Financial Results for 1Q/FY 2013 Ending March 31, 2014

August 1, 2013

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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/FY2013

1Q/FY2013: From April through June 2013

(Billion YEN)

	1Q/ FY2012	1Q/ FY2013	Change	1H/FY2013 Forecasts	Progress per 1H Forecasts
Net sales	243.2	275.8	+13.4%	567.0	48.7%
COGs as % of sales	73.4 30.2%	86.6 31.4%	-		
R&D Expenses as % of sales	42.8 17.6%	52.0 18.9%	+21.4%	105.0	49.6%
Other SG&A	74.0	98.6	+33.2%		
Operating Income	52.8	38.5	-27.1%	83.0	46.4%
Ordinary income	55.7	37.4	-32.9%	83.0	45.1%
Net Income	35.4	22.1	-37.7%	52.0	42.5%

-Special gains and losses (net) -6.9 billion YEN
Restructuring costs in connection with reshaping research framework etc.

◆ Exchange Rates (YEN)

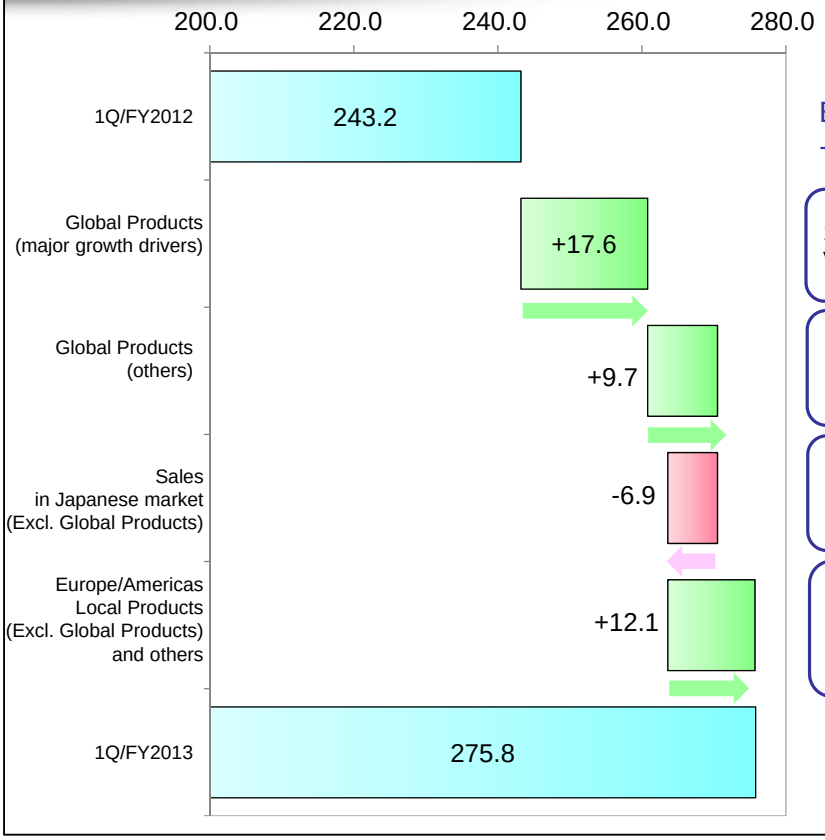
[Average for terms]	1Q/FY2012	1Q/FY2013	Change	1H/FY2013 Forecasts
USD	80	99	19 weakening of YEN	100
EUR	103	129	26 weakening of YEN	130

[Change from beginning to end of terms]	1Q/FY2012	1Q/FY2013
USD	3 strengthening of YEN	5 weakening of YEN
EUR	11 strengthening of YEN	8 weakening of YEN

Depreciation and amortization (Billion YEN)
-1Q/FY2012: 11.0
-1Q/FY2013: 14.8

Amortization of goodwill (Billion YEN)
-1Q/FY2012: 2.9
-1Q/FY2013: 1.4

Results of 1Q/FY2013: Analysis of Change in Sales (vs. Previous Year)



Breakdown of sales increase: +32.6 billion YEN

1) Global Products (major growth drivers): +17.6
Vesicare +5.0/Mirabegron +4.0/XTANDI +8.5

