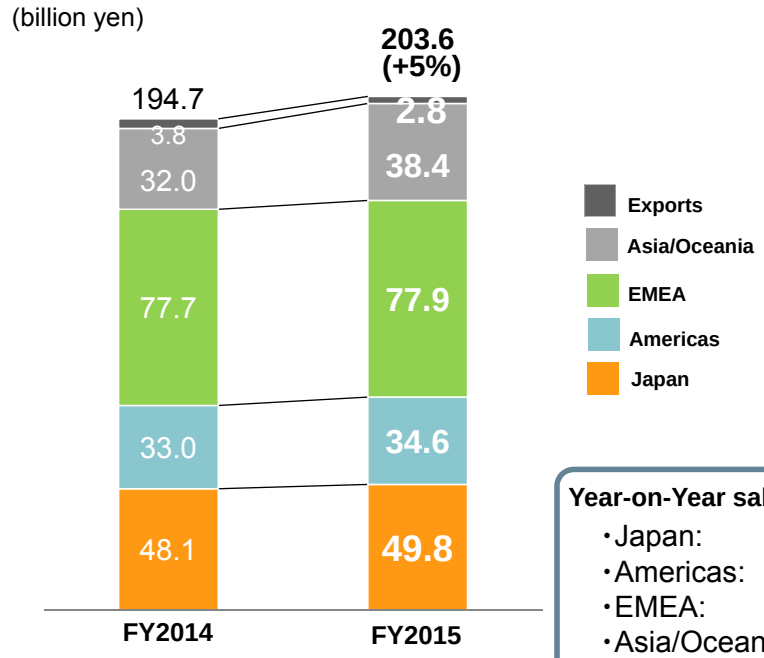
Transplantation Franchise

Global sales maintained by growth in Japan, EMEA and Asia/Oceania

Sales by region



Year-on-Year sales growth

- Japan: +3%
- Americas: - 4% (USD basis)
- EMEA: +5% (EUR basis)
- Asia/Oceania: +16% (CER basis)

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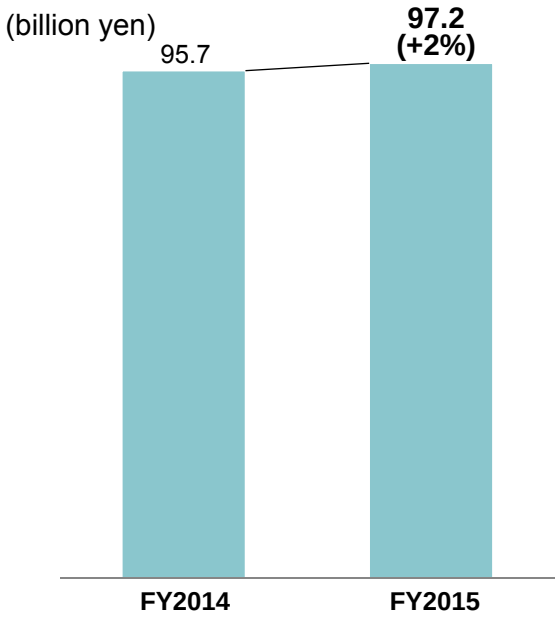
Transplantation franchise: Prograf (including Advagraf/Graceptor/Astagraf XL)

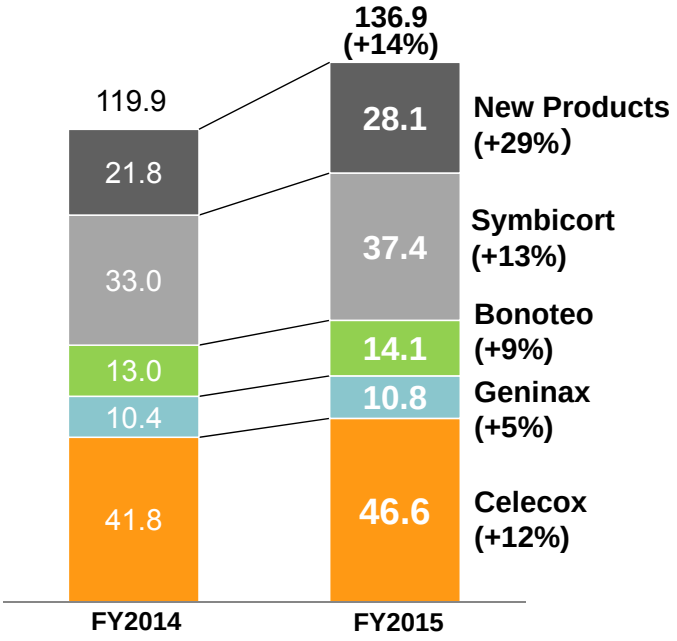
Key Products in Japan (excl. Global Products)

New & Growing Products sales steadily increased

Micardis Family



New & Growing Products



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New Products: Aggregated sales of major products launched from April 2012 onward (Argamate, Kiklin, Regnite, Gonax, Cimzia, Acofide and Suglat)

FY2016 Forecasts (Core Basis)

(billion yen)

	FY2015 ACT	FY2016 FCST	Change	(ref) CER* growth
Net sales	1,372.7	1,350.0	-1.7%	+4%
R&D expenses as % of sales	225.7 16.4%	231.0 17.1%	+2.4%	
Core operating profit	267.5	270.0	+1.0%	+9%
Core profit for the year	198.8	199.0	+0.1%	
Core EPS (yen)	92.12	93.65	+1.7%	

<Exchange rate>	FY2015 ACT	FY2016 FCST	Change
USD: Average	120	110	-10
EUR: Average	133	125	-8

*CER: Constant Exchange Rate

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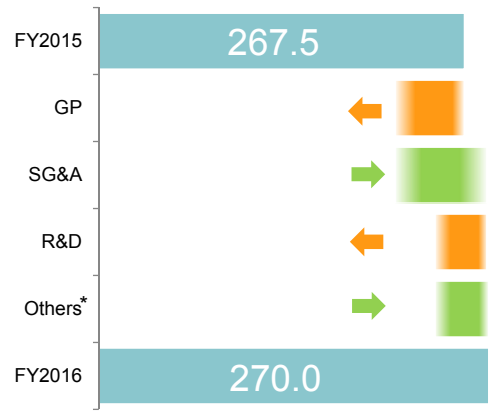
FY2016 Forecasts (Core Basis)

