Financial Results for 2Q/FY 2013 Ending March 31, 2014

November 1, 2013
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Financial Results for 2Q/FY2013

2Q/FY2013: From Apr. through Sep. 2013

(Billion YEN)

	2Q/ FY2012	2Q/ FY2013	Change	2Q/FY2013 Initial Forecasts#	Progress per 2Q Forecasts
Net sales	476.8	556.7	+16.7%	567.0	98.2%
COGs as % of sales	150.2 31.5%	169.4 30.4%	-		
R&D Expenses as % of sales	83.5 17.5%	102.2 18.4%	+22.3%	105.0	97.3%
Other SG&A	154.6	200.5	+29.7%		
Operating Income	88.3	84.5	-4.4%	83.0	101.9%
Ordinary income	90.3	83.0	-8.0%	83.0	100.1%
Net Income	57.4	48.1	-16.0%	52.0	92.7%

Special gains and losses (net): -13.8
-Restructuring costs (reshaping research framework, succession of Fuji Plant)
-Impairment loss of patents etc.

◆ Exchange Rates (YEN)

#Announced with FY2012 financial results in May 2013

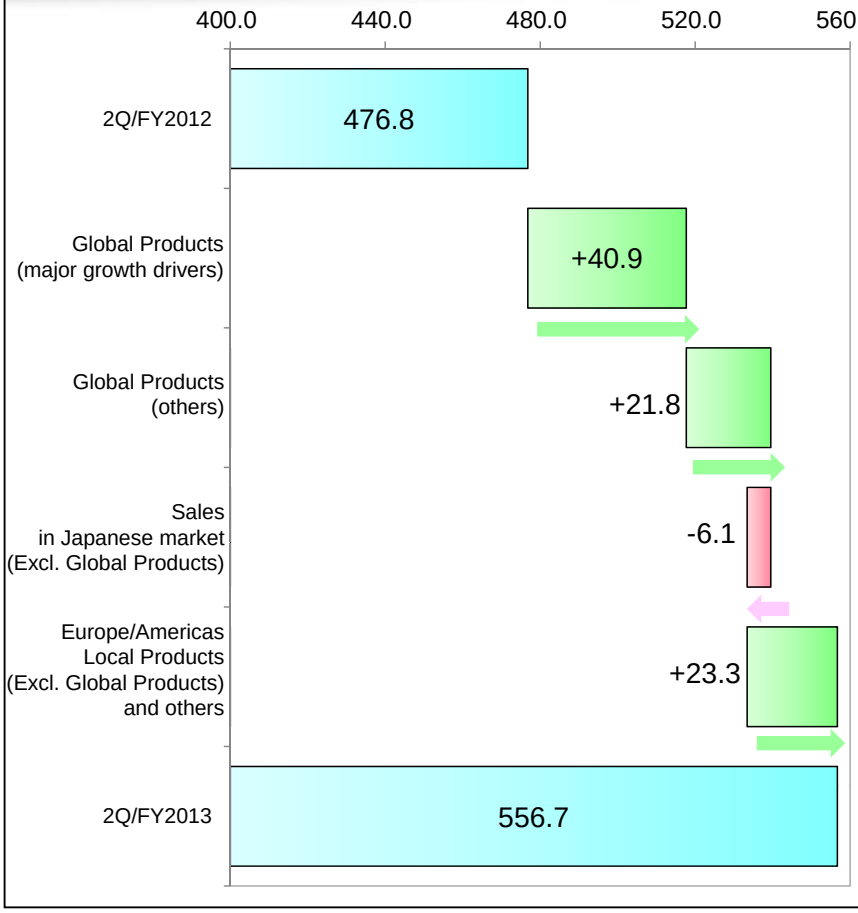
[Average for terms]	2Q/FY2012	2Q/FY2013	Change	2Q/FY2013 Forecasts
USD	79	99	19 weakening of YEN	100
EUR	101	130	29 weakening of YEN	130

[Change from beginning to end of terms]	2Q/FY2012	2Q/FY2013
USD	5 strengthening of YEN	4 weakening of YEN
EUR	10 strengthening of YEN	11 weakening of YEN

Depreciation and amortization
-2Q/FY2012: 22.3
-2Q/FY2013: 29.9

Amortization of goodwill
-2Q/FY2012: 5.7
-2Q/FY2013: 2.9

Results of 2Q/FY2013: Analysis of Change in Sales (vs. Previous Year)