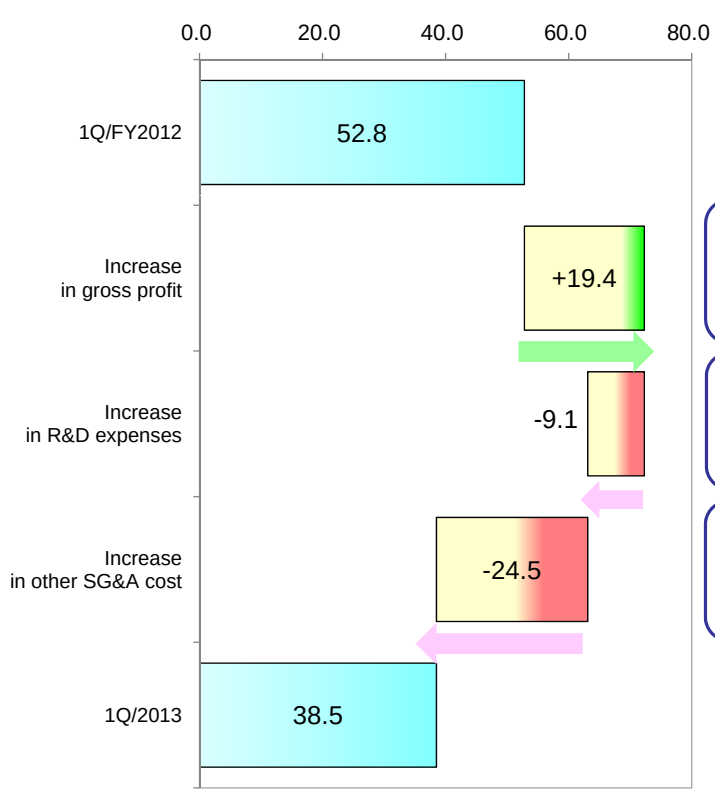
2) Global Products (others): +9.7
Prograf +4.5/Harnal +1.4/Funguard +0.9/
Protopic +1.7/Eligard +1.0

3) Sales in Japanese market:
(Excl. Global Products): -6.9
New Products and Growing Products +4.8/
Micardis +1.0
Lipitor -3.1/Gaster -1.5/Myslee -2.1/Seroquel -2.5

4) Europe/Americas Local Products
(Excl. Global Products) and others: +12.1
Scan +4.0/Tarceva +2.9/
Other European products: Approx. +3.0

-Forex impact: +28.3 billion YEN

Results of 1Q/FY2013: Analysis of Change in Operating Income (vs. Previous Year)



Breakdown of operating income decrease: -14.3 billion YEN

Increase in sales: +32.6
Increase in COGs: -13.1
} Increase in gross profit: +19.4
Increase in COGs ratio +1.2ppt (30.2%→31.2%)
-Change in product mix etc. -1.2ppt
-Forex impact on elimination of unrealized gain +2.4ppt

Increase in R&D expenses: -9.1
-Increase in upfront/milestone payment for alliance

Increase in other SG&A cost: -24.5
-Cost for oncology business in the US/Europe
-Cost for strengthening sales force in emerging markets
-Cost for product launches

-Forex impact: -0.6 billion YEN

Sales by Region (Local Currency Basis)

*Calculated based on the location of the seller

Sales expanded steadily in Americas, Europe and Asia while sales decreased in Japan

Japan

(Billion YEN)
137.7
130.3
(-5.4% YonY)
1Q/FY2012
1Q/FY2013

Sales in Japanese market: 126.6 bn YEN (-5.5%)

-Sales decrease due to generic impact etc.
-Steady sales expansion of major growing products and new products



Europe

*Incl. Middle and Near East and Africa

(€ million)
477
485
(+1.7% YonY)
1Q/FY2012
1Q/FY2013

-Growth of Vesicare and Mycamine



Americas

($ million)
579
698
(+20.5% YonY)
1Q/FY2012
1Q/FY2013

-Contribution of newly launched XTANDI and Myrbetriq
-Growth of Vesicare, Scan and Tarceva



Asia

*Incl. Oceania

(Billion YEN)
9.9
13.9
(+40.5% YonY)
+12.1%
Excl. forex impact
1Q/FY2012
1Q/FY2013

