Financial Results (IFRS) for 1Q/FY2014

Ending March 31, 2015

August 1, 2014

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Astellas Pharma Inc.

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This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.

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Financial Results for 1Q/FY2014 (Core Basis)

(Billion YEN)

	1Q/ FY2013	1Q/ FY2014	Change %	FY2014 Forecasts	Progress per Forecasts
Sales	269.5	295.2	+9.5%	1,192.0	24.8%
COGs as % of sales	81.2 30.1%	76.0 25.7%	-6.4%		
SG&A expenses	91.1	96.9	+6.3%		
R&D expenses as % of sales	44.1 16.4%	47.6 16.1%	+8.0%	198.0 16.6%	24.1%
Amortisation of intangible assets	8.8	8.9	+0.8%		
Share of profits of associates and joint ventures	0.2	0.2	-1.6%		
Core operating profit	44.5	66.0	+48.2%	208.0	31.7%
Core profit for the period	31.8	46.4	+46.2%	154.0	30.1%

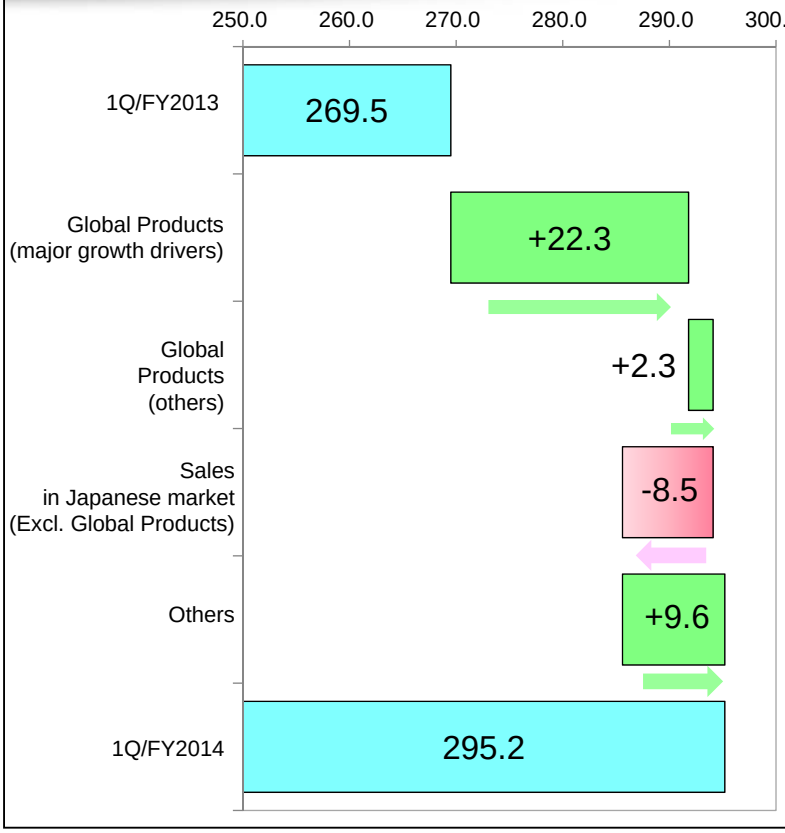
◆ Exchange Rates (YEN)

[Average for terms]	1Q/FY2013	1Q/FY2014	Change	FY2014 Forecasts
USD	99	102	3 weakening of YEN	100
EUR	129	140	11 weakening of YEN	140

[Change from beginning to end of terms]	1Q/FY2013	1Q/FY2014
USD	5 weakening of YEN	2 strengthening of YEN
EUR	8 weakening of YEN	3 strengthening of YEN

Depreciation and amortisation
-1Q/FY2014: 15.5
-1Q/FY2013: 15.7

Results of 1Q/FY2014: Analysis of Change in Sales (vs. Previous Year)



Sales: +25.7

Forex impact: +10.0

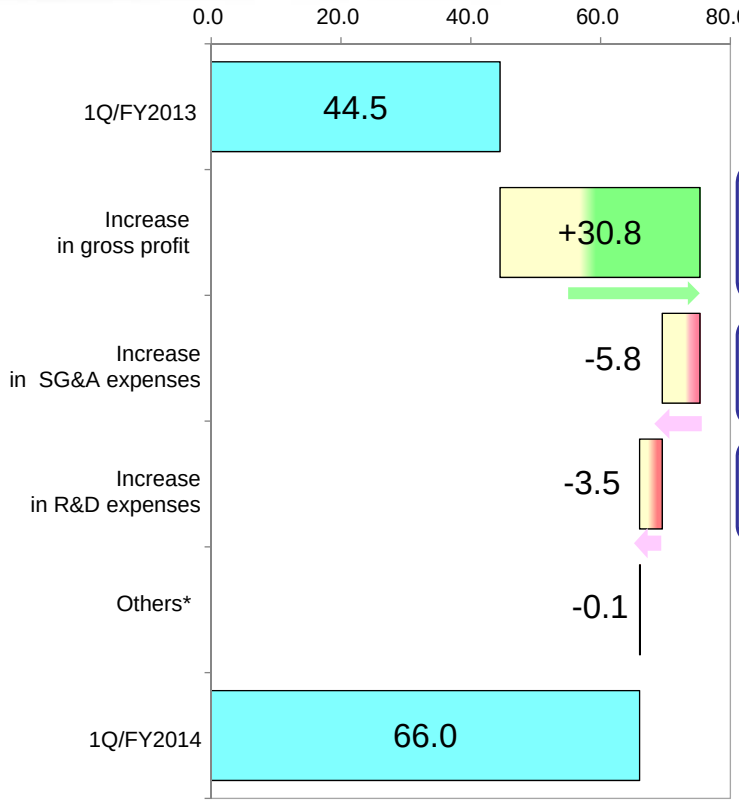
Vesicare + Mirabegron +7.4 / XTANDI +14.9