Sales increase:
+79.8 billion YEN

-Forex impact: +61.3 billion YEN

1) Global Products (major growth drivers): +40.9
Vesicare +12.1/Mirabegron +9.3/XTANDI +19.4

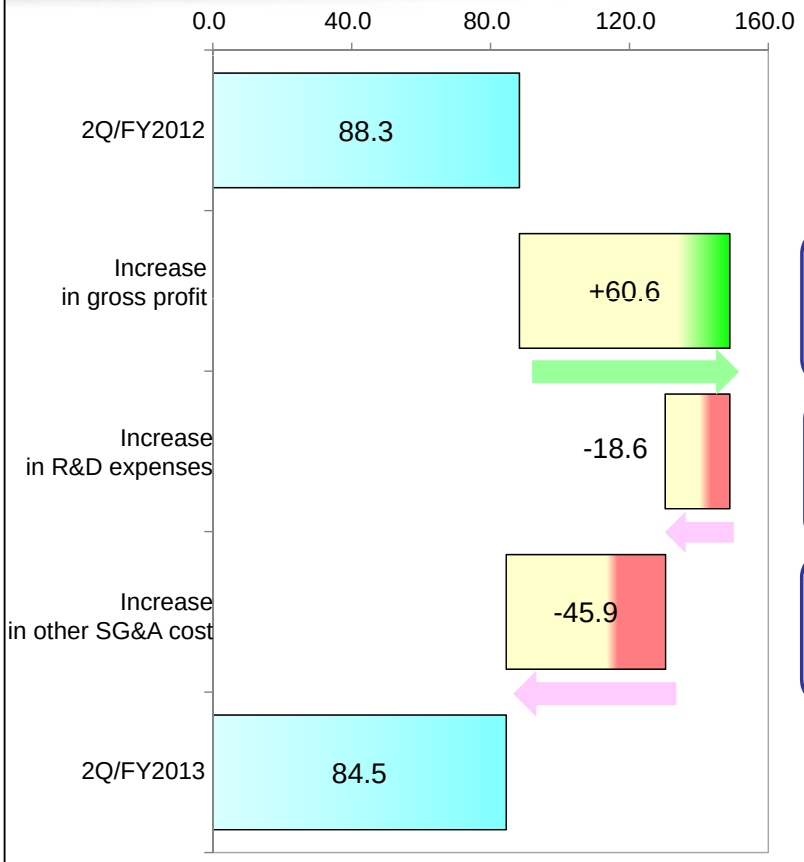
2) Global Products (others): +21.8
Prograf +11.3/Harnal +2.3/Funguard +2.6/
Protopic +3.4/Eligard +2.0

3) Sales in Japanese market:
(Excl. Global Products): -6.1
New Products and Growing Products +10.3/
Micardis +3.3
Lipitor -4.5/Gaster -2.2/Myslee -2.8/Seroquel -4.7

4) Europe/Americas Local Products
(Excl. Global Products) and others: +23.3
Scan +7.2/Tarceva +5.4/
Other European products: Approx. +8.0

[vs. forecasts] -10.2 [Forex impact: -2.2]
- Japan: -15.2 (generic impact etc.)
- Americas: +5.8
(Favorable sales in Scan, Myrbetriq and Vesicare)

Results of 2Q/FY2013: Analysis of Change in Operating Income (vs. Previous Year)



Operating income decrease: -3.8 billion YEN

-Forex impact: +7.7 billion YEN

Increase in sales: +79.8
Increase in COGs: -19.1
} Increase in gross profit: +60.6
Decrease in COGs ratio: -1.1ppt (31.5%→30.4%)
-Change in product mix etc.: -2.4ppt
-Forex impact on elimination of unrealized gain: +1.3ppt

Increase in R&D expenses: -18.6
-Increase in upfront/milestone payment for alliance

Increase in other SG&A cost: -45.9
-Cost for oncology business in the US/Europe
-Cost for strengthening sales force in emerging markets
-Cost for product launches

[vs. Forecast] +1.5 [Forex impact: -0.3]
- Lower sales than expected
- Lower COGs ratio than expected: Change in product mix
- Lower SG&A cost than expected: Deferral of expenses to a later accounting period

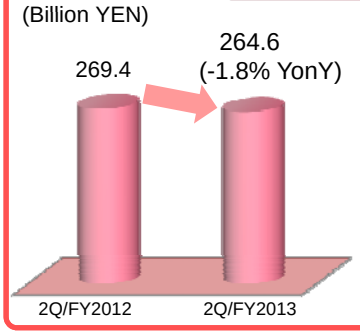
Sales by Region (Local Currency Basis)