-Growth in all major products



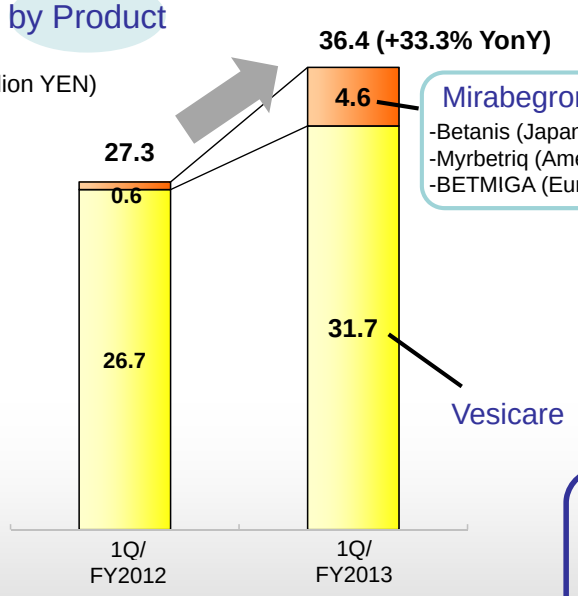
Overactive Bladder Franchise in Urology

Sales expansion driven by Vesicare growth and Mirabegron contribution

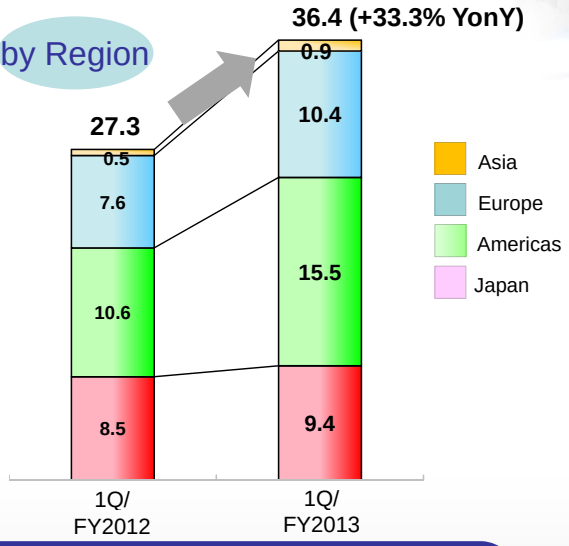
Total sales of Vesicare and Mirabegron

by Product

(Billion YEN)



by Region



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

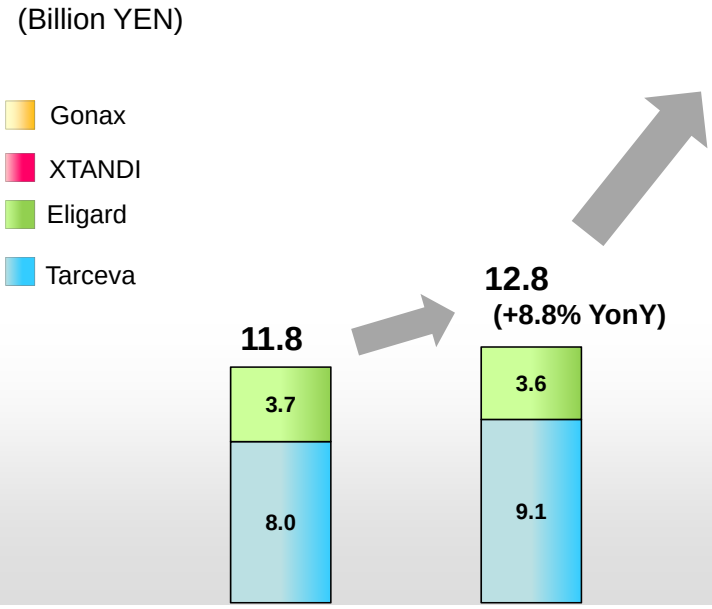
- Japan: +11%
- Americas: +19% (USD basis)
- Europe: +9% (EUR basis)
- Asia: +27% (Excl. forex impact)

Oncology Franchise

Expansion of oncology franchise driven by contribution of XTANDI

Total sales of XTANDI, Tarceva, Eligard and Gonax

(Billion YEN)