Sales decrease while OP increase (both show growth on a CER basis)
Fundamental business shows steady progress

Core OP analysis vs FY2015

(billion yen)



Net sales	4% growth excl. Fx impact of -71.7 bil Impact of NHI price revision: approx. -30.0 bil
Cost of sales	COGs ratio: Less than 1ppt lower vs FY2015
SG&A expenses	(Increase) US XTANDI co-promotion fee (Decrease) Fx rate SG&A ratio: Similar level to FY2015
R&D expenses	(Increase) Ocata's R&D expenses etc. R&D ratio: 17.1%
Core OP	9% growth excl. Fx impact of -22.3 bil Positive impact of global dermatology business transfer

Estimated Fx sensitivity of FY2016 forecasts by 1 yen appreciation**

Currency	Change	Net sales	Core OP
USD	1 yen	Approx. - 4.9 bil	Approx. - 0.8 bil
EUR	1 yen	Approx. - 2.7 bil	Approx. - 0.8 bil

*Amortisation of intangibles and share of profit of associates/JVs

**Sensitivity to fluctuation of Fx rates used for consolidation of overseas affiliates' results compared to forecast rates

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FY2016 Forecasts: Sales in Three Key Areas

Oncology : XTANDI drives continued franchise growth on a global basis
OAB: Betanis/Myrbetriq/BETMIGA sales to reach 100 billion yen
Transplantation: Steady business despite lower forecast due to Fx etc.

(billion yen)

	FY2015 ACT	FY2016 FCST	Change	(ref) CER growth
Oncology	**320.3**	**-***	**-**	**-**
XTANDI	252.1	295.9	+17%	+26%
OAB in Urology	**217.4**	**219.4**	**+1%**	+7%
Vesicare	135.6	119.1	-12%	-7%
Betanis/Myrbetriq/ BETMIGA	81.7	100.4	+23%	+30%
Transplantation	**203.6**	**187.9**	**-8%**	-2%

*Sales forecasts on Oncology franchise is not disclosed

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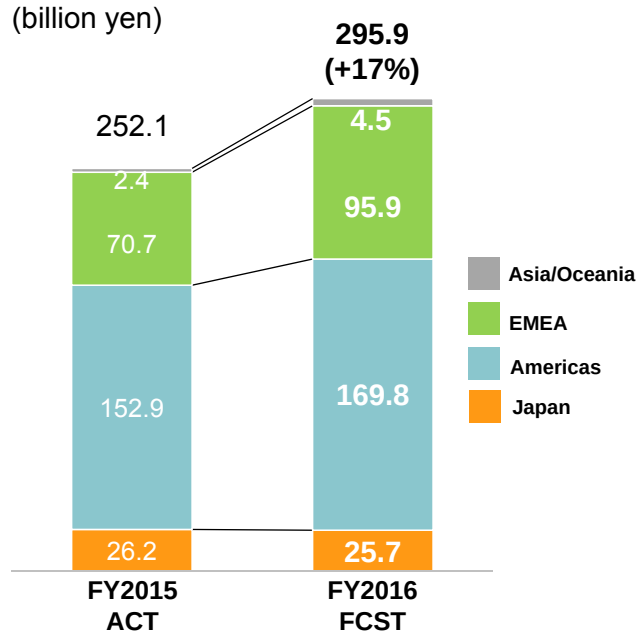
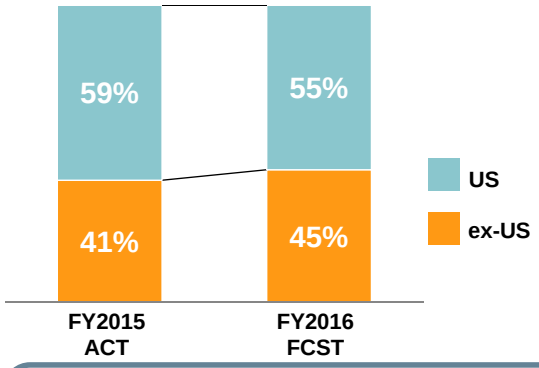
FY2016 Forecasts: XTANDI

Pursue further penetration in chemo-naive mCRPC indication
Expansion in ex-US regions to contribute to profit

Sales by region



Sales composition ratio by region



Year-on-Year sales growth

Japan:	- 2%
Americas:	+21% (USD basis)
EMEA:	+44% (EUR basis)
Asia/Oceania:	+104% (CER basis)

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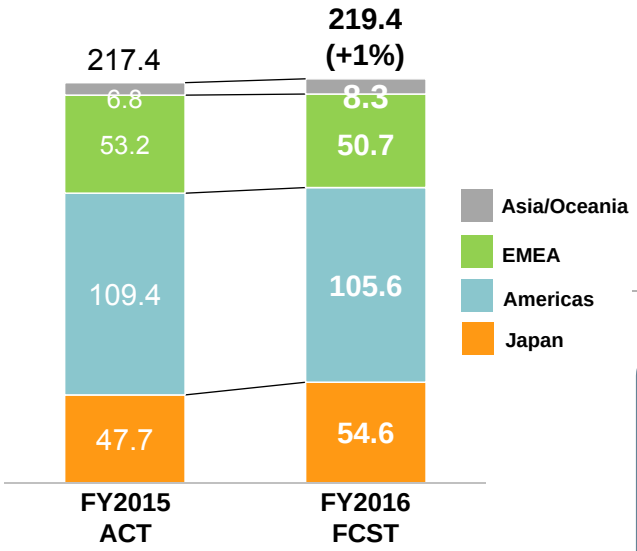
mCRPC: Metastatic castration-resistant prostate cancer