Prograf +2.9 / Harnal -1.6 / Funguard/ MYCAMINE +0.6 / Protopic -0.1 / Eligard +0.4

New Products and Growing Products -0.9 / Micardis -0.4 / Lipitor -3.6 / Gaster -1.8 / Myslee -2.1 / Seroquel -1.8

Scan -0.5 / Tarceva +1.4 / Other European products +8.7

Results of 1Q/FY2014: Analysis of Change in Core Operating Profit (vs. Previous Year)



Core operating profit: +21.5

Forex impact: +8.3

Increase in sales: +25.7
Decrease in COGs : +5.2
Decrease in COGs ratio: -4.4ppt (30.1%→25.7%)
-Change in product mix etc.: -2.8ppt
-Forex impact on elimination of unrealized gain: -1.5ppt

-Mainly forex impact
-Cost for co-promotion of XTANDI in US
-Cost for product launches etc.

-Forex impact
-Cost for development project etc.

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

Financial Results for 1Q/FY2014 (Full Basis)

(Billion YEN)

	1Q/ FY2013	1Q/ FY2014	Change %
Sales	269.5	295.2	+9.5%
COGs as % of sales	81.2 30.1%	76.0 25.7%	-6.4%
SG&A expenses	91.1	96.9	+6.3%
R&D expenses as % of sales	44.1 16.4%	47.6 16.1%	+8.0%
Amortisation of intangible assets	8.8	8.9	+0.8%
Share of profits of associates and joint ventures	0.2	0.2	-1.6%
Other income	0.1	2.7	-
Other expense	18.2	18.1	-0.6%
Operating profit	26.4	50.6	+91.5%
Profit before tax	26.4	50.3	+90.6%
Profit for the period	19.8	35.9	+80.9%

Other expense : 18.1
-Restructuring costs : 9.3
(premium severance benefit in early retirement incentive program)
-Impairment loss of intangible assets : 8.1

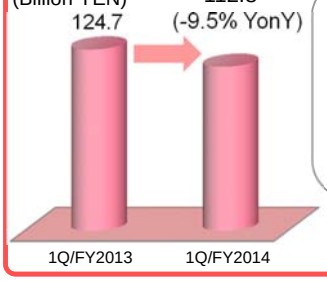
Sales by Region (Local Currency Basis)

Calculated based on the location of the seller

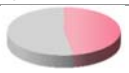
Continuous sales increase in Americas, Europe and Asia/Oceania but decrease in Japan

Japan

(Billion YEN)



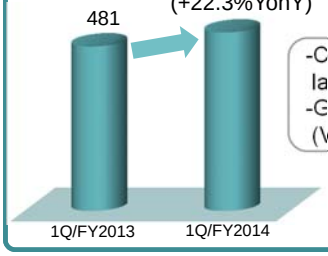
Sales in Japanese market: 109.0 bn YEN (-9.9%)
-Sales decrease due to NHI drug price reduction, generic impact and temporary fluctuations in supply and demand conditions before and after the consumption tax hike



Europe

Incl. Middle and Near East / Africa

(EUR million)

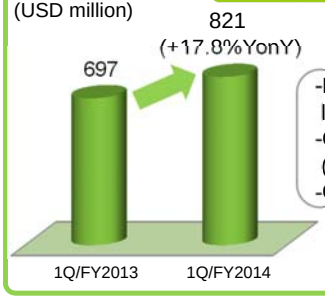


-Contribution of newly launched XTANDI
-Growth of OAB treatments (Vesicare and BETMIGA)



Americas

(USD million)

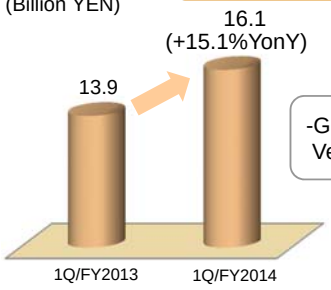


-Expansion of newly launched XTANDI
-Growth of OAB treatments (VESIcare and Myrbetriq)
-Growth of Tarceva



Asia/Oceania

(Billion YEN)



