Financial Results for 2Q/FY2015

Ended March 31, 2016

October 30, 2015
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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Financial Results for 2Q/FY2015 (Core Basis)

(Billion YEN)

2Q/FY2015: From Apr. 2015 through Sept. 2015

	2Q/FY2014 Results	2Q/FY2015 Results	Change %	FY2015 Initial Forecasts#	Progress per Forecasts %
Sales	594.5	687.5	+15.7%	1,362.0	50.5%
COGs as % of sales	159.1 26.8%	168.4 24.5%	+5.8%		
SG&A expenses as % of sales	201.8 33.9%	239.7 34.9%	+18.8%		
R&D expenses as % of sales	97.0 16.3%	112.0 16.3%	+15.5%	229.0 16.8%	48.9%
Amortisation of intangible assets	17.9	21.9	+22.1%		
Share of profits of associates and joint ventures	0.5	-0.3	-		
Core operating profit	119.2	145.2	+21.8%	238.0	61.0%
Core profit for the period	81.1	103.9	+28.2%	170.0	61.1%

#Announced with FY2014 financial results in May 2015

Exchange Rates (YEN)

[Average for terms]	2Q/FY2014	2Q/FY2015	Change	FY2015 Forecasts
USD	103	122	19 weakening of YEN	120
EUR	139	135	4 strengthening of YEN	125

[Change from beginning to end of terms]	2Q/FY2014	2Q/FY2015
USD	7 weakening of YEN	0 strengthening of YEN
EUR	3 strengthening of YEN	5 weakening of YEN

Depreciation and amortisation
- -2Q/FY2014: 31.4
- -2Q/FY2015: 35.1

Forex impact
- -Sales: +36.0
- -Core operating profit: +9.6

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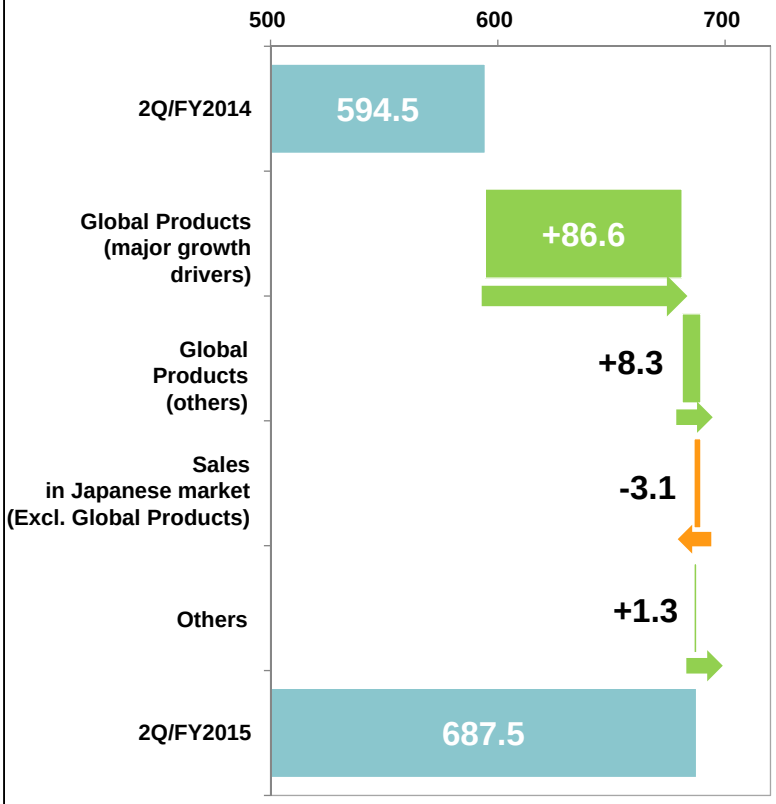
Results of 2Q/FY2015: Analysis of Change in Sales (vs. 2Q/FY2014)



Sales: +93.0

Forex impact: +36.0

- XTANDI +67.7/ Vesicare and Betanis/Myrbetriq/BETMIGA +18.9
- Eligard -0.6/ Harnal -0.3/ Prograf +9.4/ Funguard/MYCAMINE +2.6/ Protopic -2.8
- New Products and Growing Products +11.0/ Micardis +1.4/ Lipitor -3.1/ Gaster -1.8
- Scan +8.4/ Tarceva +0.8/ Other EMEA* products etc. -7.9

*Europe, Middle East and Africa

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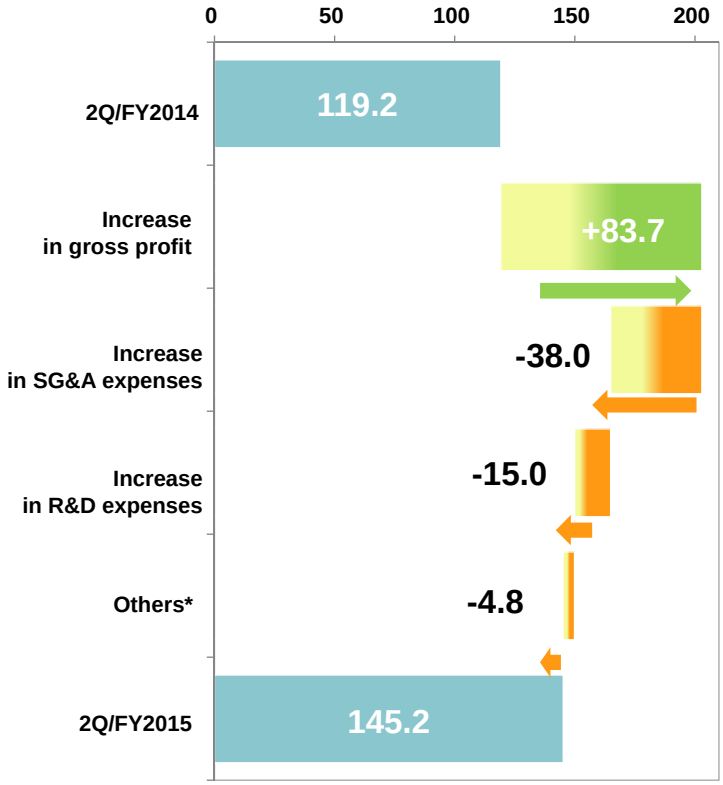
Results of 2Q/FY2015: Analysis of Change in Core Operating Profit (vs. 2Q/FY2014)