FY2016 Forecasts: OAB Franchise in Urology

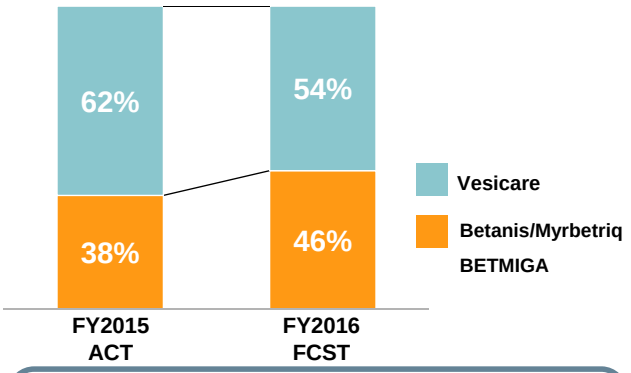
Betanis/Myrbetriq/BETMIGA penetration enhances OAB Franchise

Sales by region

(billion yen)



Sales composition ratio by product



Year-on-Year sales growth

Japan:	+14%
Americas:	+5% (USD basis)
EMEA:	+1% (EUR basis)
Asia/Oceania:	+35% (CER basis)

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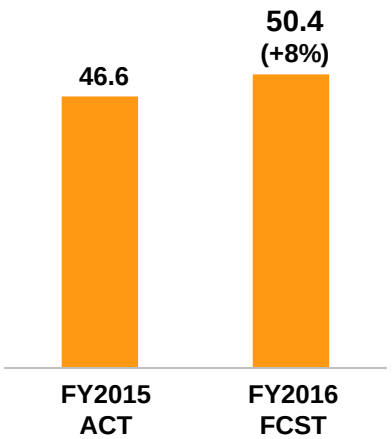
FY2016 Forecasts: Sales in Japanese Market

Growth drivers such as Celecox, Symbicort and Suglat expand sales
Sales in Japanese market decrease by 5.5% due to NHI price revision, etc.

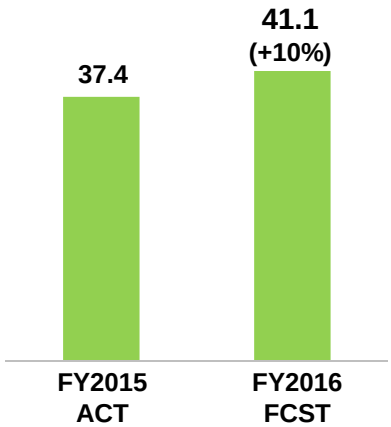
Celecox

(billion yen)



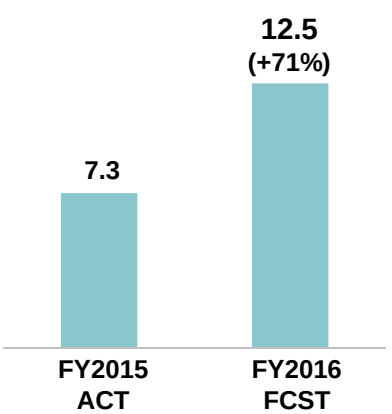
Symbicort

(billion yen)



Suglat

(billion yen)



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FY2016 Forecasts (Full Basis)

(billion yen)

	FY2015 ACT	FY2016 FCST	Change
Net sales	1,372.7	1,350.0	-1.7%
R&D expenses as % of sales	225.7 16.4%	231.0 17.1%	+2.4%
Operation profit	249.0	267.0	+7.2%
Profit before tax	261.8	268.0	+2.4%
Profit for the year	193.7	197.0	+1.7%
EPS (yen)	89.75	92.71	+3.3%

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Robust Pipeline of Astellas

Phase 1	Phase 2	Phase 3	Filed
ASP2205	YM311 (FG-2216) (Renal anemia, EU)	solifenacin (Pediatric NDO, US/EU)	solifenacin (Pediatric OAB, EU)
ASP6282	ASP8232 (Diabetic nephropathy)	solifenacin/mirabegron (Concomitant use, US/EU/Asia)	bixalomer (Granule formulation, JP)
YM311 (JP)	enzalutamide (Breast cancer, HCC)	mirabegron (Pediatric NDO, EU)	enzalutamide (Tablet, US/EU)
ASP7398	AGS-16C3F (Renal cell carcinoma)	roxadustat (Anemia associated with CKD, EU/JP)	ASP7374 (Seasonal influenza, JP)
ASP6294	ASP0113 (VCL-CB01) (CMV SOT)	enzalutamide (M0 CRPC, M0 BCR: US/EU/Asia, M1 HSPC: US/EU/JP/Asia)	linaclotide (IBS-C, JP)
ASG-22ME	ASKP1240 (Transplant, US)	degarelix (3-month, JP)	
ASG-15ME	ASP015K (US/EU)	gilteritinib (AML, US/EU/JP/Asia)	
ASP5878	ASP3662 (PDPN)	ASP8273 (NSCLC, US/EU/JP/Asia)	
AGS67E	ASP7962 (Osteoarthritis)	ASP0113 (VCL-CB01) (CMV HCT, US/EU/JP)	
ASP4132	ASP1707 (Endometriosis)	ASP015K (Rheumatoid arthritis, JP)	
gilteritinib (NSCLC)	linaclotide (Chronic constipation, JP)	quetiapine (BPD, JP)	
blinatumomab	ASP8232 (Diabetic macular edema)	romosozumab (Osteoporosis, JP)	
ASKP1240 (JP)	ipragliflozin (Type 1 diabetes, JP)	fidaxomicin (Infectious enteritis: JP, pediatric: EU)	
ASP5094	ASP7373 (Influenza H5N1, JP)	ipragliflozin/sitagliptin (Fixed dose combination, JP)	
ASP3662 (Alzheimer)	CK-2127107 (SMA, COPD)		
ASP4345	RPE cell program (Dry AMD etc.)		
ASP4070			
ASP0819			
ASP8062			
ASP7266			

Therapeutic area:

- Urology, Nephrology
- Oncology
- Immunology, Neuroscience
- Others
- New molecular/biological entity

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

NSCLC: Non-small cell lung cancer, HCC: Hepatocellular carcinoma, CMV: Cytomegalovirus, SOT: Solid organ transplant, PDPN: Painful diabetic peripheral neuropathy, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, AMD: Age-related macular degeneration, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, M1 HSPC: Metastatic hormone sensitive prostate cancer, AML: Acute myeloid leukemia, HCT: Hematopoietic cell transplant, BPD: Bipolar disorders, IBS-C: Irritable bowel syndrome with constipation