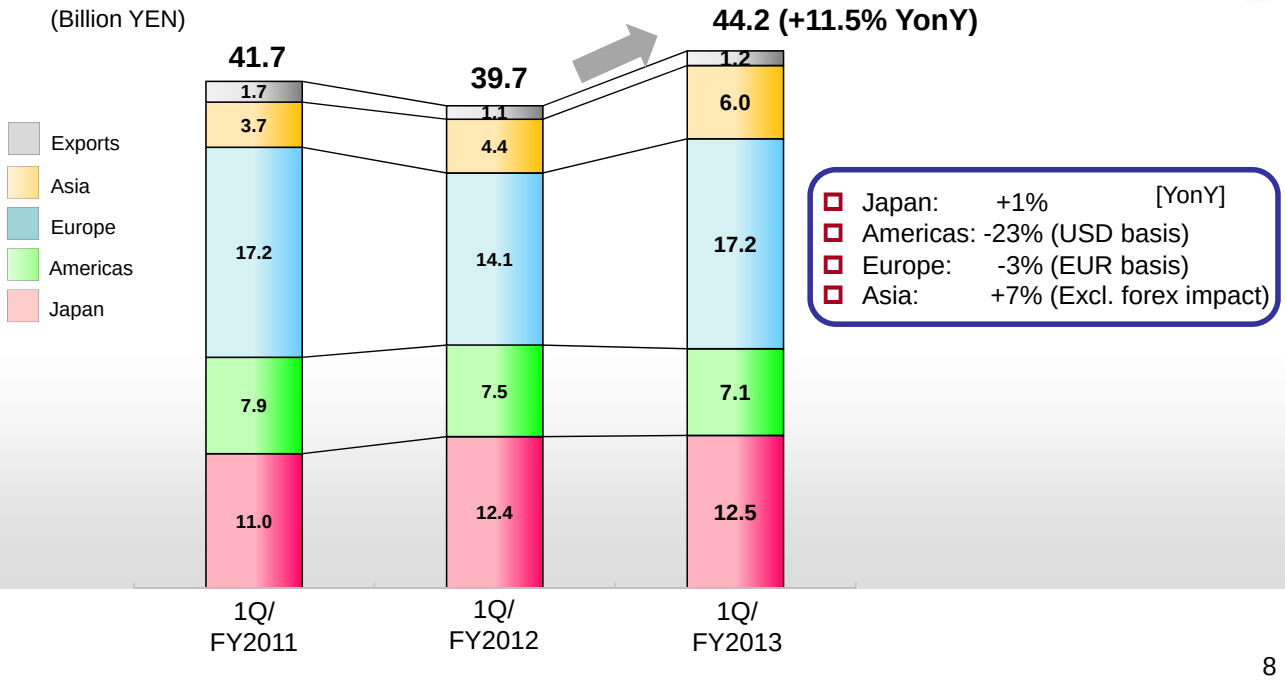


- XTANDI
  -US: 82 million USD
  -Europe: 2 million EUR
  Launched in Jul. 2013 (UK)
- Eligard
  -Europe: 36 million EUR
  +2% YonY (EUR basis)
- Tarceva-related revenues
  123 million USD
  +7% YonY (USD basis)

Transplantation Franchise

Maintaining global sales by growth in Japan and Asia

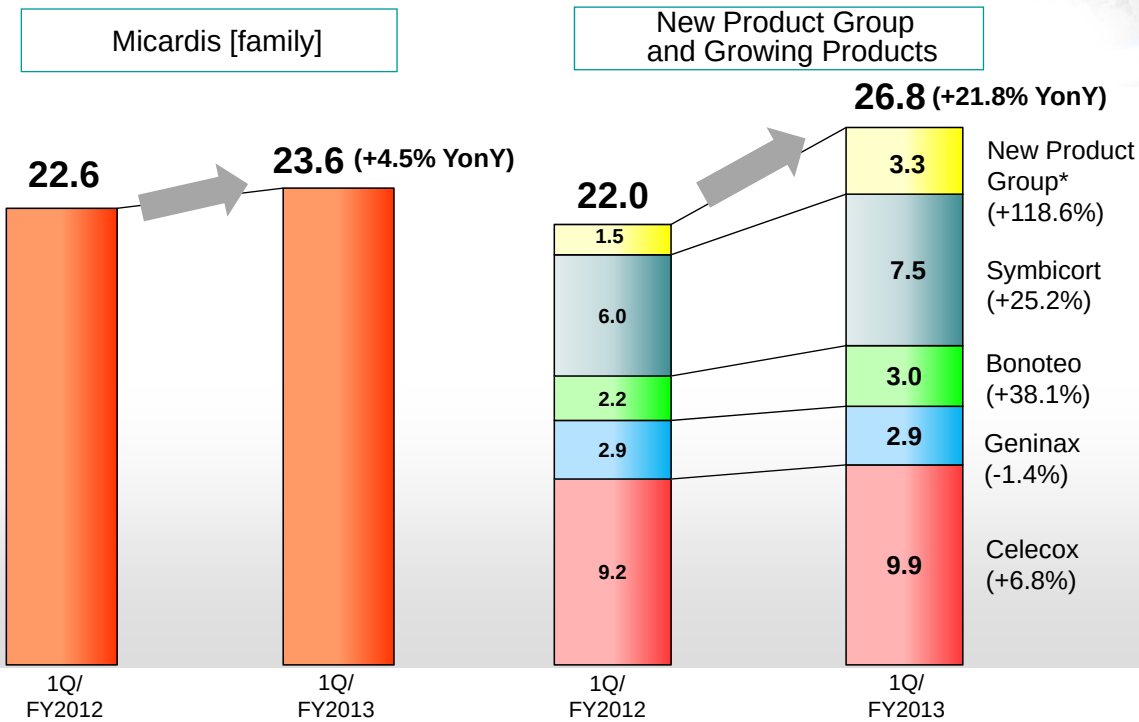
Total sales of Prograf and Advagraf/Graceptor



- Japan: +1% [YonY]
- Americas: -23% (USD basis)
- Europe: -3% (EUR basis)
- Asia: +7% (Excl. forex impact)

Major Products in Japan (Excluding Global Products)

Steady sales expansion in Growing Products and New Product Group



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

Launches: Acofide in Japan, XTANDI in Europe

Acofide

Launch: Jun. 2013 in Japan

- Functional Dyspepsia (FD) treatment

[Indication]
Postprandial fullness, upper abdominal bloating, and early satiation due to functional dyspepsia



XTANDI

Launch: Jul. 2013 in Europe (UK)

-Oral androgen receptor inhibitor

[Indication]
Metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy



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Continuous Introduction of New Products and Optimization of Resource Allocation (Efforts from April 2013 onward)

■Continuous introduction of new products (approvals and launches)

[Japan]
- ➢May Micamlo BP launch (Hypertension)
- ➢Jun. Acofide launch (Functional dyspepsia)
- ➢Jun. Prograf new indication (Interstitial pneumonia associated with polymyositis/ dermatomyositis)
- ➢Jun. Bisono Tape approval (Hypertension)