(Billion YEN)

Core operating profit: +26.0

Forex impact: +9.6

Increase in sales: +93.0
Increase in COGs: -9.3
Increase in COGs ratio: -2.3ppt (26.8%→24.5%)
- Change in product mix etc.: -2.3ppt
- Forex impact on elimination of unrealized gain: +0.0ppt

- 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

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Financial Results for 2Q/FY2015 (Full Basis)

(Billion YEN)

	2Q/FY2014 Results	2Q/FY2015 Results	Change %	FY2015 Initial Forecasts#	Progress per Forecasts %
Sales	594.5	687.5	+15.7%	1,362.0	50.5%
COGs as % of sales	159.1 26.8%	168.4 24.5%	+5.8%		
SG&A expenses as % of sales	201.8 33.9%	239.7 34.9%	+18.8%		
R&D expenses as % of sales	97.0 16.3%	112.0 16.3%	+15.5%	229.0 16.8%	48.9%
Amortisation of intangible assets	17.9	21.9	+22.1%		
Share of profits of associates and joint ventures	0.5	-0.3	-		
Other income	4.9	0.9	-81.7%		
Other expense	20.8	13.4	-35.6%		
Operating profit	103.2	132.6	+28.5%	238.0	55.7%
Financial income	2.3	13.3	+488.2%		
Financial expense	2.8	0.6	-79.6%		
Profit before tax	102.7	145.4	+41.6%	239.0	60.8%
Profit for the period	70.0	102.9	+47.1%	170.0	60.5%

Other expense: 13.4
- Loss on sales and disposal of property, plant and equipment: 6.6
  (Buildings of Kashima Office etc., Booked in 1Q)
- Net foreign exchange losses: 5.9
  (RUB basis transactions etc.)

Financial income: 13.3
- Gain on sales of available-for-sales financial assets: 12.1
  (Gain on sales of securities etc.)

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#Announced with FY2014 financial results in May 2015

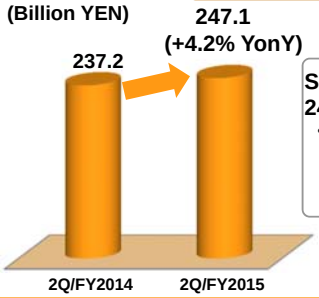
Sales by Region (Local Currency Basis)

Calculated based on the location of the seller

Sales increase in all the regions of Japan, Americas, EMEA and Asia/Oceania

Japan

(Billion YEN)



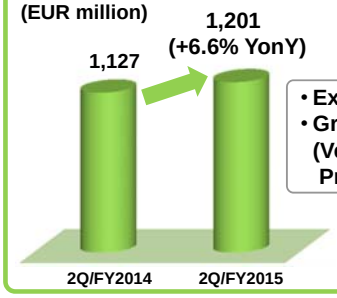
Sales in Japanese market:
240.0 bn YEN (+4.6% YonY)
- Growth of New Product Group and Growing Product Group exceeding generic impact



EMEA*

*Europe, Middle East and Africa

(EUR million)

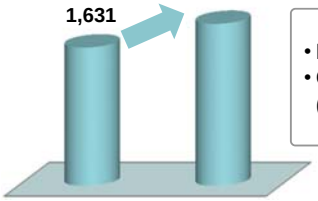


- Expansion of XTANDI
- Growth of OAB products (Vesicare and BETMIGA) and Prograf



Americas

(USD million)

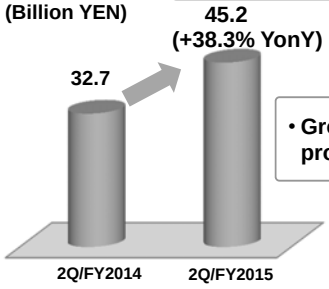


- Expansion of XTANDI
- Growth of OAB products (VESIcare and Myrbetriq)



Asia/Oceania

(Billion YEN)



+23.6% YonY
(Excl. forex impact)

- Growth of all the mainstay products



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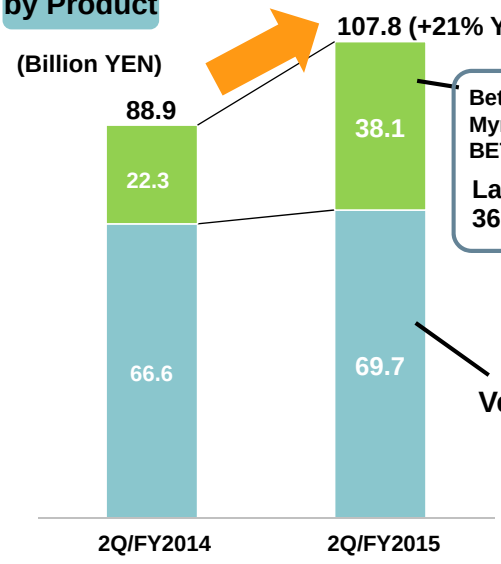
Overactive Bladder Franchise in Urology

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

Total sales of Vesicare and Betanis/Myrbetriq/BETMIGA

by Product

(Billion YEN)