*Calculated based on the location of the seller

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

Japan

(Billion YEN)



Sales in Japanese market: 257.2 bn YEN (-1.8%)

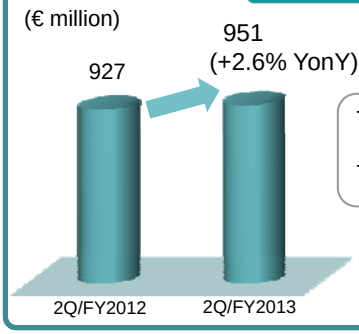
-Sales decrease due to generic impact etc.
-Steady sales expansion of major growing products and new products



Europe

*Incl. Middle and Near East and Africa

(€ million)

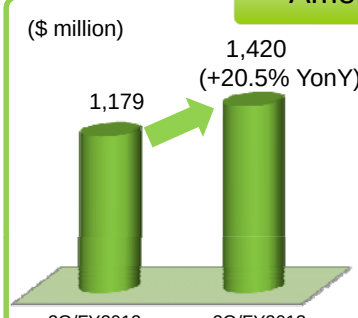


-Growth of Vesicare and Mycamine
-Contribution of newly launched XTANDI



Americas

($ million)



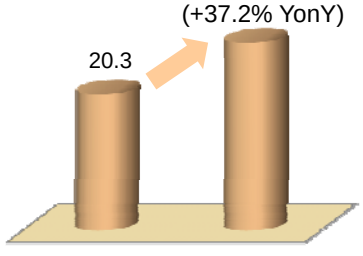
-Contribution of new products (XTANDI and Myrbetriq)
-Growth of Vesicare, Scan and Tarceva



Asia

*Incl. Oceania

(Billion YEN)



+8.4%
Excl. forex impact

-Growth in all major products



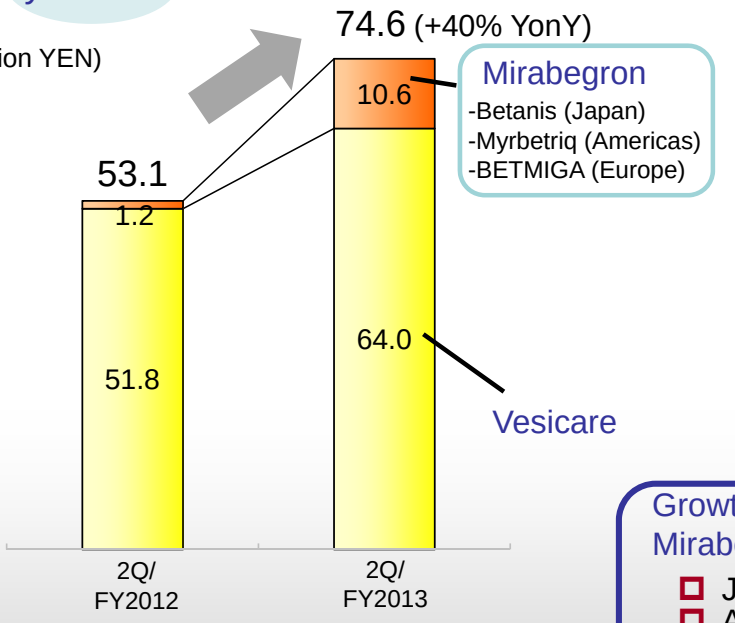
Overactive Bladder Franchise in Urology

Sales expansion driven by Vesicare growth and Mirabegron contribution

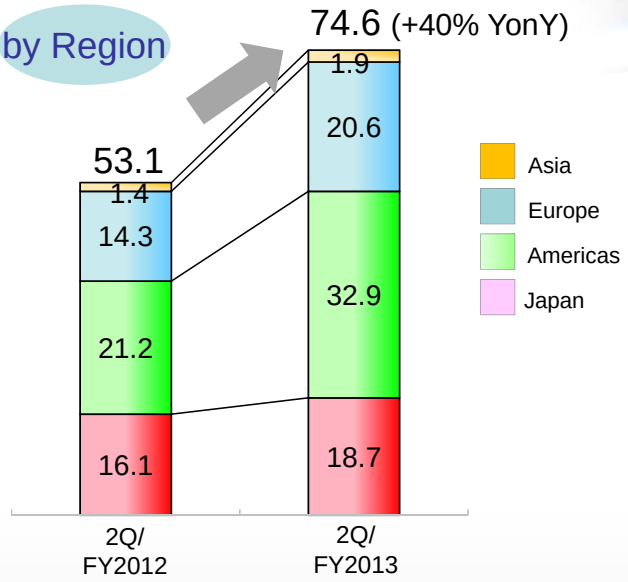
Total sales of Vesicare and Mirabegron

by Product

(Billion YEN)