[Americas]
- ➢Apr. Canada Myrbetriq launch
- ➢May US Tarceva new indication (First line for NSCLC with EGFR activating mutations)
- ➢Jun. US Mycamine new indication (Pediatric)
- ➢Jun. Canada XTANDI launch*
- ➢Jul. US ASTAGRAF XL approval (tacrolimus extended release capsules)

[Europe]
- ➢May VESOMNI approval (Benign prostate hyperplasia)
- ➢Jul. UK XTANDI launch*

[Asia and Oceania]
- ➢May Australia Mycamine approval
- ➢Jun. Hong Kong Eligard launch
- ➢Jun. South Korea XTANDI approval*

NSCLC: Non-small cell lung cancer

*Metastatic castration-resistant prostate cancer in patients who have received chemotherapy

■Optimization of resource allocation

- Apr. 2013: Collaboration with Ambrx (next-generation ADC technology) — Ambrx
- Apr. 2013: Partnership with Drais (ASP7035) -"Multi-track R&D"-
- May 2013: Reshaping our research framework by introducing new initiatives
- May 2013: Strategic alliance with Amgen in Japan — AMGEN
- Jun. 2013: Collaboration with Cytokinetics (for skeletal muscle disease) — CYTOKINETICS

ADC: Antibody Drug Conjugates

Strategic Alliance with Amgen for the Japanese Market

Strategic Alliance: Structure

To be in place until 2032 at the latest on a product-by-product basis

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Long-term collaboration

Co-development & Co-commercialization

5 pipeline medicines*

49% Ownership of shares

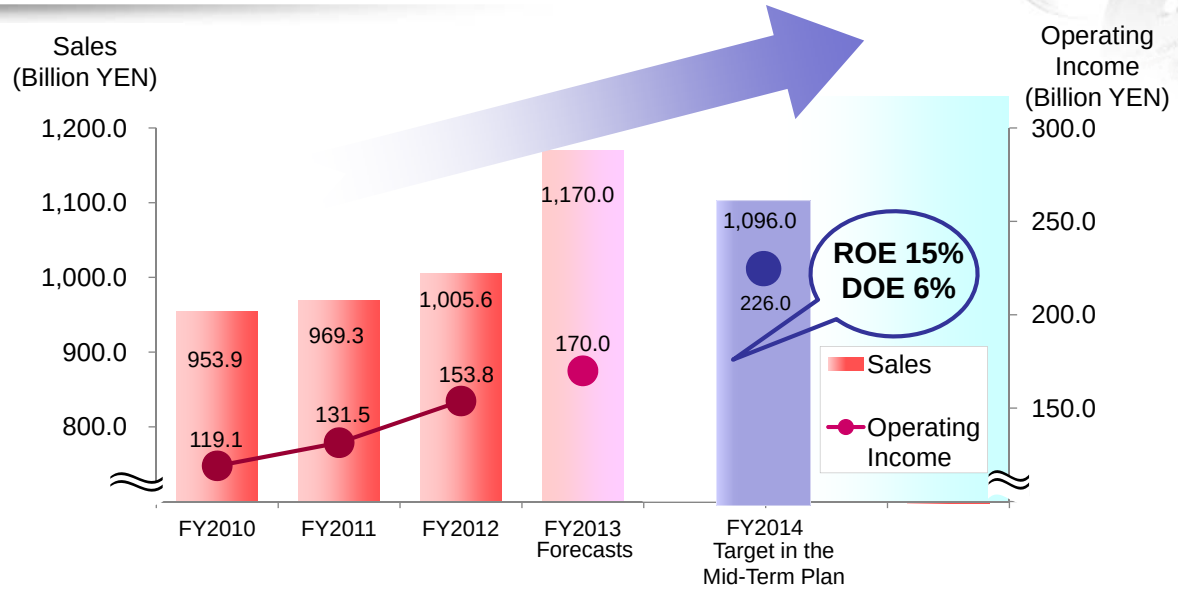
51% Ownership of shares

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***5 pipeline medicines**
- AMG 145
- AMG 785 (Romosozumab)
- AMG 102 (Rilotumumab)
- AMG 337
- AMG 103 (Blinatumomab)

To become a wholly owned Amgen affiliate as soon as in 2020

Resiliently Respond to the Changing Environment and Aim for Sustainable Growth



No change in FY2013 forecasts announced in May 2013

- Favorable sales in Americas making up lower-than-expected sales in Japan.
- Expecting sales expansion of new products such as Mirabegron and XTANDI.
- Expenses in-line with our forecast. Continuously promoting efficient expenses.