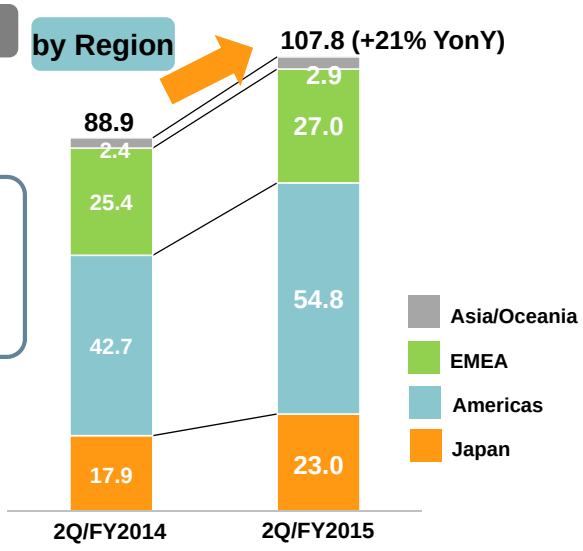


Betanis (Japan)
Myrbetriq (Americas)
BETMIGA (EMEA etc.)
Launched in
36 countries/areas

Vesicare

OAB: Overactive Bladder

by Region



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

-Japan: +29%
-Americas: +8% (USD basis)
-EMEA: +9% (EUR basis)
-Asia/Oceania: +11% (Excl. forex impact)

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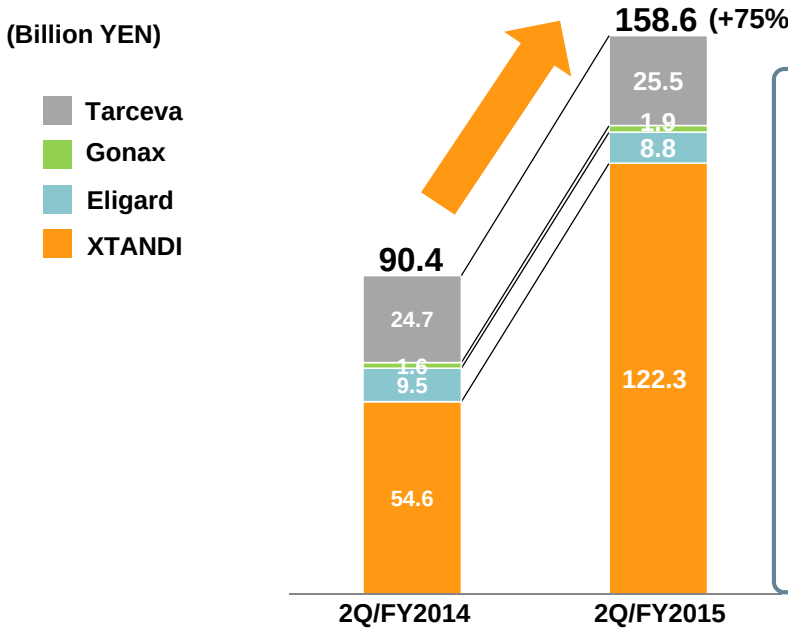
Oncology Franchise

Significant expansion of oncology franchise driven by XTANDI

Total sales of XTANDI, Tarceva, Eligard and Gonax



XTANDI
- Japan: 13.1 billion Yen
- Americas: USD 630 million
- EMEA: EUR 233 million
- Asia/Oceania: 1.0 billion Yen

Launched in 46 countries/areas

Eligard
- EMEA: EUR 65 million
  -5% YonY (EUR basis)

Tarceva-related revenues
- USD 210 million
  -13% YonY (USD basis)

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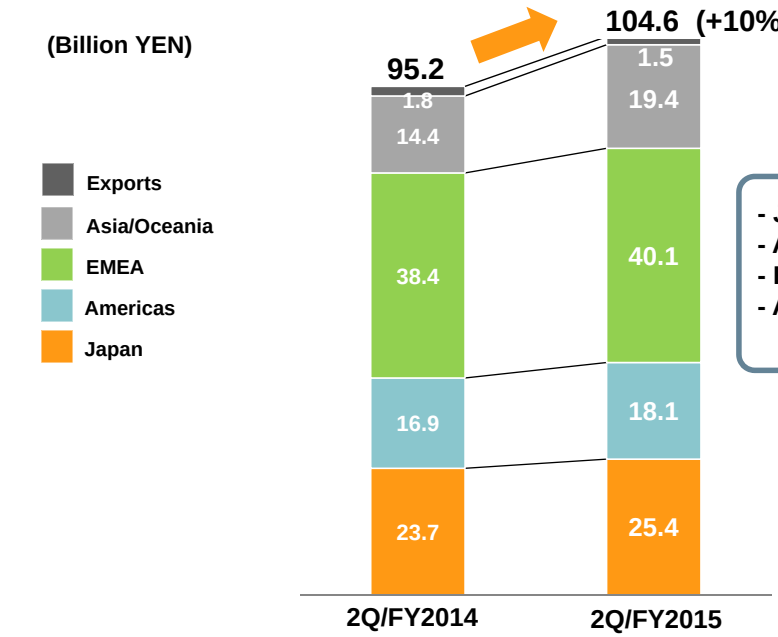
Transplantation Franchise

Maintaining global sales by growth in Japan, EMEA and Asia/Oceania

Total sales of Prograf and Advagraf/Graceptor/ASTAGRAF XL



[YonY]
- Japan: +7%
- Americas: -10% (USD basis)
- EMEA: +8% (EUR basis)
- Asia/Oceania: +20% (Excl. forex impact)