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Steady Progress in Development

Summary of changes from January to May 2016

*Regions show where studies are performed

P1 Entry → P2 Entry → P3 Entry → Filing → Approval

mirabegron
Neurogenic detrusor overactivity in pediatric patients
Europe

roxadustat
Anemia associated with chronic kidney disease
Japan

enzalutamide
Filed in Feb. 2016 in US, and in Mar. 2016 in Europe (New formulation)
Tablet
US/Europe

linaclotide
Filed in Feb. 2016
Irritable bowel syndrome with constipation
Japan

bixalomer
Kiklin
Approved in Feb. 2016 (New indication)
Hyperphosphatemia in patients with chronic kidney disease*
Japan

* Previous indication was hyperphosphatemia in patients on dialysis with chronic kidney disease. The label was extended to include hyperphosphatemia in patients not receiving dialysis.

Discontinuation

P1 project: ASP1707, Prostate cancer
ASP6858, Chronic kidney disease

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Oncology Pipeline

Stage in the most advanced territory

	Project	Target Cancer	Characteristics	P1	P2	P3	Filed
Small molecule	**enzalutamide (XTANDI)**	Prostate cancer (M0 CRPC, M0 BCR, M1 HSPC), Breast cancer, Hepatocellular carcinoma	Androgen receptor inhibitor	PC			
				BC, HCC			
	degarelix (Gonax)	Prostate cancer	GnRH antagonist	3-month: JP			
	ASP2215 gilteritinib	Acute myeloid leukemia, Non-small cell lung cancer	FLT3/AXL inhibitor	AML			
				NSCLC			
	ASP8273	Non-small cell lung cancer	Mutant-selective irreversible EGFR inhibitor				
	ASP5878	Solid tumors	FGFR inhibitor				
	ASP4132	Advanced cancer					
Antibody	**AGS-16C3F**	Renal cell carcinoma	Antibody utilizing ADC (target: ENPP3)				
	ASG-22ME	Solid tumors	Antibody utilizing ADC (target: Nectin-4)	To be presented at ASCO			
	ASG-15ME	Bladder cancer	Antibody utilizing ADC (target: SLITRK6)	To be presented at ASCO			
	AGS67E	Lymphoid malignancy	Antibody utilizing ADC (target: CD37)				
	AMG 103 blinatumomab	Acute lymphoblastic leukemia	Anti-CD19 BiTE antibody				

ADC: Antibody-drug conjugate, PC: Prostate cancer, BC: Breast cancer

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Enzalutamide: Development Progress

*The region where the study is performed

	Phase/Region*	Population	Design	P1	P2	P3
Prostate cancer	**P3 US/EU/Asia [PROSPER study]**	**M0 CRPC** Non-metastatic CRPC	Placebo-controlled, combination with ADT, 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		
	P3 US/EU/JP/Asia [ARCHES study]	**M1 HSPC** Metastatic hormone-sensitive prostate cancer	Placebo-controlled, combination with ADT, n=1,100	First Patient In: Mar. 2016		
Breast cancer	**P2 US/EU**	**Triple-negative** Advanced, androgen receptor-positive, triple-negative breast cancer	Open-label, n=118	Primary analysis done		
	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 breast cancer	Open-label, n=80	First Patient In: Sept. 2014		
HCC	**P2 US/EU/Asia**	**Hepatocellular carcinoma**	Placebo-controlled, n=144	First Patient In: Jan. 2016		

- Submitted sNDA for label update within current indication based on TERRAIN/STRIVE data in US
- Added TERRAIN data in summary of product characteristics (SmPC) in Europe

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

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Gilteritinib: Development Progress

*The region where the study is performed

	Phase/Region*	Population	Design	P1	P2	P3
AML	**P3 Global** ADMIRAL	**Relapsed or refractory** 1st relapsed or refractory, FLT3 mutation positive	Open-label, randomized Monotherapy vs salvage chemo (2:1), n=369	First Patient In: Oct. 2015		
	P1/2 US/EU CHRYSALIS	**Relapsed or refractory**	Dose-escalation and expansion, n=258	Enrollment completed		
	P1 JP	**Relapsed or refractory**	Dose-escalation and expansion	Enrollment completed		
	P2/3 Global LACEWING	**1st line intensive chemo ineligible** Newly diagnosed, FLT3 mutation positive	Open-label, randomized, 3 arms (monotherapy, combo with azacitidine and azacitidine alone), n=528	First Patient in: Expected in 1H/FY2016		
	P3 Global	**HSCT maintenance** FLT3-ITD positive	-	Under preparation Collaborating with Blood and Marrow Transplant – Clinical Trial Network (BMT-CTN)		
	P1 US	**1st line intensive chemo eligible** Newly diagnosed	Combination with induction and consolidation chemo			
	P1 JP	**1st line intensive chemo eligible** Newly diagnosed	Combination with induction and consolidation chemo			
NSCLC	**P1/2 US/JP**	EGFR activating mutation-positive, resistant to an EGFR inhibitor	Dose escalation and expansion, combination with erlotinib, n=90	First Patient In: Sept. 2015		

FLT3: FMS-like tyrosine kinase 3, ITD: Internal tandem duplication,
EGFR: Epidermal growth factor receptor