R&D Pipeline

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Status of Astellas' Pipeline

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

	Filed	P3	P2	P1
Urology		solifenacin (Pediatric, EU/US) solifenacin/mirabegron (EU/US/Asia)	ASP3652 (BPS/IC, EU) ASP4901 (AKP-002, BPH, JP)	ASP0306 ASP3652 (JP) ASP6432
Immunology (including Transplantation) and Infectious Diseases		certolizumab pegol (MTX-naive RA, JP) isavuconazole (Aspergillosis, candidemia, EU/US) ASP0113 (CMV reactivation in HCT, EU/US) ASP7374 (Influenza, JP)	ASKP1240 (Transplant, US) ASP015K (RA, JP) ASP7373 (Influenza, JP) ASP0113 (SOT, EU/US, HCT, JP)	ASKP1240 (JP) ASP2408 ASP2409 fidaxomicin (JP)
Oncology	enzalutamide (PC, JP)	enzalutamide (PC, Pre-Chemo etc., EU/US/JP/Asia) erlotinib (NSCLC etc., US) degarelix (3M, JP)	linsitinib (OC, NSCLC, US) tivozanib (BC, CRC, EU/US) enzalutamide (BC, EU/US)	AGS-16M8F/AGS-16C3F ASG-22ME ASP1707(PC, EU) ASP3026 ASP9853 rilotumumab ASG-15ME, ASP2215
Neuroscience	midazolam (Dentistry, JP)	quetiapine (BPD, JP) capsaicin (PDN, EU)	quetiapine (MDD, JP)	ASP8477 ASP9226, ASP3662
DM Complications and Kidney Diseases, Others	ipragliflozin (Diabetes, JP) ramosetron (IBS OD tablet, JP)	ASP1517 (Anemia associated with CKD, EU) beraprost (Chronic renal failure, JP/Asia) bixalomer (Hyperphosphatemia in patients not on dialysis, JP) ramosetron (IBS Female, JP) nateglinide (Diabetes, JP) AMG 785 (Osteoporosis, JP)	ASP1517 (Anemia associated with CKD, JP) YM311 (Renal anemia, EU) linaclotide (IBS, JP) ASP1707 (Endometriosis, EU/JP) AMG 145 (Hyperlipidemia, JP)	ASP7991 YM311 (JP) ASP8232 ASP3325 CK-2127107

BPS/IC: Bladder pain syndrome/Interstitial cystitis, BPH: Benign prostatic hyperplasia, MTX: Methotrexate, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant, SOT: Solid organ transplant, RA: Rheumatoid arthritis, PC: Prostate cancer, OC: Ovarian cancer, NSCLC: Non-small cell lung cancer, BC: Breast cancer, CRC: Colorectal cancer, OD: Orally disintegrating, BPD: Bipolar disorders, MDD: Major depressive disorder, IBS: Irritable bowel syndrome, PDN: Peripheral diabetic neuropathy, CKD: Chronic kidney disease

Changes in Pipeline Status Since May 2013 <Approved>

Product Name (Generic Name)	Target Disease	Area	Stage	Changes
Tarceva (Erlotinib)	First-line treatment of people with metastatic non-small cell lung cancer whose tumors have certain epidermal growth factor receptor activating mutations as detected by an FDA-approved test	US	Approved	Approved in the US in May 2013. (CDx developed by Roche Molecular Diagnostics was approved at the same time.)
VESOMNI [Fixed dose combination of solifenacin and tamsulosin]	Moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia in men who are not adequately responding to treatment with monotherapy	Europe	Approved	First European approval in Netherlands in May 2013.
Prograf (tacrolimus)	Interstitial pneumonia associated with polymyositis/dermatomyositis	Japan	Approved	Approved in Japan in June 2013.
XTANDI (enzalutamide)	Metastatic castration-resistant prostate cancer whose disease has progressed on or after docetaxel therapy	Europe	Approved	Approved in Europe in June 2013.
Mycamine (micafungin)	Treatment of pediatric patients four months and older with candidemia, acute disseminated candidiasis, Candida peritonitis and abscesses, esophageal candidiasis, and prophylaxis of Candida infections in patients undergoing hematopoietic stem cell transplants	US	Approved	Approved in US in June 2013.
ASTAGRAF XL (tacrolimus)	Prophylaxis of organ rejection in adult kidney transplant recipients [Extended release capsules]	US	Approved	Approved in US in July 2013.

CDx: Companion diagnostics

Changes in Pipeline Status Since May 2013 <Filed and Stage-up>

■ Filed

Code No. Generic Name	Target Disease	Area	Stage	Changes
MDV3100 enzalutamide	Prostate cancer	Japan	Filed	NDA filed in Japan in May 2013. Priority review granted in July.

■ Stage up

Code No. Generic Name	Target Disease	Area	Stage	Changes
EB178 solifenacin/ mirabegron	Urinary frequency, urinary incontinence or urgency associated with overactive bladder	Europe/ US/ Asia	P3	Entered into P3 in Europe/US/Asia.
ASP4901 (AKP-002)	Lower urinary tract symptoms associated with benign prostatic hyperplasia	Japan	P2	Entered into P2 in Japan.
MDV3100 enzalutamide	Breast cancer	US/ Europe	P2	Entered into P2 in US/Europe.