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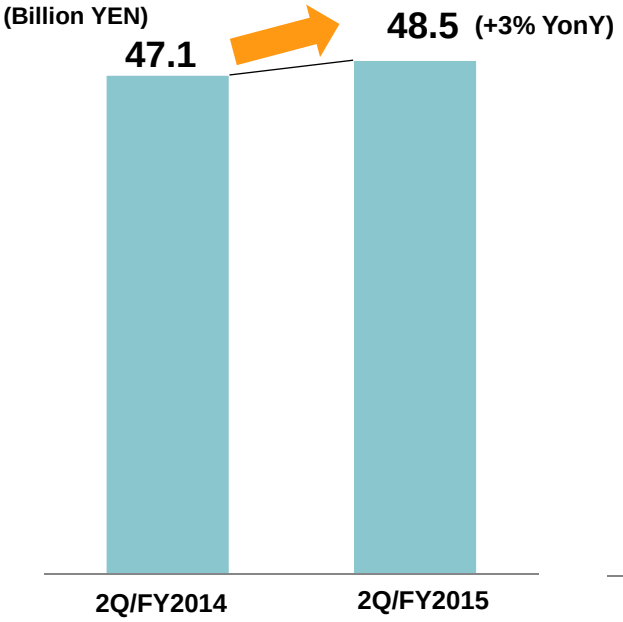
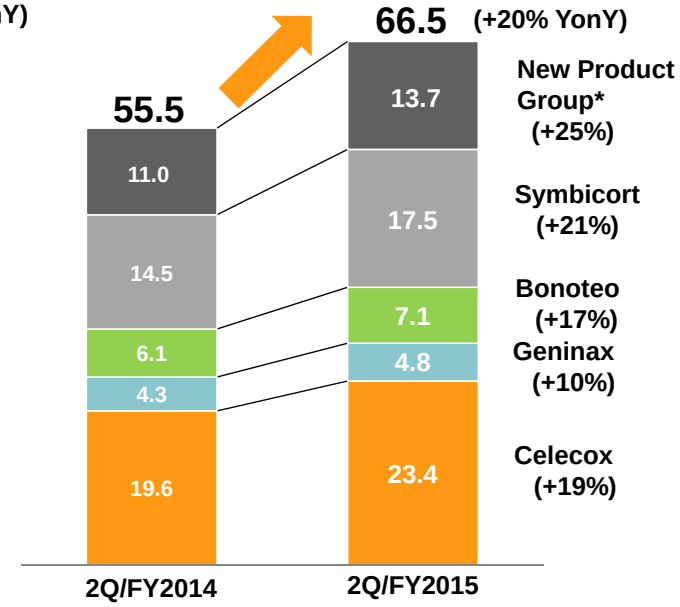
Major Products in Japan (Excluding Global Products)

Steady growth of New Product Group and Growing 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)

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Revised Forecasts for FY2015 (Core Basis)

Based on 2Q/FY2015 results and Forex trend, revised initial forecasts

(Billion YEN)

	FY2015 Initial Forecasts	FY2015 Revised Forecasts	Change
Sales	1,362.0	1,384.0	+22.0
R&D expenses as % of sales	229.0 16.8%	238.0 17.2%	+9.0
Core operating profit	238.0	244.0	+6.0
Core profit for the year	170.0	175.0	+5.0
Core EPS (YEN)	78.08*	80.76	

Exchange Rates [Average for Terms] (YEN)

USD	120	121
EUR	125	133

Forecasted exchange rates from 3Q/FY2015 onwards: 120 USD/YEN, 130 EUR/YEN

Upward revision of forecast for sales

by Product
- Upward revision for XTANDI, Prograf and Lexiscan
- Downward revision for local products in Japan such as Micardis, Celecox and Suglat

by Region (Billion YEN)
- Japan: -17.2
- Americas: +12.3
- EMEA: +25.7
- Asia/Oceania: +1.3

Upward revision of forecast for core operating profit

Gross profit: Higher than initial expectation
- Upward revision of forecast for sales
- COGs ratio: Lower than initial expectation (Change in product mix)

SG&A: Higher than initial expectation
- Increased expenditures for co-promotion of XTANDI in US etc.

R&D expenses: Higher than initial forecast

Forex impact on initial forecasts (Billion YEN)
- **Sales: +19.9**
- **Core operating profit : +3.9**

*Updated at 1Q/FY2015 earnings disclosure, taking into account of share buyback conducted from May to July, etc.

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Revised Forecasts for FY2015 (Full Basis)

Based on 2Q/FY2015 results and forex trend, revised initial forecasts

(Billion YEN)

	FY2015 Initial Forecasts	FY2015 Revised Forecasts	Change
Sales	**1,362.0**	**1,384.0**	**+22.0**
R&D expenses as % of sales	**229.0** 16.8%	**238.0** 17.2%	**+9.0**
Operating profit	**238.0**	**229.0**	**-9.0**
Profit before tax	**239.0**	**242.0**	**+3.0**
Profit for the year	**170.0**	**172.0**	**+2.0**
EPS (YEN)	**78.08***	**79.37**	

Downward revision of forecast for Core operating profit
- Expects Other expense of 16.0 billion YEN

Upward revision of forecast for Profit before tax and Profit for the year
- Expects Financial income/expense (net) of +13.0 billion YEN

Exchange Rates [Average for Terms] (YEN)

USD	120	121
EUR	125	133

Forecasted exchange rates from 3Q/FY2015 onwards:
120 USD/YEN, 130 EUR/YEN

*Updated at 1Q/FY2015 earnings disclosure, taking into account of share buyback conducted from May to July, etc.