-Growth of Prograf, Harnal and Vesicare



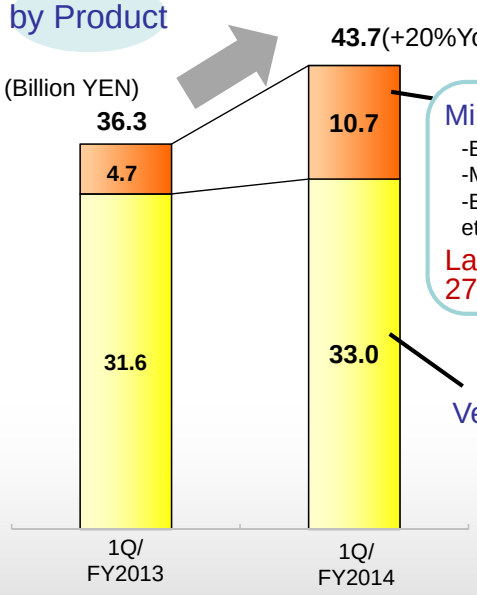
Overactive Bladder Franchise in Urology

Continuous sales increase in OAB franchise (Vesicare and Mirabegron)

Total sales of Vesicare and Mirabegron

by Product

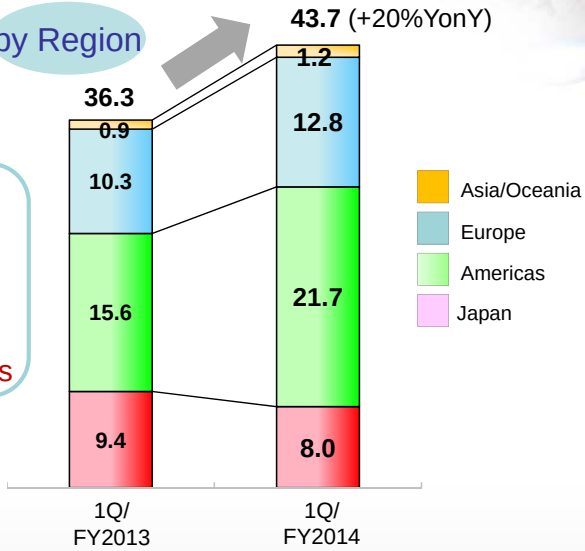
(Billion YEN)



Mirabegron
-Betanis (Japan)
-Myrbetriq (Americas)
-BETMIGA (Europe, etc.)
Launched in 27 countries/areas

Vesicare

by Region

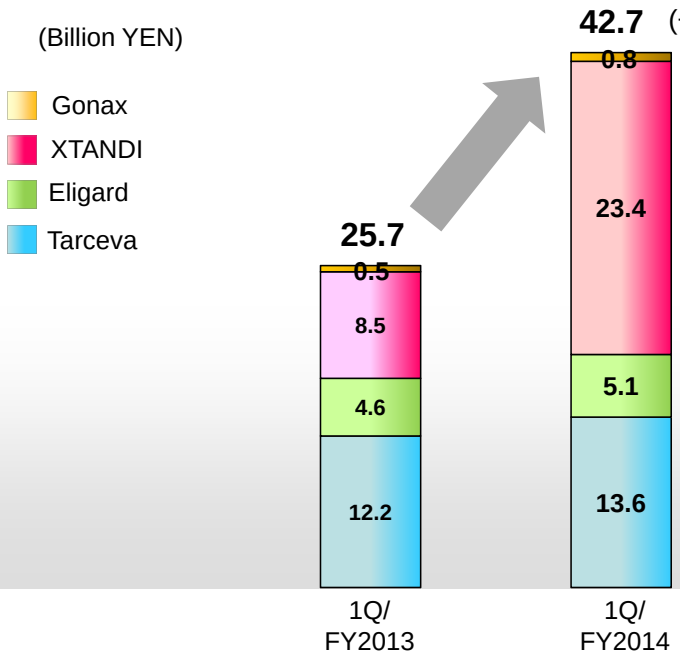


Growth rate in total sales of Vesicare and Mirabegron [YonY]
- Japan: -16%
- Americas: +35% (USD basis)
- Europe: +15% (EUR basis)
- Asia/Oceania: +17% (Excl. forex impact)