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NDA: New drug application

Changes in Pipeline Status Since May 2013 <New>

■ Alliance with Amgen

Code No. Generic name	Target Disease	Area	Stage	Changes
AMG 785 romosozumab	Osteoporosis	Japan	P3	Entered into an alliance for a long-term collaboration between Amgen and Astellas, focusing on the co-development and co-commercialization in Japan.
AMG 145	Hyperlipidemia	Japan	P2	
AMG 102 rilotumumab	Gastric cancer	Japan	P1	

■ New P1

Code No.	Target Disease	Stage	Changes
ASG-15ME	Cancer (ADC technology)	P1	Entered into P1. (co-development with Seattle Genetics)
ASP2215	Cancer	P1	Entered into P1.
ASP3325	Hyperphosphatemia	P1	Entered into P1.
CK-2127107	Skeletal muscle disease (non-neuromuscular indications)	P1	In-licensed. (co-development with Cytokinetics)

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

■ Discontinued

Code No. Generic name	Target Disease	Area	Stage	Reason for Discontinuation
YM155 sepantronium bromide	Non-Hodgkin's lymphoma	US Europe Japan	P2 P2 P1	Discontinued for strategic reasons after comprehensive consideration of prioritization of this product in our pipeline etc.
ASP0777	Alzheimer's disease [Dementia]	-	P1	Discontinued for strategic reasons after comprehensive consideration of prioritization of this product in our pipeline etc.
ASG-5ME	Cancer (ADC technology)	-	P1	Discontinued for strategic reasons after comprehensive consideration of P1 study results and prioritization of this product in our pipeline etc. (We remain interested in the target, SLC44A4, for treatment of oncologic indications.)

■ Discontinuation in a part of indications

Code No. Generic name	Target Disease	Area	Stage	Reason for Discontinuation
ASP4130 tivozanib	~~Advanced renal cell carcinoma (RCC)~~	~~US Europe~~	~~Filed P3~~	-Decided not to support future trials in RCC or submit MAA for tivozanib for RCC. -Our partner AVEO received a Complete Response Letter from the FDA in June 2013. -The development for other indications is ongoing.
	CRC, Breast cancer	US/ Europe	P2	
ASP3652	~~CP/CPPS~~	~~Europe~~	~~P2~~	-Discontinued the development for the indication of CP/CPPS due to lack of efficacy in P2 study. The development for the other indication is ongoing.
	BPS/IC	Europe Japan	P2 P1	
erlotinib	NSCLC (Adjuvant, combination with MetMAb), ~~CRC,~~ Pediatric ependymoma	US	P3	-Discontinued the development for the indication of CRC due to lack of efficacy in P3 study. -The development for other indications is ongoing.

RCC: Renal cell carcinoma, CRC: Colorectal cancer, CP: Chronic prostatitis, CPPS: Chronic pelvic pain syndrome,
BPS: Bladder pain syndrome, IC: Interstitial cystitis, NSCLC: Non-small cell lung cancer

Oncology Pipeline

	Project	Target cancer	Characteristics	P1	P2	P3	Filed
Small molecule	Enzalutamide (XTANDI)	Prostate cancer (PC), Breast cancer (BC)	Androgen receptor inhibitor	PC: Post-chemo **EU: Launch**			
				PC **Japan: Filed**			
				PC: Pre-chemo EU/US/JP/Asia			
				BC:US/EU			
	Erlotinib (Tarceva)	NSCLC (1st line for patients with EGFR mutation, adjuvant, combination with MetMAb), Pediatric ependymoma	HER1/EGFR tyrosine kinase inhibitor	1st line for NSCLC with EGFR mutations **US: Approved**			
				Others: US			
	Degarelix (Gonax)	Prostate cancer	1st GnRH antagonist in Japan	3M: JP			
	Tivozanib ASP4130	Colorectal cancer (CRC), Breast cancer (BC),	Potent, selective, long half-life inhibitor of VEGF receptors 1, 2 and 3	CRC, BC: EU/US			
	Linsitinib ASP7487 (OSI-906)	Ovarian cancer, NSCLC	IGF-1R/IR tyrosine kinase inhibitor	US			
	ASP1707	Prostate cancer*	Oral GnRH antagonist				
	ASP3026	Cancer	ALK tyrosine kinase inhibitor				
	ASP9853	Cancer					
	ASP2215	Cancer					
Antibody	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)				
	Rilotumumab AMG 102	Gastric cancer	Anti-HGF mAb	JP			