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R&D Pipeline

Robust Pipeline of Astellas

Phase 1	Phase 2	Phase 3	Filed
mirabegron (Pediatric)	roxadustat (JP)	solifenacin (Pediatric NDO, US/EU)	solifenacin (Pediatric OAB, EU)
ASP2205	YM311 (FG-2216) (Renal anemia, EU)	solifenacin/mirabegron (Concomitant use, US/EU/Asia)	bixalomer (Not on dialysis, JP)
ASP6282	ASP8232 (Diabetic nephropathy: EU)	roxadustat (Anemia associated with CKD, EU)	bixalomer (Granule formulation, JP)
YM311 (JP)	enzalutamide (Breast cancer, HCC, US/EU)	enzalutamide (M0 CRPC, M0 BCR, US/EU/Asia)	ASP7374 (Seasonal influenza, JP)
ASP6858	AGS-16C3F (Renal cell carcinoma, US/EU)	degarelix (3-month, JP)	evolocumab (Hypercholesterolemia, JP)
ASG-22ME	ASP0113 (VCL-CB01) (CMV SOT, US/EU)	gilteritinib (ASP2215) (AML, US/EU/JP/Asia)	
ASP1707 (Prostate cancer, EU)	ASKP1240 (Transplant, US)	ASP8273 (NSCLC, US/EU/JP/Asia)	
ASG-15ME	ASP015K (Rheumatoid arthritis, US/EU)	ASP0113 (VCL-CB01) (CMV HCT, US/EU/JP)	
ASP5878	ASP3662 (PDPN, US)	ASP015K (Rheumatoid arthritis, JP)	
AGS67E	ASP7962 (Osteoarthritis, EU)	quetiapine (BPD, JP)	
ASP4132	ASP1707 (Endometriosis, EU/JP)	romosozumab (Osteoporosis, JP)	
gilteritinib (ASP2215) (NSCLC, US/JP/Asia)	linaclotide (Chronic constipation, JP)	linaclotide (IBS-C, JP)	
blinatumomab	ASP8232 (Diabetic macular edema: US)	fidaxomicin (Infectious enteritis: JP, pediatric: EU)	
ASKP1240 (JP)	ipragliflozin (Type 1 diabetes, JP)	isavuconazonium sulfate (Candidemia, US)	
ASP5094	ASP7373 (Influenza H5N1, JP)	ipragliflozin/sitagliptin (Fixed dose combination, JP)	
ASP3662 (Alzheimer, US)	CK-2127107 (SMA, COPD, US)		
ASP4345			
ASP4070			
ASP0819			
ASP8062			

Therapeutic area:

- Urology, Nephrology
- Oncology
- Immunology, Neuroscience
- 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, HCC: Hepatocellular carcinoma, CMV: Cytomegalovirus, SOT: Solid organ transplant, PDPN: Painful diabetic peripheral neuropathy, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, 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 July to October

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

P1 Entry

ASP0819
Fibromyalgia

ASP8062
Fibromyalgia

P2 Entry

AGS-16C3F
Renal cell carcinoma
US/Europe

ASP7962
Osteoarthritis
Europe

CK-2127107
Chronic obstructive pulmonary disease
US

P3 Entry

ASP8273
Non-small cell lung cancer
US/Europe/Japan/Asia

Ipragliflozin/Sitagliptin
Fixed dose combination
Japan

Filing

solifenacin YM905
Filed in Sept. 2015 (Pediatric use)
Overactive bladder in pediatric patients of 5-18 years
Europe

bixalomer ASP1585
Filed in Sept. 2015 (New formulation)
Hyperphosphatmeia in patients on dialysis with chronic kidney disease (granule formulation)
Japan

Approval

capsaicin patch
Qutenza
Approved in Aug. 2015 (New indication)
Peripheral neuropathic pain in adults*
Europe

* Previous indication was peripheral neuropathic pain in non-diabetic adults. The label was extended to include adult diabetic patients with peripheral neuropathic pain.

Discontinuation

P2 project: ASP8477 (Europe), Neuropathic pain
(Phase 2 study did not demonstrate the expected efficacy.)

P1 project: ASP5633, Stress urinary incontinence

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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), Breast cancer, Hepatocellular carcinoma	Androgen receptor inhibitor	M0 CRPC, M0 BCR			
				BC, HCC			
	Degarelix (Gonax)	Prostate cancer	1st GnRH antagonist in Japan	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				
	ASP1707	Prostate cancer*1	Oral GnRH antagonist				
	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)				
	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				

*1: P2 for indication of endometriosis

ADC: Antibody-drug conjugate

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Enzalutamide: Development Progress

*The region where the study is performed

	Study Phase/Region*	Target	Design	P1	P2	P3
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**		
Breast cancer	**P2 US/EU**	**Triple-negative** Advanced, androgen receptor-positive, triple-negative breast cancer	Open-label, n=118	**Last Patient In: Jul. 2014**		
	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: Sept. 2014**		
HCC	**P2 US/EU**	**Hepatocellular carcinoma**	Placebo-controlled, n=144	**First Patient In: Planned in 3Q/FY15**		

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

MEDIVATION

Gilteritinib (ASP2215): Development Progress

*The region where the study is performed

	Phase/ Region*	Population	Design	P1	P2	P3
AML (relapsed or refractory)	P3 Global	1st relapsed or refractory, FLT3 mutation positive AML	Open-label, randomized Monotherapy vs salvage chemo (2:1), n=369	First Patient In: Oct. 2015		
	P1/2 US/EU	Relapsed or refractory AML	Dose-escalation and expansion, n=258	Enrollment completed		
	P1 JP	Relapsed or refractory AML	Dose-escalation and expansion			
AML (1st line intensive chemo eligible)	P1 US	Newly diagnosed AML	Combination with induction and consolidation chemo			
	P1 JP	Newly diagnosed AML	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		

Selected by the Japanese MHLW as one of the projects for Sakigake designation

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MHLW: The Ministry of Health, Labor and Welfare

Gilteritinib (ASP2215): Phase 3 Initiation

Study Design

Population	Patients with 1st relapsed or refractory (R/R) acute myeloid leukemia (AML) with positive FLT3 activating mutation
Number of subjects	369
Design	Open-label
Treatment arms	Gilteritinib 120 mg versus salvage chemotherapy* (2:1) *Low-dose cytarabine, azacitidine, MEC (mitoxantrone, etoposide and intermediate-dose cytarabine) or FLAG-IDA (fludarabine, cytarabine and granulocyte colony-stimulating factor with idarubicin)
Primary endpoint	Overall survival