Oncology Franchise

Expansion of oncology franchise driven by XTANDI

Total sales of XTANDI, Tarceva, Eligard and Gonax

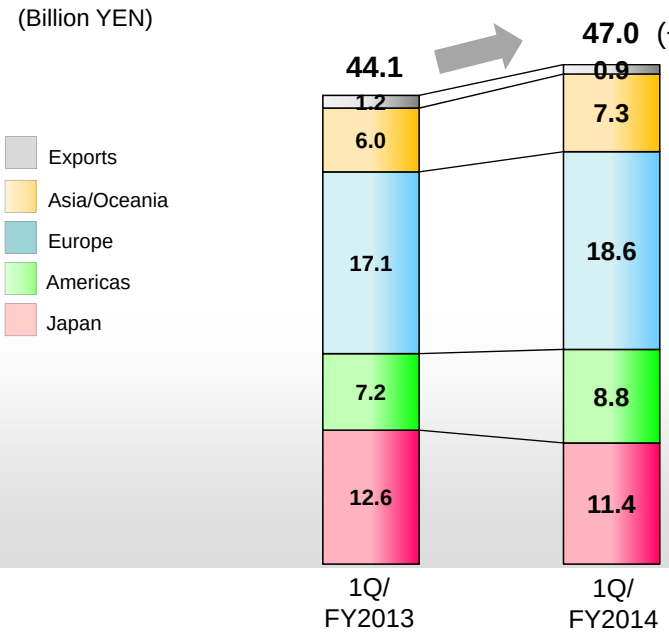


- XTANDI
  - -Japan: 1.5 billion Yen
  - -Americas: USD 148 million
  - -Europe: EUR 48 million
  - Launched in 26 countries/areas
- Eligard
  - Europe: EUR 36 million
  - +1% YonY (EUR basis)
- Tarceva-related revenues
  - USD 133 million
  - +8% YonY (USD basis)

Transplantation Franchise

Maintaining global sales of Prograf

Total sales of Prograf and Advagraf/Graceptor/ASTAGRAF XL

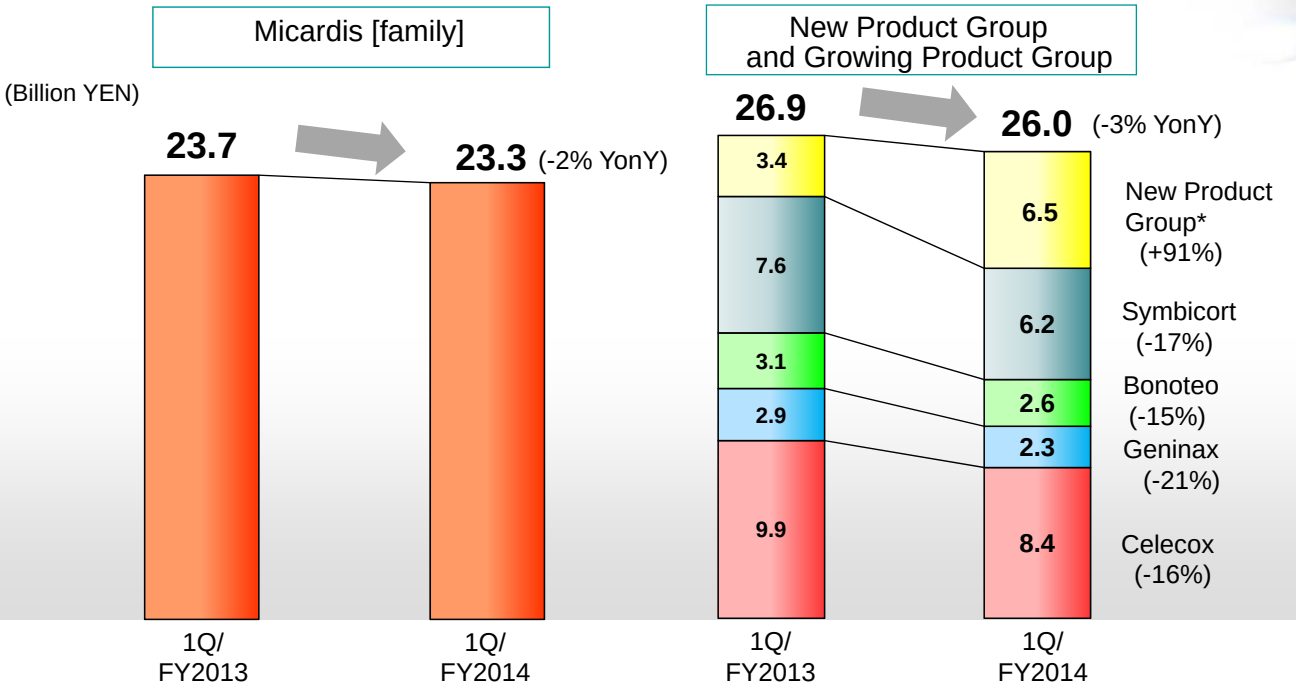


[YonY]

- Japan: -9%
- Americas: +18% (USD basis)
- Europe: +0% (EUR basis)
- Asia/Oceania: +16% (Excl. forex impact)

Major Products in Japan (Excluding Global Products)

Contribution of New Product Group meanwhile decrease of Growing Product Group by temporary fluctuations in supply and demand conditions before and after consumption tax hike



*New Product Group: Total sales of products launched within the last 3 years (ARGAMATE, Kiklin, Regnite, Gonax, Cimzia, Acofide and Suglat)

Continuous Introduction of New Products

(Efforts from April 2014 onward)

■ Approvals and launches in 4 regions

(Updates from the previous announcement shown in red)

[Europe]