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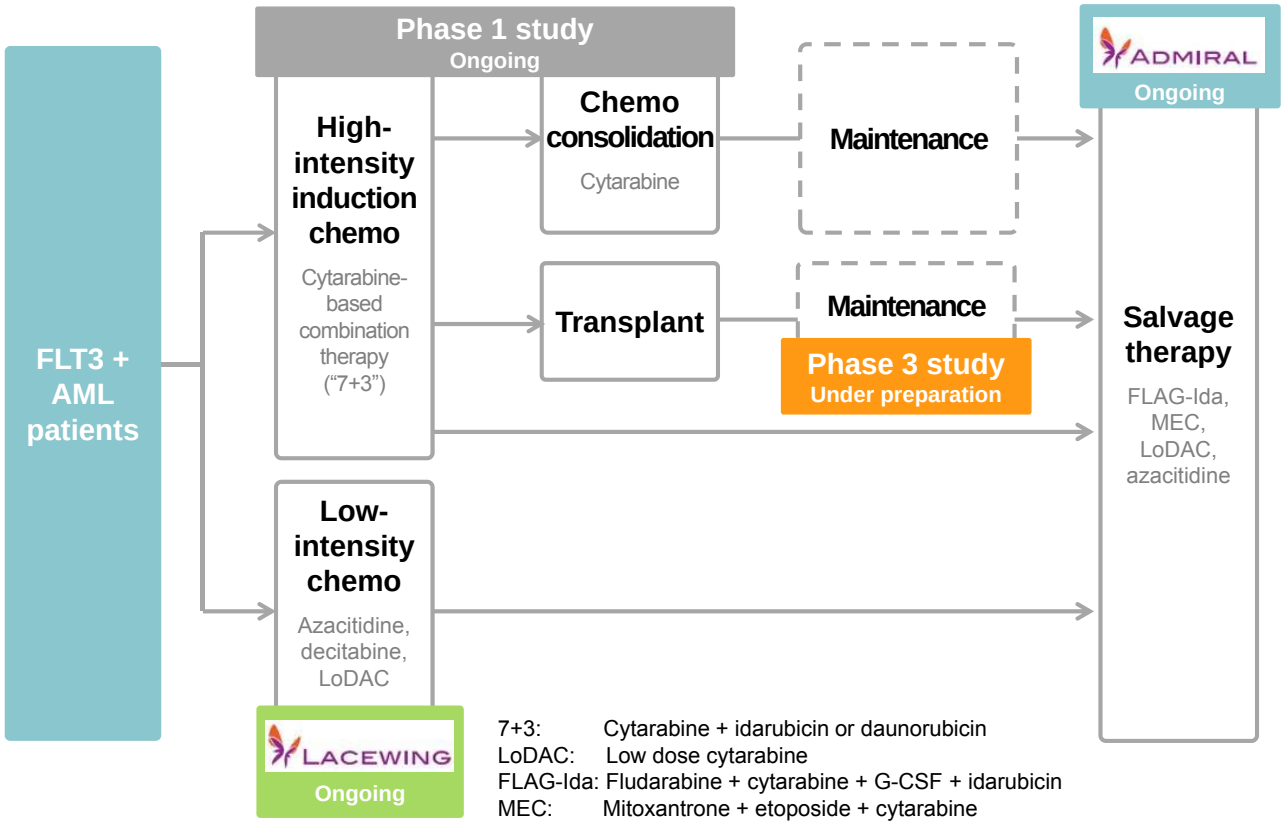
Gilteritinib: Treatment Landscape in AML



7+3: Cytarabine + idarubicin or daunorubicin
LoDAC: Low dose cytarabine
FLAG-Ida: Fludarabine + cytarabine + G-CSF + idarubicin
MEC: Mitoxantrone + etoposide + cytarabine

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Roxadustat: Moving Forward with Results from Two Phase 2 Studies in Japan

Results from Studies in Patients on Dialysis and Not on Dialysis

- Both studies supported dose selection for and progression to Phase 3.
- Roxadustat was well tolerated.

Overview of Phase 2 Non-dialysis Study

Target	Anemia in CKD patients not on dialysis (n=107)
Primary endpoint	Rate-of-rise in hemoglobin (Hb, g/dL/week) at Week 6
Dose	**Rate of rise in Hb (g/dL/week)** Adjusted difference (roxadustat – placebo), its 95% confidence interval, and p-value of pairwise comparison
50 mg TIW (n=27)	0.254 (0.143, 0.365), p<0.001
70 mg TIW (n=26)	0.508 (0.396, 0.619), p<0.001
100 mg TIW (n=27)	0.623 (0.512, 0.733), p<0.001
Placebo TIW (n=27)	-

Preparing Phase 3 studies in Japan

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Romosozumab: Obtained Top Line Results from Phase 3 FRAME and BRIDGE Studies

Top Line Results

	FRAME (Pivotal)	BRIDGE
Population	Post-menopausal women with osteoporosis (n=7,180)	Men with osteoporosis (n=245)
Design	Double-blind, placebo-controlled	Double-blind, placebo-controlled
Duration	Romosozumab or placebo treatment for 12 months followed by denosumab treatment in both arms in months 12-24	12 months
Results	• **Met the co-primary endpoints by reducing the incidence of new vertebral fracture through months 12 and 24** • Also met the secondary endpoint of reducing the incidence of clinical fractures* through 12 months • Did not meet the secondary endpoint of reducing the incidence of non-vertebral fractures through months 12 and 24 • The percentages of patients with AEs and SAEs in the 12-month and 24-month in both arms were balanced overall between the treatment groups.	• **Met the primary endpoint by increasing BMD at the lumbar spine over placebo at 12 months** • Also met all the secondary endpoints of increasing BMD at the femoral neck and total hip at 12 months and increasing BMD at the lumbar spine, femoral neck and total hip at 6 months over placebo • The overall patient incidence of AEs and SAEs was generally balanced between arms.

*Clinical fractures: Composite of symptomatic vertebral and non-vertebral fractures

Potential NDA anticipated in FY2016

AEs: Adverse events, SAEs: Serious adverse events,
BMD: Bone mineral density

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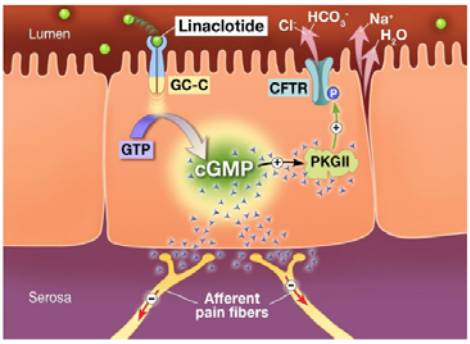
Linaclotide: NDA Submitted in Japan

IBS-C

- Functional disease causing abdominal pain and/or discomfort with abnormal defecation
- 2.9%* of adults are estimated to suffer from IBS-C in Japan, with no approved medicines

Linaclotide



- Activates GC-C receptor on the luminal surface of intestinal epithelium
- Increases intestinal fluid secretion and accelerates intestinal transit, and improves visceral hypersensitivity
- Phase 3 in Japan showed statistically significant improvement compared to placebo for both of the co-primary endpoints. Linaclotide was generally well-tolerated.