by Region



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

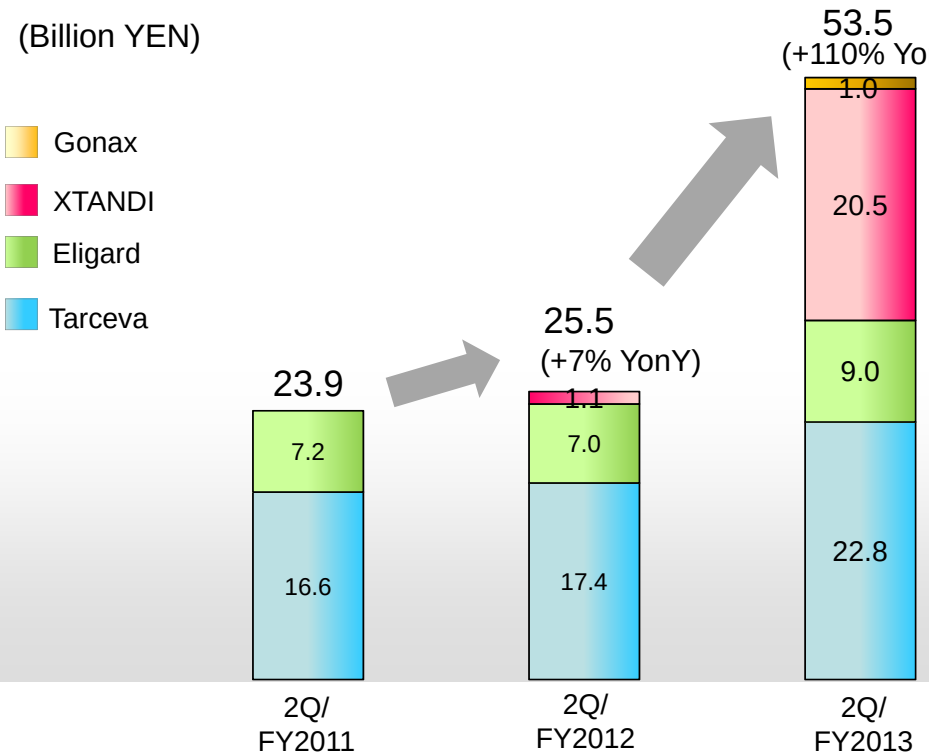
- Japan: +16%
- Americas: +25% (USD basis)
- Europe: +12% (EUR basis)
- Asia: +14% (Excl. forex impact)

Oncology Franchise

Expansion of oncology franchise driven by contribution of XTANDI

Total sales of XTANDI, Tarceva, Eligard and Gonax

(Billion YEN)