Expansion of the number of countries where BETMIGA, XTANDI and VESOMNI were launched

- Jun. Germany BETMIGA launch

[Asia and Oceania]

- Apr. Australia BETMIGA launch
- May Taiwan/Malaysia Eligard approval
- May Hong Kong MYCAMINE approval (pediatric indication)
- May Philippines Advagraf approval
- Jun. Australia XTANDI approval
- Jun. Hong Kong BETMIGA launch
- Jun. Singapore MYCAMINE launch

[Japan]

- Apr. Suglat launch
- May XTANDI launch

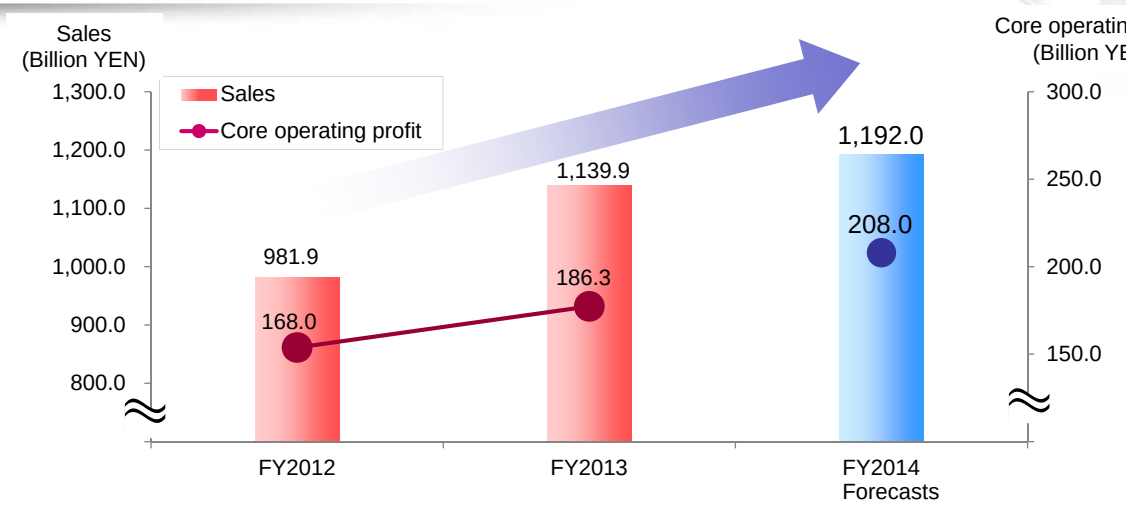
[Americas]

- Apr. Argentina XTANDI launch

No. of countries/areas where the following have been launched:

- **Mirabegron: 27**
- **XTANDI: 26**

Resiliently Respond to the Changing Environment and Aim for Sustainable Growth



No changes have been made to FY2014 forecasts announced in May 2014

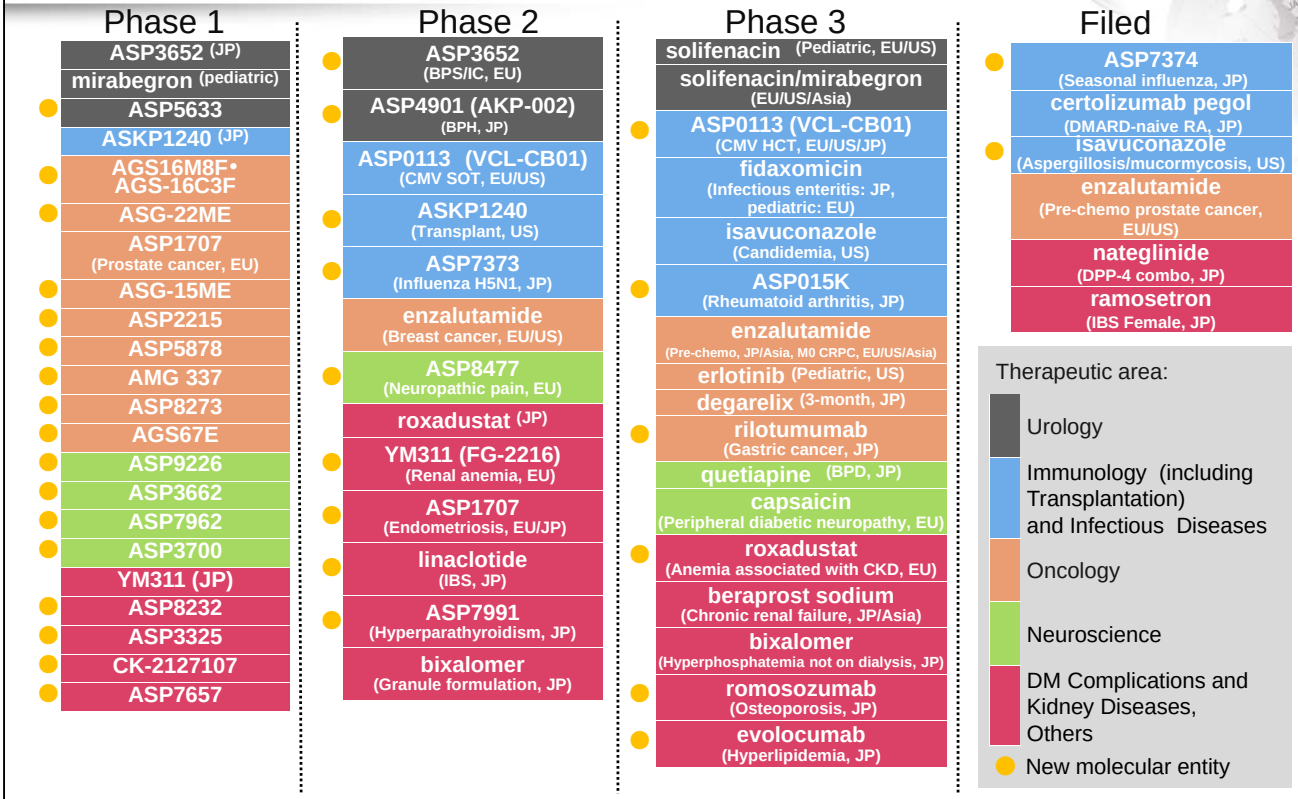
- Continuous growth of XTANDI and OAB treatments (Vesicare and Mirabegron)
- Expenses in-line with our forecasts, pursuing further cost optimization