Development Progress in Chronic Constipation

- Top-line data showed statistically significant improvement compared to placebo for the primary endpoint of change in weekly mean SBM frequency during 1 week. Linaclotide was well tolerated in all dose groups within this study.

NDA submitted in Japan for IBS-C in February 2016

SBM: Spontaneous bowel movement

**Neurogastroenterol Motil.* 2011 Mar;23(3):249-54.

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FY2015 Progress of Late Phase Compounds

	Phase 3	Filing	Approval	Launch
US	XTANDI New formulation			
	XTANDI			
	VESIcare			
	ASP0113			
	EB178			
	gilteritinib			
	ASP8273			
Europe	New indication			Qutenza (capsaicin) 8% patch
	Vesicare pediatric			
	XTANDI New formulation			
	roxadustat			
	XTANDI			
	ASP0113			
	EB178			
	Dificlir			
	gilteritinib			
	ASP8273			
	BETMIGA			cimzia (certolizumab pegol)
Japan	New indication			Irribow
	New indication			
				Repatha (evolocumab)
	New indication			
	ASP7374			
	Kiklin New formulation			Kiklin
	linaclotide			
	Seroquel			
	Gonax			
	romosozumab			
	fidaxomicin			
	ASP0113			
	ASP015K			
	gilteritinib			
	XTANDI			
	ASP8273			
	ipragliflozin/sitagliptin			
Asia	roxadustat			
	XTANDI, Eligard, BETMIGA, Suglat, Feburic were approved and launched in Asian countries			

>>>: Progress since April 2015

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FY2016 Expected Key Pipeline Events

*Subject to internal assessment, decision and regulatory consultation, as appropriate

Data Readouts and Phase Transition*

Data Readouts

- **Solifenacin/mirabegron**
  Phase 3 long term study (SYNERGY II)
- **Enzalutamide**
  Phase 2 in ER/PgR+ breast cancer
- **ASP0113:**
  Phase 2 in solid organ transplants
- **ASP3662:** Phase 2 in PDPN
- **ASP8232:** Phase 2 in DME
- **Gilteritinib:**
  Phase 1/2 final results in AML
- **ASP8273:**
  Phase 1/2 final results in NSCLC

Phase Transition

- **Enzalutamide:** TNBC to Phase 3
- **Linaclotide:** CC to Phase 3

Filing*

- **Solifenacin:**
  Pediatric OAB
  (US)
- **Enzalutamide**
  Tablet (Japan)
- **Degarelix:**
  3-months formulation
  (Japan)
- **Romosozumab:**
  Osteoporosis
  (Japan)
- **Quetiapine:**
  BP-D
  (Japan)
- **Fidaxomicin:**
  CDI (Japan)

Regulatory Decisions

- **Enzalutamide:**
  TERRAIN/STRIVE
  (US)
  Tablet (US/Europe)
- **Solifenacin:**
  Pediatric OAB
  (Europe)
- **Bixalomer:**
  Granule formulation
  (Japan)
- **Linaclotide:**
  IBS-C
  (Japan)
- **ASP7374:**
  Seasonal influenza
  (Japan)

PDPN: Painful diabetic peripheral neuropathy, DME: Diabetic macular edema, TNBC: Triple negative breast cancer, CC: Chronic constipation, BP-D: Bipolar disorder, depressive episodes, CDI: *Chrostridium difficile* infection, IBS-C: Irritable bowel symptom with constipation

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I. Full Year FY2015 Highlights

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Achieving Sustainable Growth

(same as Strategic Plan 2015-2017 slide)

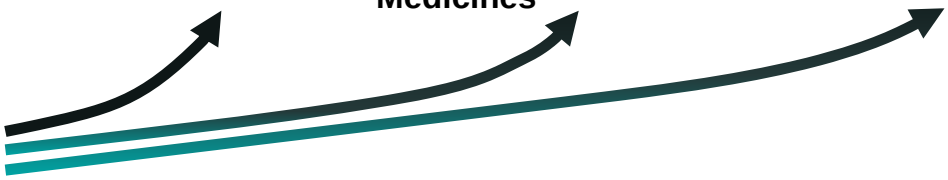
**New products will drive mid-term growth;
Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation**

Creating Innovation

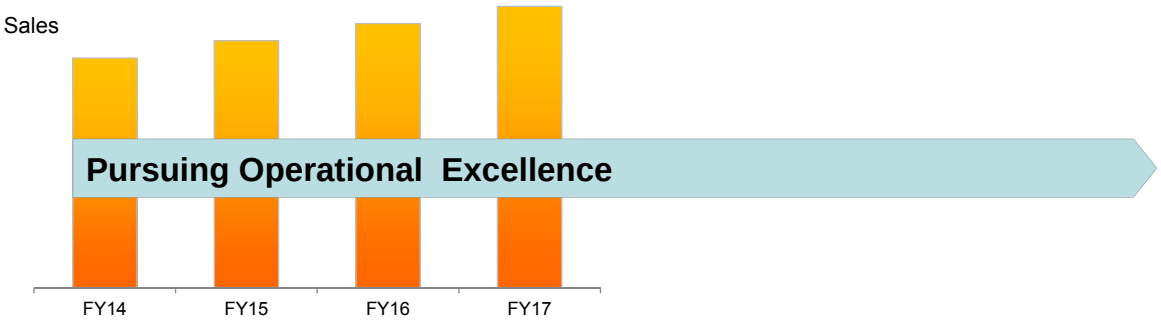
Maximizing the Product Value

Enhancing Capabilities to Deliver Innovative Medicines

Advancing into New Opportunities



Explore and capture external business opportunities through acquisition, collaboration and in-licensing



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Strategic Priorities and Recent Activities

(Update from previous announcement)