Initiated patient recruitment in Phase 3 study

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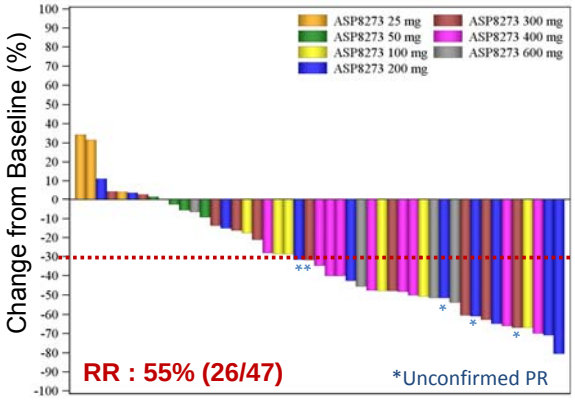
ASP8273: Preparing Phase 3

Updated Data from Japanese Phase 1

in NSCLC with EGFR activating mutations previously treated with at least an EGFR-TKI

Response rate in Phase I (overall, n=47)



RR: Response rate (based on ≥ 30% of best percentage change from base line in target legion).
PR: Partial response. Both confirmed and un-confirmed responses are included.
RR of 67% (16/24), 33% (2/6) and 47% (8/17) responses have been observed in T790M(+), T790M(-) and T790M unknown patients respectively.
This data is shown as the initially assigned dose. Data cutoff : 10th April. 2015.

- Tumor responses have been observed at ≥100 mg
- Further data to be presented in future meetings

Shimizu *et al*., Japanese Society of Medical Oncology 2015

Characteristics

Unique characteristics from nonclinical data

- Potent, mutant-selective irreversible EGFR inhibitor.
- Inhibits growth of EGFR mutant cells more potently than EGFR-wild type cells

Current clinical data

- Clinical responses have been observed at doses of 100 mg or greater
- ASP8273 has been well tolerated

Phase 3 Study

1st line indication

- Global study to start in 2015
- Patients with EGFR activating mutations

2nd line indication

- Pursue in Japan/Asia (in addition to 1st line indication)

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Progress of ADC Projects

AGS-16C3F

Characteristics

- Auristatin-F-linked ADC targeting ENPP3
- ENPP3 expression is high in kidney and a subset of liver cancers and restricted in normal tissue

Phase 2 Study

- To start in early 2016
- Targeting metastatic RCC

Phase 1 Results Presented at ASCO

Conclusions

- AGS-16C3F is tolerable in the majority of patients when dosed at 1.8 mg/kg iv every 3 weeks
- Durable anti-tumor effects have been seen in refractory patients as measured by partial responses and prolonged stable disease
- Protocol development is underway for a Phase 2 study in refractory renal cell carcinoma to start in early 2016

Thompson *et al*., ASCO2015

ASG-22ME*

Development Progress

- The first Phase 1 has been completed
- Phase 1 in metastatic urothelial cancer is ongoing
- Report Phase 1 data in the first half of 2016

Antibody targeting nectin-4 — Linker — MMAE

ASG-15ME*

Development Progress

- Phase 1 in metastatic urothelial cancer is ongoing
- Report Phase 1 data in the first half of 2016

Antibody targeting SLITRK6, identified at Agensys — Linker — MMAE

ENPP3: Ectonucleotide pyrophosphatase-phosphodiesterase 3
RCC: Renal cell carcinoma, MMAE: Monomethyl Auristatin E

*Co-developed with Seattle Genetics

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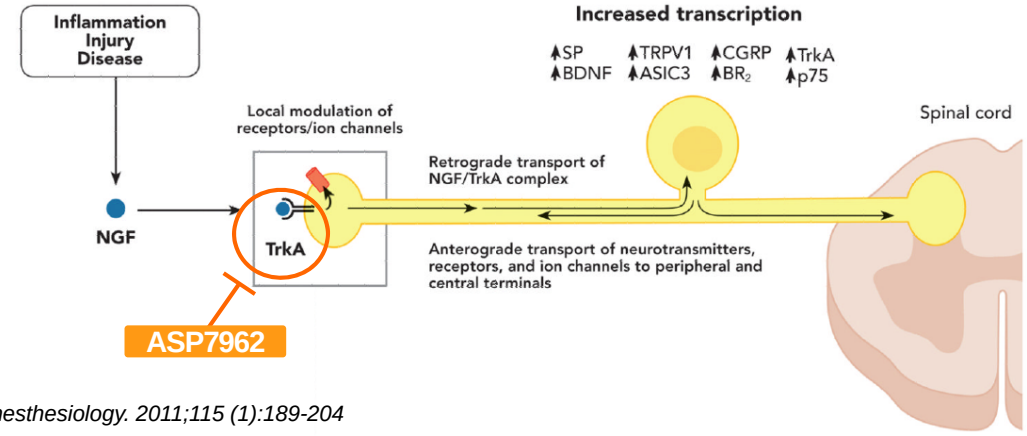
ASP7962: Preparing Phase 2

Mechanism of Action



Anesthesiology. 2011;115 (1):189-204

- Tropomyosin-related kinase A (TrkA) is a high affinity receptor of nerve growth factor (NGF). NGF is released after tissue injury/inflammation and facilitates pain transmission by peripheral sensory neurons.
- ASP7962 is an orally available small molecule with a short half-life, which inhibits TrkA.

Phase 2 Study

- To start in early 2016
- POC study in knee osteoarthritis

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FY2015 Progress of Late Phase Compounds

>>>: Progress since April 2015

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

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Initiatives to Build Resilience for Sustainable Growth

Achieving Sustainable Growth

(same as Strategic Plan 2015-2017 slide)

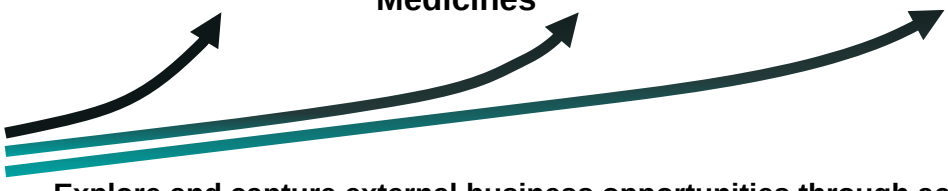
**New products will drive mid-term growth;
Sustainable growth will be reinforced by continuous selective investment in innovation and strengthening of the business foundation**