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R&D Pipeline

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Status of Astellas' Pipeline



BPS/IC: Bladder pain syndrome/Interstitial cystitis, BPH: Benign prostatic hyperplasia, CMV: Cytomegalovirus, SOT: Solid organ transplant, IBS: Irritable bowel syndrome, HCT: Hematopoietic cell transplant, M0 CRPC: Non-metastatic castration-resistant prostate cancer, BPD: Bipolar disorders, CKD: Chronic kidney disease, DMARD: Disease modifying anti-rheumatic drugs

Changes in Pipeline Status Since May 2014 <Filing>

Code No. Generic Name	Target Disease	Area	Stage	Changes
ASP7374	Prophylaxis of seasonal influenza	Japan	Filed	Submitted a NDA in Japan in May 2014.
certolizumab pegol	DMARD-naive rheumatoid arthritis	Japan	Filed	Submitted an sNDA in Japan in June 2014.
nateglinide	Type 2 diabetes Combination with DPP-4 inhibitor	Japan	Filed	Submitted an sNDA in Japan in July 2014.
isavuconazole	Invasive aspergillosis and invasive mucormycosis	US	Filed	Submitted a NDA in the US in July 2014.
YM060 ramosetron	Irritable bowel syndrome with diarrhea in female patients	Japan	Filed	Submitted an sNDA in Japan in July 2014.

NDA: New drug application,
DMARD: Disease modifying anti-rheumatic drugs,
sNDA: Supplemental NDA

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Changes in Pipeline Status Since May 2014 <Progress of the Stage, New P1 >

■ Progress of the Stage

Code No. Generic Name	Target Disease	Area	Stage	Changes
ASP015K	Rheumatoid arthritis	Japan	P3	Entered into P3 in Japan.
fidaxomicin	*Clostridium difficile* infection in pediatric patients	Europe	P3	Entered into P3 in Europe.

■ New P1

Code No.	Target Disease	Stage	Changes
ASP5633	Stress urinary incontinence	P1	Entered into P1.

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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 (pre-chemo, non-metastatic), Breast cancer (BC)	Androgen receptor inhibitor	Pre-chemo: EU/US/JP/Asia			Filed in US/EU
				Non-Metastatic: EU/US/Asia			
				BC:US/EU			
	Erlotinib (Tarceva)	Pediatric ependymoma	HER1/EGFR tyrosine kinase inhibitor	US			
	Degarelix (Gonax)	Prostate cancer	1st GnRH antagonist in Japan	3-month: JP			
	ASP1707	Prostate cancer*	Oral GnRH antagonist				
	ASP2215	Acute myeloid leukemia	FLT3/AXL inhibitor				
	ASP5878	Cancer					
	AMG 337	Gastric cancer	MET inhibitor	JP			
	ASP8273	Non-small cell lung cancer	EGFR T790M inhibitor				
Antibody	Rilotumumab AMG 102	Gastric cancer	Anti-HGF monoclonal antibody	JP			
	AGS-16M8F/ 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)				

*P2 for indication of endometriosis

ADC: Antibody-drug conjugate

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Enzalutamide: Development Progress