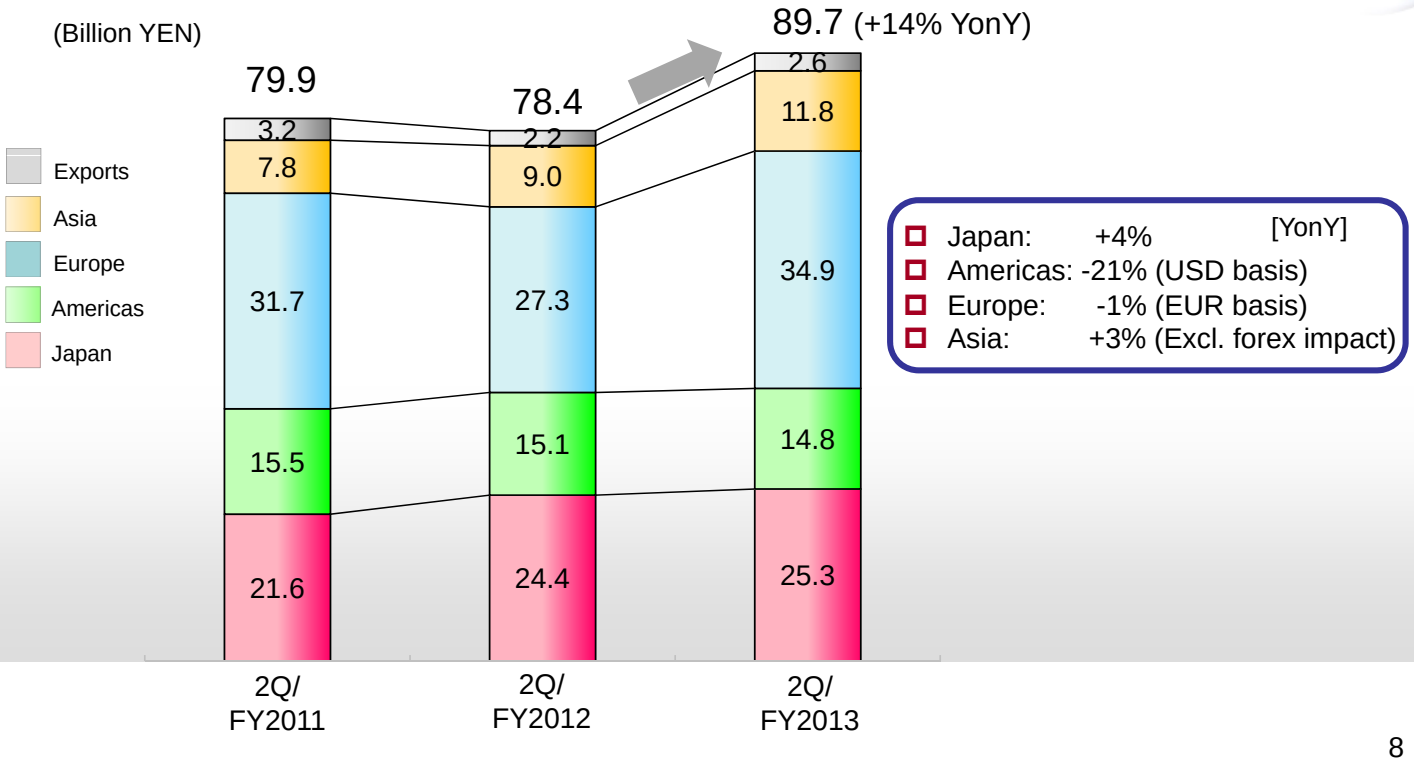


- XTANDI
  - -US: 192 million USD
  - -Europe: 11 million EUR
- Eligard
  - -Europe: 69 million EUR
  - Remained the same as the previous year
- Tarceva-related revenues
  - 231 million USD
  - +6% YonY (USD basis)

Transplantation Franchise

Maintaining global sales by growth in Japan and Asia

Total sales of Prograf and Advagraf/Graceptor/ASTAGRAF XL

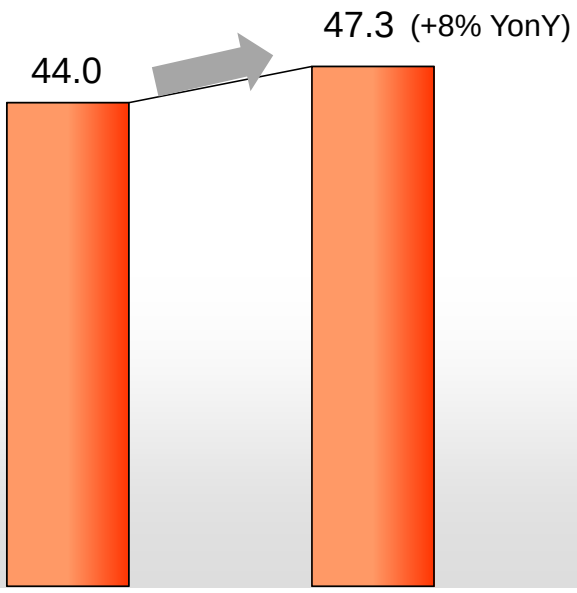


- Japan: +4% [YonY]
- Americas: -21% (USD basis)
- Europe: -1% (EUR basis)
- Asia: +3% (Excl. forex impact)