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 for Sustainable Growth

Maximize the Product Value

Extension of growth drivers

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

Create Innovation

Enhancing capabilities to deliver innovative medicines

Advancing into new therapeutic areas and novel technology platform

- **New exclusive license for next-generation vaccines from Immunomic Therapeutics** (Immunology, Next-generation vaccine)
- **Collaboration with Chromocell for therapeutics to treat neuropathic pain and other pain conditions** (Neuroscience)
  - Obtained worldwide development and commercialization rights for CC8464, an oral, peripherally-acting inhibitor of NaV1.7 and back-up compounds

Pursue Operational Excellence

Optimal allocation of resources

- **Transfer of Kiyosu Plant business to MicroBiopharm Japan**
- **Transfer of Dantrium and Astomin to OrphanPacific (on Oct. 1st)**

Creating organizations and systems that can respond to rapidly changing environments

- **Changes in sales and marketing structure in Japan**
  - Changed from product specific representative system to One-to-One system with customer
  - Introduced therapeutic area specialists (oncology, immunology and transplantation)

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Continuous Introduction of New Products

(Efforts from April 2015 onward)

Maximize the Product Value

Approvals and launches in 4 regions

(Underlined items show updates from the previous announcement)

EMEA

- **XTANDI:** Launch (Lebanon, Macedonia, Azerbaijan)
  Chemo-naive indication launch (France, Switzerland)
- **BETMIGA:** Launch (Croatia)
- **VESOMNI:** Launch (Finland)

Americas

- **XTANDI:** Launch (Uruguay, Brazil)
  Chemo-naive indication approval (Canada)
- **CRESEMBA:** Launch (US)
- **VESOMNI:** Launch (Argentine, Brazil)

Japan

- **Orfadin:** Launch
- **Cimzia:** DMARD-naive RA indication approval
- **Irribow:** Female indication approval

Asia/Oceania

- **XTANDI:** Launch (Philippines, Hong Kong), Approval (New Zealand, Singapore)
  Chemo-naive indication approval (Republic of Korea)
- **Eligard:** Launch (Taiwan)
- **BETMIGA:** Launch (Singapore, Thailand)
- **Suglat:** Launch (Republic of Korea)
- **Feburic:** Approval (Thailand)

No. of countries/areas where the following have been launched:
Betanis/Myrbetriq/BETMIGA: 36
XTANDI: 46

RA: Rheumatoid arthritis

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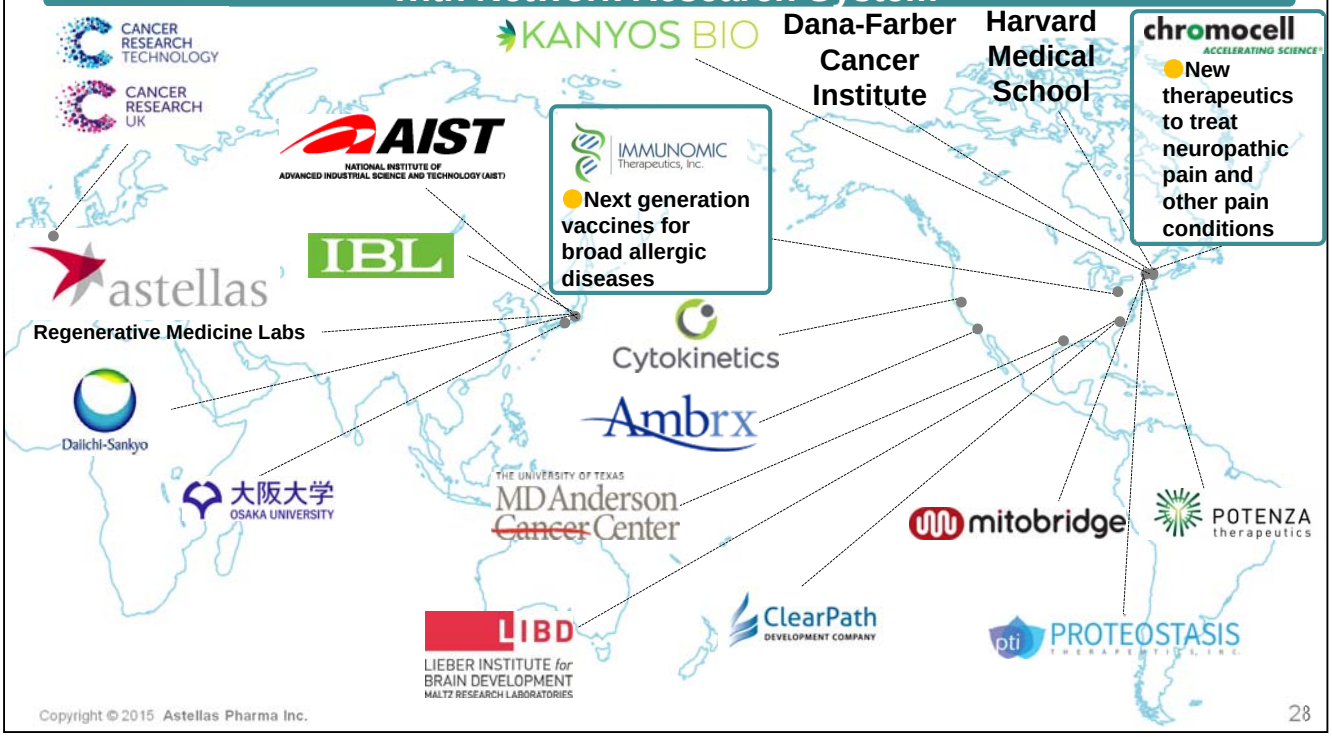
Develop New Therapeutic Areas and Novel Technology Platform (●: Updates from the previous announcement)

astellas Leading Light for Life

Create Innovation

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



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Develop New Therapeutic Areas and Novel Technology Platform: Recent Initiative

astellas Leading Light for Life

Create Innovation

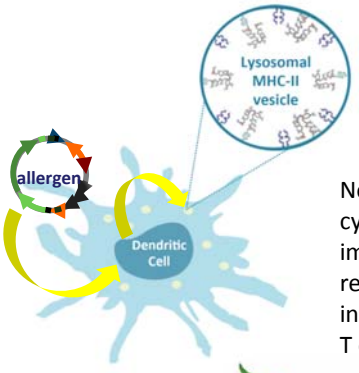
Newly obtained an exclusive license for next-generation vaccines from Immunomic Therapeutics