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

Enzalutamide: Development Progress

Study	Target	Design	P1	P2	P3	Filed
P3 EU/US [AFFIRM study]	Post-chemo Metastatic castration-resistant prostate cancer (CRPC)	Placebo-controlled, n=1,199	Study completed. -US Launch: Sep. 13, 2012 -EU Launch: Jul. 11, 2013 (UK)			
P1/2 JP	Post-chemo Metastatic CRPC	Open-label, n=46	Filed: May 24, 2013 (for prostate cancer, priority review granted)			
P3 EU/US/JP/Asia [PREVAIL study]	Pre-chemo Metastatic CRPC	Placebo-controlled, n=1,717	Completed enrollment: May 2012, Planned interim analysis:2013			
P3 EU/US [PROSPER study]	M0 CRPC Non-metastatic CRPC	-	Preparing Planned to start in 2013			
P2 EU/US [TERRAIN study]	Pre-chemo Metastatic CRPC	To compare with bicalutamide, n=370	Ongoing			
P2 US [STRIVE study]	Pre-chemo Metastatic or non-metastatic CRPC	To compare with bicalutamide, n=400	Ongoing			
P2 US	Neoadjuvant therapy Undergoing prostatectomy	Monotherapy or combo with leuprolide or dutasteride, n=50	Completed enrollment: March 2013			
P2 EU	Hormone-naive Progressive prostate cancer	Open-label, n=67	Completed			
P2 US/EU	Breast Cancer Advanced, androgen receptor-positive, triple-negative breast cancer	Open-label, n=80	First Patient In: Jun. 2013			

EB178: Development Progress ~Entered into P3 in US/Europe/Asia~

Current status

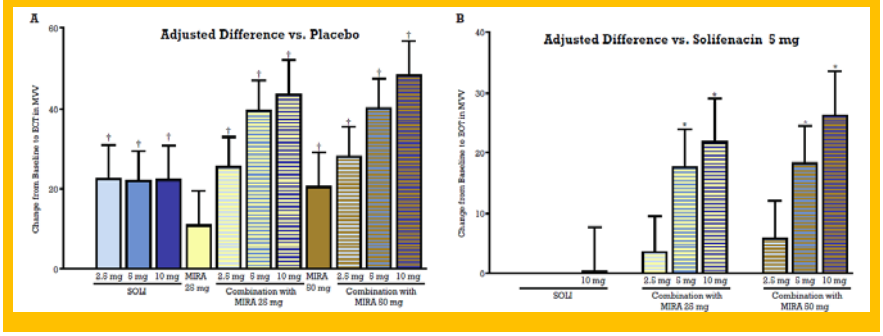
- Target disease: Urinary frequency, urinary incontinence or urgency associated with overactive bladder
- Development status: P3 in US/Europe/Asia (Preparing a double-blind study and a long-term study)

Results of P2 Symphony study in Europe

Excerpt from the poster presented at AUA on May 7, 2013 by Dr. Abrams P, Bristol Urological Institute, Southmead Hospital, Bristol, UK

Target disease	OAB
Design	Double-blind, dose-ranging study
Treatment arms	6 combinations of solifenacin (3 doses, 2.5, 5, 10 mg) and mirabegron (2 doses, 5, 10 mg) or monotherapy solifenacin (3 doses), mirabegron (2 doses) or placebo
Duration	12 weeks
Number of subjects	1306
Primary endpoint	Change from baseline to end of treatment (EOT) in mean volume voided per micturition

Changes from baseline to EOT in mean voided volume per micturition versus placebo (A), and versus solifenacin 5 mg (B)



Mirabegron combination therapy with solifenacin demonstrated greater efficacy than solifenacin alone on change from baseline to EOT in mean volume voided per micturition.

FY2013 Progress of Late Phase Compounds

	Phase 3	NDA Filing	Approval
US	erlotinib (Tarceva) NSCLC etc. EB178** solifenacin Pediatric enzalutamide Pre-chemo PC*		ASTAGRAF XL Tarceva 1st line for NSCLC with EGFR mutations Mycamine Pediatric
Europe	ASP0113 (VCL-CB01) isavuconazole ASP1517 (FG-4592) capsaicin (Qutenza)		Launched XTANDI Post-chemo PC VESOMNI
Japan	nateglinide (Starsis) ASP7374 beraprost sodium (Careload) degarelix (Gonax) 3-month formulation ramosetron (Irribow) IBS Female quetiapine (Seroquel) AMG 785 romosozumab bixalomer (Kiklin) Not on dialysis certolizumab pegol (Cimzia) MTX-naive RA	ipragliflozin ramosetron (Irribow) OD Tablet enzalutamide Prostate cancer midazolam (Dormicum)	Prograf IP Launched Acofide

Japan Europe US EU/US

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

Profit Distribution Policy

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

	FY2011	FY2012	FY2013 (Forecasts)
EPS	169.38 YEN	180.40 YEN	243.79 YEN
Dividends per Share	125 YEN	130 YEN	135 YEN
ROE	7.7%	8.0%	-
DOE	5.7%	5.7%	-
Share Buybacks	-	10.8 million shares (49.3 billion YEN)	Implemented in a flexible manner
Cancellation of Treasury Stock	-	-	11 million shares (Cancelled in May 2013)

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