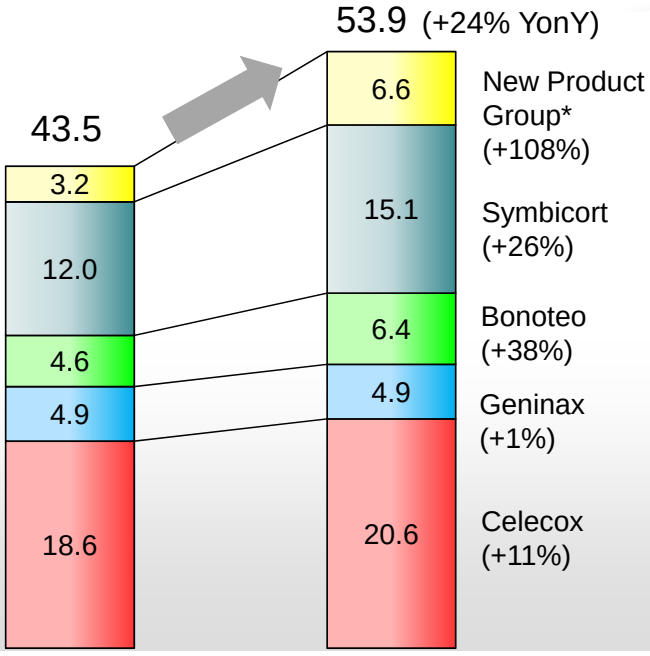
Major Products in Japan (Excluding Global Products)

Steady sales expansion in Growing Products and New Product Group

Micardis [family]



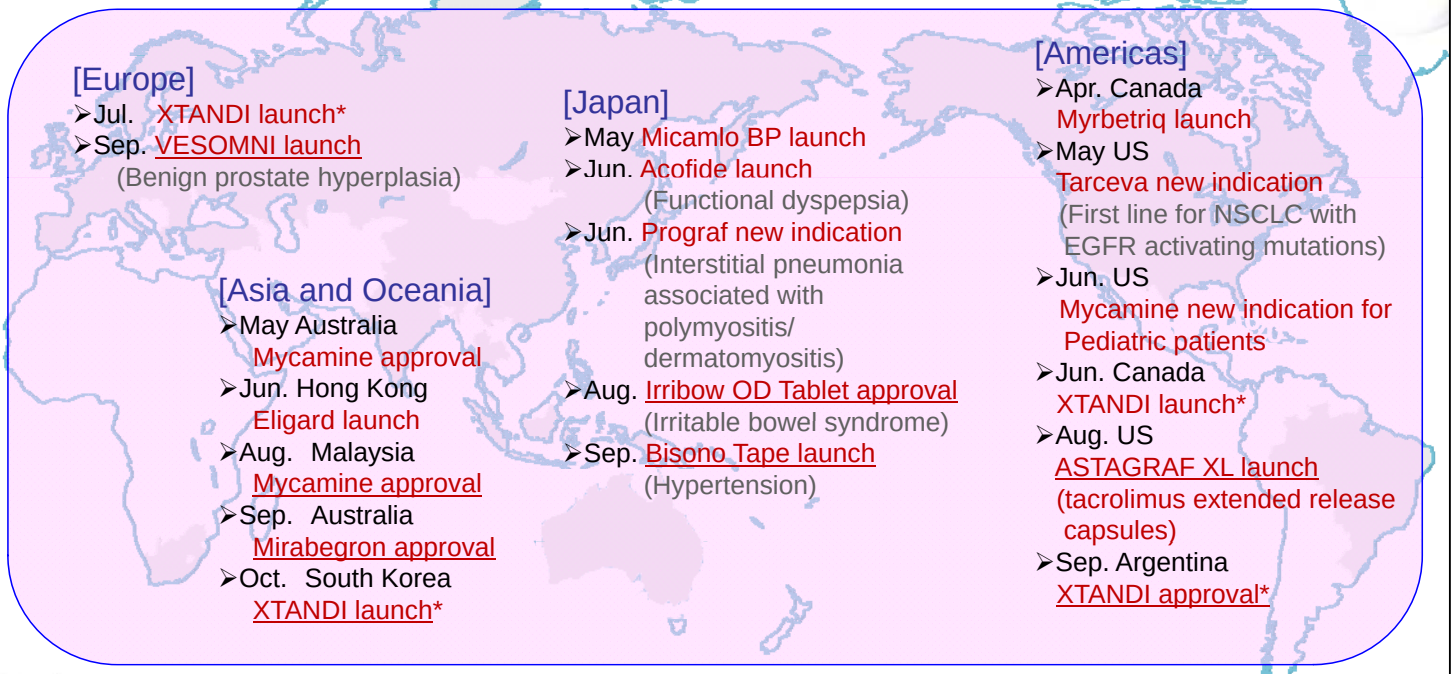
New Product Group and Growing Products



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

Continuous Introduction of New Products
(Efforts from April 2013 onward)