Maximize the Product Value

- Enhance oncology franchise (XTANDI sales growth, label expansion)
- Maximize OAB franchise (expansion of Vesicare + Betanis/ Myrbetriq/BETMIGA)
- New product launches in many countries (e.g. Repatha in Japan)

Create Innovation

- Completion of acquisition of Ocata Therapeutics, Inc.
  Ophthalmology | Regenerative medicine
- Collaboration with CLINO Ltd. for gene therapy for retinitis pigmentosa
  Ophthalmology
- Share of compound libraries with Mitsubishi Tanabe Pharma Corporation

Pursue Operational Excellence

[Optimal allocation of resources]

- Completion of transfer of global dermatology business to LEO Pharma A/S

[Continually enhance organization structure]

- Establishment and start of operations of Malaysia subsidiary and umbrella organization covering South East and South Asia regions

[Active preparation for various regulations and societal standards (compliance)]

- Establishment of a new function “Ethics & Compliance”

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Maximize the Product Value

Continuous Introduction of New Products

(Efforts from April 2015 onward)

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

EMEA

XTANDI
- Post-chemo indication Launch (Lebanon, Macedonia, Azerbaijan, Qatar, Serbia, Estonia)
- Chemo-naive indication Launch (France, Switzerland, Spain, Portugal, Slovenia, Hungary, Luxembourg, Belgium, Finland, Greece, Ireland, Italy)

BETMIGA:
- Launch (Croatia, France, Russia, Israel, Lebanon, Jordan)

VESOMNI
- Launch (Finland, Greece, Slovenia, Italy, Armenia, Azerbaijan, Georgia, Moldova, Turkmenistan, Kazakhstan, Ireland, Bulgaria, Hungary, Romania, Russia)

QUTENZA
- Label expansion (Diabetic patients)

Japan

REPATHA
- Launch

ORFADIN
- Launch

CIMZIA
- Label expansion (DMARD-naive RA)

IRRIBOW
- Label expansion (Female patients)

KIKLIN
- Label expansion (Patients not on dialysis)

Americas

XTANDI
- Post-chemo indication Launch (Uruguay, Brazil, Ecuador*, Peru*)
- Chemo-naive indication Launch (Uruguay, Canada, Paraguay, Ecuador*, Peru*)

BETMIGA:
- Launch (Peru)

CRESEMBA
- Launch (US)

VESOMNI
- Launch (Argentina, Brazil)



No. of countries/areas where the following have been launched:
XTANDI: Approx. 60
BETANIS / MYRBETRIQ / BETMIGA: Approx. 50

Asia/Oceania

XTANDI
- Post-chemo indication Launch (Philippines, Hong Kong, Singapore, Macau), Approval (New Zealand, Taiwan*)
- Chemo-naive indication Launch (Republic of Korea, Philippines), Approval (Taiwan*, Hong Kong, Australia)

BETMIGA
- Launch (Singapore, Thailand, Malaysia)

ELIGARD
- Launch (Taiwan)

SUGLAT
- Launch (Republic of Korea)

FEBURIC
- Launch (Thailand), Approval (Singapore)

*Post-chemo/chemo-naive simultaneous approval / launch

DMARD: Disease modified anti-rheumatic drug
RA: Rheumatoid arthritis

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Maximize the Product Value

Repatha: Launched in Japan as the 1st PCSK9 Inhibitor

Launch date

April 21, 2016

Indication

The treatment of patients with familial hypercholesterolemia or hypercholesterolemia who have high risk of cardiovascular events and are not adequately controlled by HMG-CoA reductase inhibitors

Precautions related to dosage and administration
Repatha should be administered as an adjunct to HMG-CoA reductase inhibitor therapy.
[Efficacy and safety of Repatha monotherapy in Japanese patients not confirmed.]

* The official guidance of point to consideration regarding Repatha under the coverage of National Health Insurance is issued by Medical Affairs Division of Ministry of Health, Labour and Welfare.



Started co-promotion by Amgen Astellas Biopharma (AABP) and Astellas as the 1st product of AABP

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Create Innovation

Develop New Therapeutic Areas and Novel Technology Platform

(●: Updates from the previous announcement)

Pursue "Best Science" with "Best Talent" in "Best Place"



*Gene therapy for retinitis pigmentosa

** Formerly known as Ocata Therapeutics, Inc.

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Create Innovation

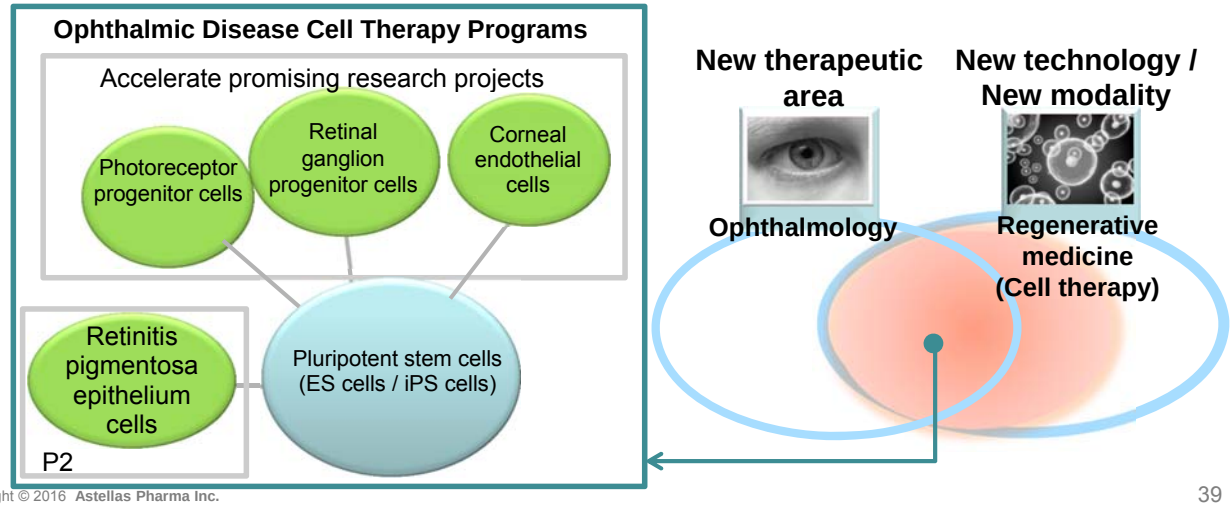
Astellas Institute for Regenerative Medicine (*fka* Ocata Therapeutics, Inc.) Pursues Activation Plan