	Study	Target	Design	P1	P2	P3	Filed
Prostate cancer	**P3** EU/US/JP/Asia [PREVAIL study]	Pre-chemo Metastatic castration-resistant prostate cancer (CRPC)	Placebo-controlled, n=1,717	US: sNDA on Mar. 17, 2014 Priority review granted PDUFA date: Sep. 18, 2014 Europe: Variation to amend MAA on Apr. 2, 2014			
	P3 EU/US/Asia [PROSPER study]	M0 CRPC Non-metastatic CRPC	Placebo-controlled, n=1,500	First Patient In: Nov. 2013			
	P2 EU/US [TERRAIN study]	Pre-chemo Metastatic CRPC	To compare with bicalutamide, n=375	Completed enrollment: Jul. 2013			
	P2 US [STRIVE study]	Pre-chemo Metastatic or non-metastatic CRPC	To compare with bicalutamide, n=400	Completed enrollment: Mar. 2014			
	P2 US	Neoadjuvant therapy Undergoing prostatectomy	Monotherapy or combo with leuprolide or dutasteride, n=50	Last Patient Out: Nov. 2013			
	P2 EU	Hormone-naive Progressive prostate cancer	Open-label, n=67	Completed			
Breast cancer	**P2** US/EU	Triple-negative Advanced, androgen receptor-positive, triple-negative breast cancer	Open-label, n=80	First Patient In: Jun. 2013			
	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	First Patient In: Dec. 2013			
	P2 US/EU	HER2 positive Advanced, HER2 positive/ER negative breast cancer	Open-label, n=80	Planned First Patient In: 3Q/2014			

ER: Estrogen receptor, PgR: Progesterone receptor, HER2: Human epidermal growth factor receptor 2

ASP7374: Vaccine for Seasonal Influenza

Filed in Japan in May 2014.

- Characteristics
  - First in the class*, next generation influenza vaccine
  - Produced by a cell-culture manufacturing method employing the baculovirus expression vector system, a recombinant technology platform
    - → Produced in approx. 6-8 weeks after obtaining the genetic information of the target influenza virus
    - → Contains same amino acid sequence of HA protein as the target influenza virus
  - Not contain egg protein
  - Administered subcutaneously and intramuscularly
- Efficacy and safety
  - ASP7374 showed non-inferiority in comparison with egg-derived trivalent inactivated vaccine (ETIV) in terms of immunogenicity in both adults and elderly.
  - ASP7374 have a similar safety profile as ETIV. No major safety problems were observed.

*First in the class in Japan as seasonal influenza vaccine produced by a cell-culture manufacturing method

Isavuconazole: Azole Antifungal

Filed in the US in July 2014 for invasive aspergillosis and invasive mucormycosis

- Characteristics
  - Long $t_{1/2}$ enabling once daily administration
  - Reduced risk of drug-drug interactions
  - No need for cyclodextrin in intravenous formulation, avoids renal impairment restriction
  - Broad antifungal spectrum of *in vitro* and *in vivo* activity including *Aspergillus spp., Candida spp.,* and *Mucorales*
  - Favorable safety profile
- FDA granted isavuconazole
  - For invasive aspergillosis and invasive mucormycosis: Orphan status and QIDP status
  - For invasive candidiasis: QIDP, newly designated in July 2014

Orphan status:	7 years exclusivity
QIDP status:	Priority review; 5 additional years exclusivity

QIDP: Qualified Infectious Disease Product

Cimzia, Irribow

- Cimzia (certolizumab pegol)

  Filed an sNDA in Japan in June 2014.

  - Current indication:
    Patients with rheumatoid arthritis (RA) who have had an inadequate response to conventional treatment (including inhibition of progression of bone structural damage)
  - The sNDA aims to administer CZP to RA patients without previous treatment with anti-RA drugs when rapid progression of structural joint destruction is expected.
  - In the Japanese Phase-III C-OPERA study in patients without previous treatment with methotrexate (MTX) within one year after onset of RA, co-administration of CZP with MTX significantly inhibited radiographic progression and improved clinical remission rate, comparing to MTX alone. No new or unexpected safety signals were observed.
- Irribow (ramosetron)