■ Approvals and launches in 4 regions
(Underlined item: Updates from the previous announcement)



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

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

[Japan]
- ➢May Micamlo BP launch
- ➢Jun. Acofide launch
  (Functional dyspepsia)
- ➢Jun. Prograf new indication
  (Interstitial pneumonia associated with polymyositis/ dermatomyositis)
- ➢Aug. Irribow OD Tablet approval
  (Irritable bowel syndrome)
- ➢Sep. Bisono Tape launch
  (Hypertension)

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

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*Metastatic castration-resistant prostate cancer in patients who have received chemotherapy
NSCLC: Non-small cell lung cancer

Forecasts for FY2013

(Billion YEN)

	FY2012 Initial Forecasts	FY2013 Revised Forecasts	Change
Net sales	1,170.0	1,155.0	-15.0
R&D Expenses as % of sales	212.0 18.1%	212.0 18.4%	0.0
Operating Income	170.0	170.0	0.0
Ordinary Income	170.0	170.0	0.0
Net Income	110.0	100.0	-10.0

◆Exchange Rates [Average for Terms] (YEN)

USD	100	99.4
EUR	130	130.0

◆Forecasted exchange rates from 3Q/FY2013 onwards: 100 YEN/USD, 130 YEN/EUR

Remarks

□ Downward revision of initial forecast for sales

[Factors]
- ➢Sales in Japanese market: Approx. -27.0
  (Generic impact, downward revision for growing products)
- ➢Americas: Approx. +13.0
  (Upward revision of Scan, Myrbetriq, and Vesicare)

[Forex impact: -2.6]

□ No change of initial forecast for operating income

[Factors]
- ➢Sales expected to be lower than initial forecasts
- ➢COGs ratio expected to be lower than initial forecasts: Change in product mix
- ➢SG&A expected to be lower than initial forecasts (No change in forecast for R&D expenses)

[Forex impact: -0.5]

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) fidaxomicin (JP)
Oncology	enzalutamide (PC, JP)	enzalutamide (PC, (Pre-chemo, EU/US/JP/Asia, non-metastatic, EU/US/Asia)) erlotinib (NSCLC etc., US) degarelix (3M, JP)	linsitinib (OC, 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 ASP5878
Neuroscience	midazolam (Dentistry, JP)	quetiapine (BPD, JP) capsaicin (PDN, EU)	quetiapine (MDD, JP) ASP8477 (Neuropathic pain etc., EU)	ASP9226 ASP3662
DM Complications and Kidney Diseases, Others	ipragliflozin (Diabetes, JP)	roxadustat (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) romosozumab (Osteoporosis, JP) AMG 145 (Hyperlipidemia, JP)	roxadustat (Anemia associated with CKD, JP) YM311 (Renal anemia, EU) linaclotide (IBS, JP) ASP1707 (Endometriosis, EU/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, OA: Osteoarthritis, CKD: Chronic kidney disease

Changes in Pipeline Status Since August 2013 <Approval and Stage-up>

■ Approval

Product Name (Generic Name)	Target Disease	Area	Stage	Changes
Irribow OD Tablets (ramosetron)	Diarrhea-predominant irritable bowel syndrome in males	Japan	Approved	Approved in Japan in August 2013.

OD: Orally disintegrating

■ Stage-up

Code No. Generic Name	Target Disease	Area	Stage	Changes
MDV3100 enzalutamide	Non-Metastatic castration-resistant prostate cancer	US Europe Asia	P3	Entered into P3 in the US, Europe and Asia.
AMG 145	Hyperlipidemia	Japan	P3	Entered into P3 in Japan.
ASP8477	Neuropathic pain	Europe	P2	Entered into P2 in Europe.

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Changes in Pipeline Status Since August 2013 <New and Discontinuation etc.>

■ New P1

Code No.	Target Disease	Stage	Changes
ASP5878	Cancer	P1	Entered into P1.

■ Discontinuation

Code No. Generic name	Target Disease	Stage	Reason for Discontinuation
ASP2408	Rheumatoid arthritis	P1	Discontinued due to strategic reasons.
ASP2409	Prevention of organ transplant rejection	P1	Discontinued due to strategic reasons.

■ Discontinuation in a part of indications

Code No. Generic name	Target Disease	Area	Stage	Reason for Discontinuation
ASP7487 (OSI-906) linsitinib	Ovarian cancer~~, Non-small cell lung cancer~~	US	P2	-Discontinued the development for the indication of non-small cell lung cancer due to lack of efficacy. -The development for ovarian cancer is ongoing.