New step forward in ophthalmology and regenerative medicine (RM)

Integration Status

- Created new leadership team
- Confirmed strong capability and programs. Promotes following activation plan;
  - Positioned as a hub of RM and R&D in Ophthalmology
  - Enhanced FTE and budget
  - Achieved retention of key employees

R&D Programs



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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**

	FY2014	FY2015	FY2016 (Forecast)
Core EPS	69.37 yen	92.12 yen	93.65 yen
Dividends per Share	30 yen	32 yen (planned)	34 yen
ROE	10.5%	15.0%	-
DOE	5.1%	5.4%	-
Share Buybacks*	38 million shares (58.2 billion yen)	68 million shares (119.3 billion yen)	Implemented in a flexible manner
Cancellation of Treasury Shares	25 million shares	38 million shares	-

*Excluding amounts for the buyback of shares consisting less than one unit

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Creating Social Value

Solve problems related to Access to Health, harnessing our strengths and taking advantage of partnerships with other organizations

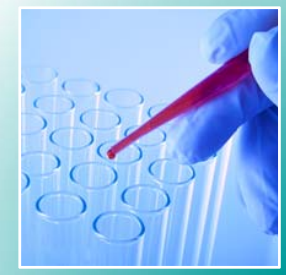
Resolve social issues and enhance our corporate reputation over the long-term

Joint drug-discovery research for NTDs

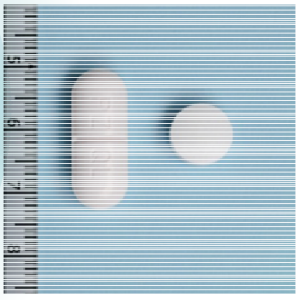
- New collaborative research agreement with National Institute of Advanced Industrial Science and Technology (AIST) for anti-protozoan parasite drugs for the treatment of Chagas' disease

AIST

Core business activities



Development of Pediatric Formulation for Schistosomiasis



NTDs: Neglected Tropical Diseases

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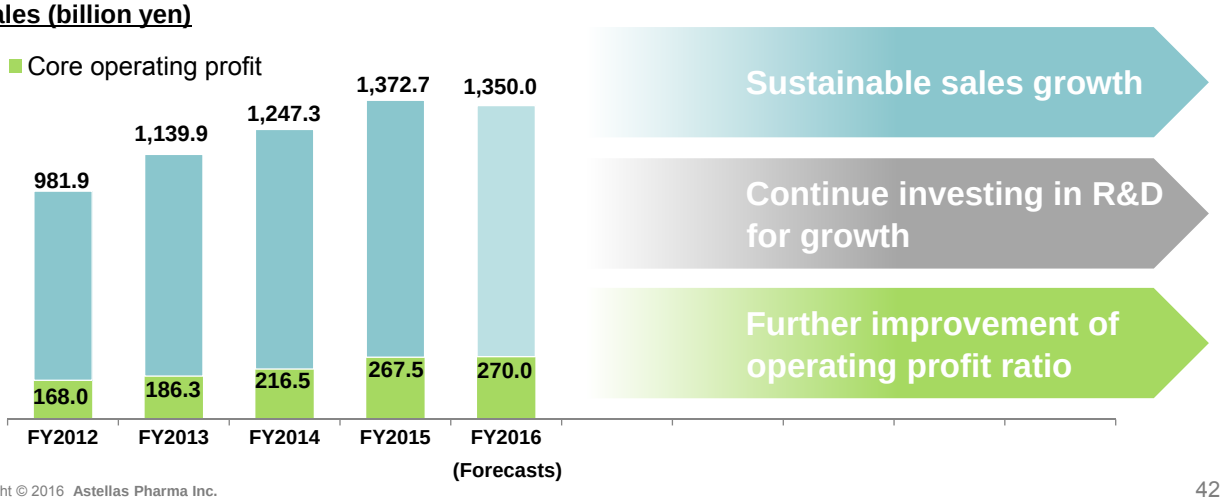
Realize Sustainable Growth

Resiliently respond to the changing environments and aim for sustainable growth

- Business goes favorably, driven by XTANDI and OAB products
- Continue investing in R&D for creating innovation that is source of future growth
- Work toward higher quality and efficiency of operations through optimization of resources and enhancement of organizational structure

Sales (billion yen)



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Schedule (Planned)

	Date
1Q Earnings Call	July 29, 2016
2Q Earnings Conference	October 28, 2016
R&D Meeting	December 2016
3Q Earnings Call	January 31, 2017

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Reconciliation of Full Basis to Core Basis

(billion yen)

	FY14			FY15		
	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	**1,247.3**	**-**	**1,247.3**	**1,372.7**	**-**	**1,372.7**
Cost of sales	333.2	-	333.2	335.6	-	335.6
Gross profit	**914.1**	**-**	**914.1**	**1,037.1**	**-**	**1,037.1**
SG&A expenses	452.5	-	452.5	500.4	-	500.4
R&D expenses	206.6	-	206.6	225.7	-	225.7
Amortisation of intangible assets	38.7	-	38.7	42.4	-	42.4
Share of profits/losses of associates and joint ventures	0.2	-	0.2	-1.2	-	-1.2
Other income *1	12.5	-12.5	-	1.7	-1.7	-
Other expense *1	43.3	-43.3	-	20.2	-20.2	-
Operating profit	**185.7**	**30.8**	**216.5**	**249.0**	**18.5**	**267.5**
Finance income *2	7.1	-5.1	1.9	14.4	-12.3	2.1
Finance expense *2	3.1	-2.7	0.4	1.6	-0.6	1.0
Profit before tax	**189.7**	**28.4**	**218.1**	**261.8**	**6.8**	**268.6**
Income tax expense	53.8	11.0	64.8	68.1	1.7	69.8
Profit for the year	**135.9**	**17.4**	**153.2**	**193.7**	**5.1**	**198.8**

*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.

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