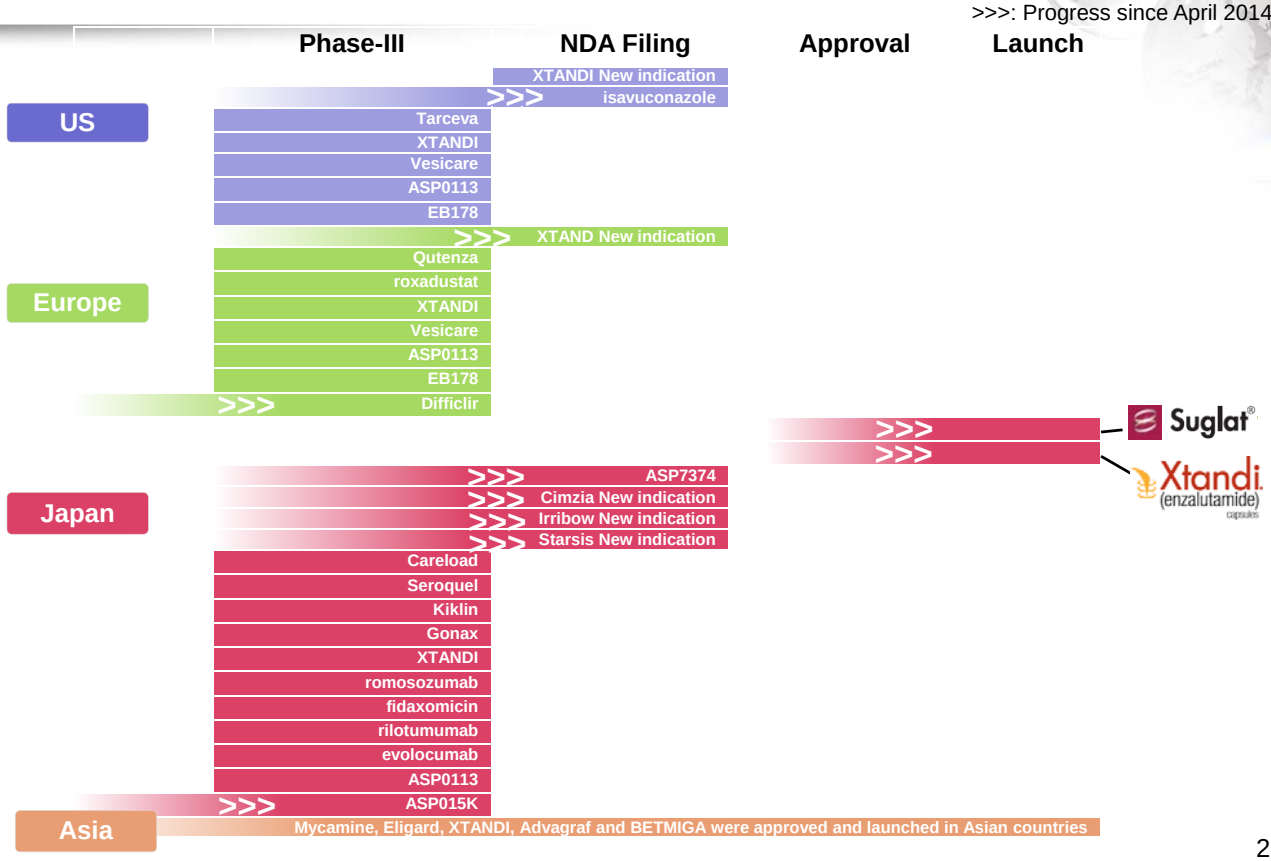
  Filed an sNDA in Japan in July 2014.

  - Current indication: Irritable bowel syndrome with diarrhea (IBS-D) in male patients
  - The sNDA aims to get an approval of Irribow in female IBS-D patients
  - In the Phase-III study with female patients, ramosetron showed significant differences in co-primary endpoints of monthly responder rate of global assessment of overall IBS symptoms relief and monthly responder rate of stool form improvement, comparing to placebo. No major safety concern was observed.

CZP: Certolizumab pegol

FY2014 Progress of Late Phase Compounds

>>>: Progress since April 2014



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

	FY2012	FY2013	FY2014
Core EPS*	51.73 YEN	59.11 YEN	69.65 YEN (Forecasts)
Dividends per Share	26 YEN	27 YEN	29 YEN (Plan)
ROE*	8.0%	7.4%	-
DOE*	5.2%	5.0%	-
Share Buybacks	54 million shares (49.4 billion YEN)	25 million shares (30.0 billion YEN)	Implemented in a flexible manner
Cancellation of Treasury Shares	-	55 million shares	25 million shares (Cancelled in May 2014)

*IFRS

-Figures from FY2012 to FY2013 have been restated in consideration of 5-for-1 stock split on April 1, 2014 for convenience purposes.
-Acquired own shares of 30.0 billion YEN (23 million shares) from May 2014 to June 2014, which is reflected to Core EPS recalculation.

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Appendix

Definition of Core Earnings

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

IFRS(Full basis)	
Sales	
Cost of Sales	*"Other income" and "Other expense" to be excluded.*
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 period	

Impairment losses, restructuring costs, etc. → Other income / Other expense

Interest income/expense, dividend income, etc. → Financial income / Financial expense

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 period → Core EPS

Reconciliation of Full Basis to Core Basis

Billion yen

Account item	FY2014 APR. - JUN.		
	Full basis	Adjustment	Core basis
Sales	**295.2**	**-**	**295.2**
Cost of sales	76.0	-	76.0
Gross profit	**219.2**	**-**	**219.2**
SG&A expenses	96.9	-	96.9
R&D expenses	47.6	-	47.6
Amortisation of intangible assets	8.9	-	8.9
Share of profits of associates and joint ventures	0.2	-	0.2
Other income *1	2.7	-2.7	-
Other expense *1	18.1	-18.1	-
Operating profit	**50.6**	**15.4**	**66.0**
Finance income *2	1.8	-0.9	1.0
Finance expense *2	2.1	-2.0	0.1
Profit before tax	**50.3**	**16.6**	**66.8**
Income tax expense	14.4	6.0	20.4
Profit for the period	**35.9**	**10.5**	**46.4**

*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, loss on the restructuring, and 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 as non-core items.