- **Target: LAMP-vax products for the treatment or prevention of broad allergic diseases**
- **Territory: Worldwide**
- **Financial Terms: upfront payment: $300 million, milestone: none, royalty: 10% of net sales**

*The initial exclusive license agreement in Jan. 2015 in Japan for ASP4070 (JRC2-LAMP-vax) designed to treat allergies induced by Japanese red cedar pollen remains in effect.

LAMP-vax products

- Next-generation DNA vaccine that stimulates an immune response against a particular allergen
- Technology platform applicable to broad allergic diseases by changing the allergen encoded by DNA plasmid
- Expected to develop a more complete immune response compared to conventional DNA vaccines, including antibody production, cytokine release and critical immunological memory.



Expressed as fusion protein with LAMP

Not decreasing a cytotoxic T cell immune response yet also inducing a helper T cell response

IMMUNOMIC Therapeutics, Inc.

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Optimize Resource Allocation: Recent Initiative

Pursue Operational Excellence

Transfer of Kiyosu Plant (Aichi Pref., Japan) business to MicroBiopharm Japan

Strategic rationale

- Promote the establishment of a stable production system that would efficiently realize “steady supply of high-quality drugs” in changing environment, by effectively utilizing external resources
- Ensure higher quality and efficiency in the manufacturing technology functions

Schedule for business transfer

- October 30, 2015: Execution of an agreement
- April 1, 2016 (tentative): Transfer of business



MicroBiopharm Japan

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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	80.76YEN
Dividends per Share	27 YEN	30 YEN	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 Bought back 35 million own shares** (63.8 billion YEN)
Cancellation of Treasury Shares	55 million shares	25 million shares	38 million shares (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

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

**Conducted from May to July and in August 2015, reflected to FY2015 forecast for Core EPS

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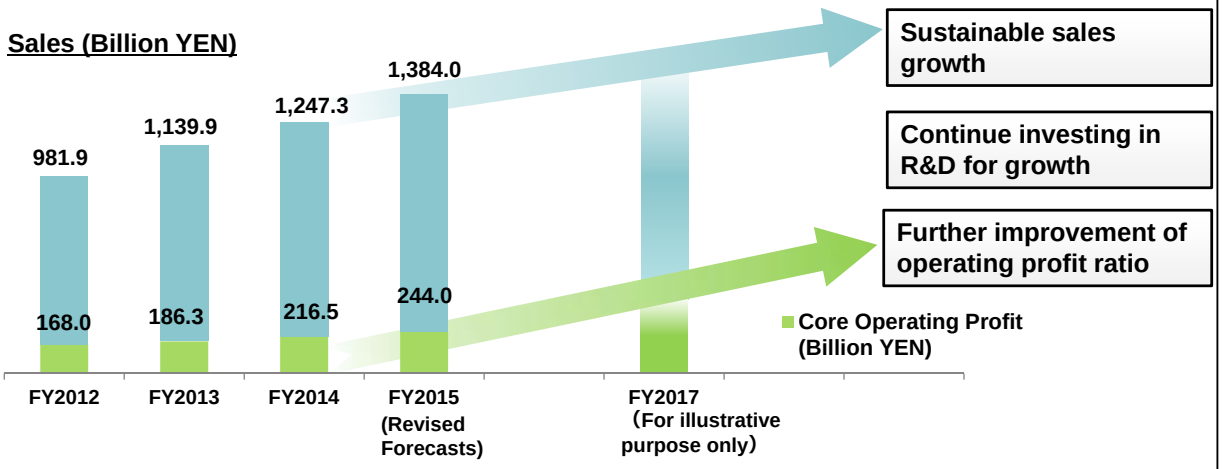
Realize Sustainable Growth

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 organization structure

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Appendix

Reconciliation of Full Basis to Core Basis

(Billion YEN)

	FY14 APR. - SEP.			FY15 APR. - SEP.		
Account item	Full basis	Adjustment	Core basis	Full basis	Adjustment	Core basis
Sales	**594.5**	**-**	**594.5**	**687.5**	**-**	**687.5**
Cost of sales	159.1	-	159.1	168.4	-	168.4
Gross profit	**435.4**	**-**	**435.4**	**519.1**	**-**	**519.1**
SG&A expenses	201.8	-	201.8	239.7	-	239.7
R&D expenses	97.0	-	97.0	112.0	-	112.0
Amortisation of intangible assets	17.9	-	17.9	21.9	-	21.9
Share of profits of associates and joint ventures	0.5	-	0.5	-0.3	-	-0.3
Other income *1	4.9	-4.9	-	0.9	-0.9	-
Other expense *1	20.8	-20.8	-	13.4	-13.4	-
Operating profit	**103.2**	**16.0**	**119.2**	**132.6**	**12.5**	**145.2**
Finance income *2	2.3	-1.0	1.2	13.3	-12.1	1.3
Finance expense *2	2.8	-2.6	0.2	0.6	-0.3	0.3
Profit before tax	**102.7**	**17.6**	**120.2**	**145.4**	**0.7**	**146.2**
Income tax expense	32.7	6.5	39.2	42.5	-0.3	42.2
Profit for the period	**70.0**	**11.1**	**81.1**	**102.9**	**1.0**	**103.9**

*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 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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On the Forefront of Healthcare Change