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Oncology Pipeline

	Project	Target cancer	Characteristics	P1	P2	P3	Filed
Small molecule	Enzalutamide (XTANDI)	Prostate cancer (PC) (pre-chemo, non-metastatic), Breast cancer (BC)	Androgen receptor inhibitor	PC: Japan Pre-chemo: EU/US/JP/Asia Non-Metastatic: EU/US/Asia BC:US/EU			
	Erlotinib (Tarceva)	NSCLC (adjuvant, combination with MetMAb), Pediatric ependymoma	HER1/EGFR tyrosine kinase inhibitor	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	EU/US			
	Linsitinib ASP7487 (OSI-906)	Ovarian cancer	IGF-1R/IR tyrosine kinase inhibitor	US			
	ASP1707	Prostate cancer*	Oral GnRH antagonist				
	ASP3026	Cancer	ALK tyrosine kinase inhibitor				
	ASP9853	Cancer					
	ASP2215	Cancer					
	ASP5878	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	Obtained interim analysis results: Oct. 2013.			
P3 EU/US/Asia [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=375	Completed enrollment: Jul. 2013			
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			

Enzalutamide: Positive Results from Interim Analysis of Phase-3 PREVAIL study

- The PREVAIL study met both co-primary endpoints of OS and rPFS
- The IDMC concluded enzalutamide demonstrated a favorable benefit-risk ratio.
- The IDMC recommended the study be stopped and patients treated with placebo be offered enzalutamide.

OS:

- ***30% reduction in risk of death, HR=0.70 (95% CI, 0.59-0.83) (p<0.0001)***
- Percentage of patients alive was 72% in the enzalutamide arm vs. 65% in the placebo arm at the time of interim analysis data cut-off date.
- Median OS was 32.4 months (95% CI, 31.5-NR) in the enzalutamide arm vs. 30.2 months (95% CI, 28.0-NR) in the placebo arm.

rPFS:

- ***81% reduction in the risk of radiographic progression or death, HR=0.19 (95% CI, 0.15-0.23) (p<0.0001)***
- Median rPFS was not yet reached (95% CI, 13.8-NR) in the enzalutamide arm vs. 3.9 months (95% CI, 3.7-5.4) in the placebo arm.

- *These are the primary analyses. Full analysis of the safety data, secondary endpoints and derivation of the Kaplan-Meier curves awaits final database lock, based on this data cut-off.*

➢ Enzalutamide is the only agent to date to demonstrate a statistically significant improvement vs. placebo in both OS and rPFS in men with mCRPC who have not yet received chemotherapy.

OS: Overall survival, rPFS: Radiographic progression-free survival, IDMC: Independent Data Monitoring Committee, HR: Hazard ratio, CI: Confidence interval, NR: Not reached

Isavuconazole: Positive Topline Results of Phase-3 SECURE Study

Phase-3 study update

Aspergillus	SECURE	Positive topline results	Invasive aspergillosis
	VITAL	Enrollment completed	Patients with invasive fungal disease caused by mucormycetes and other emerging fungal pathogens and patients with aspergillosis and pre-existing renal impairment
Candida	ACTIVE	Ongoing	Invasive candidiasis

SECURE Study

Summary	Target disease	Primary treatment of invasive fungal disease caused by Aspergillus species or certain other filamentous fungi
	Design	In comparison with voriconazole, double-blind
	Treatment arms	Isavuconazole (q.d.), voriconazole (b.i.d.)
	Duration	Up to 84 Days
	Numbers of subjects	516 (intent-to-treat population)
	Primary endpoint	All-cause mortality at Day 42

- Achieved its primary objective in demonstrating non-inferiority versus voriconazole, with all-cause-mortality at Day 42 of 18.6% in the isavuconazole group and 20.2% in the voriconazole group.
- Adverse events (all causalities) were reported in 96.1% and 98.5% of patients in the isavuconazole and voriconazole treatment groups, respectively.
- Study drug-related adverse events were reported in 42.4% and 59.8% of patients in the isavuconazole and voriconazole treatment groups, respectively.

ASP015K: Positive Topline Results of Phase-2b Study in Japan

Development status update

Japan	P2b Monotherapy	Positive topline results
US/ Europe	P2b (with MTX)	Ongoing
	P2b (without MTX)	Ongoing

A license agreement was executed with Janssen Biotech, Inc. for the development and commercialization worldwide except for Japan.

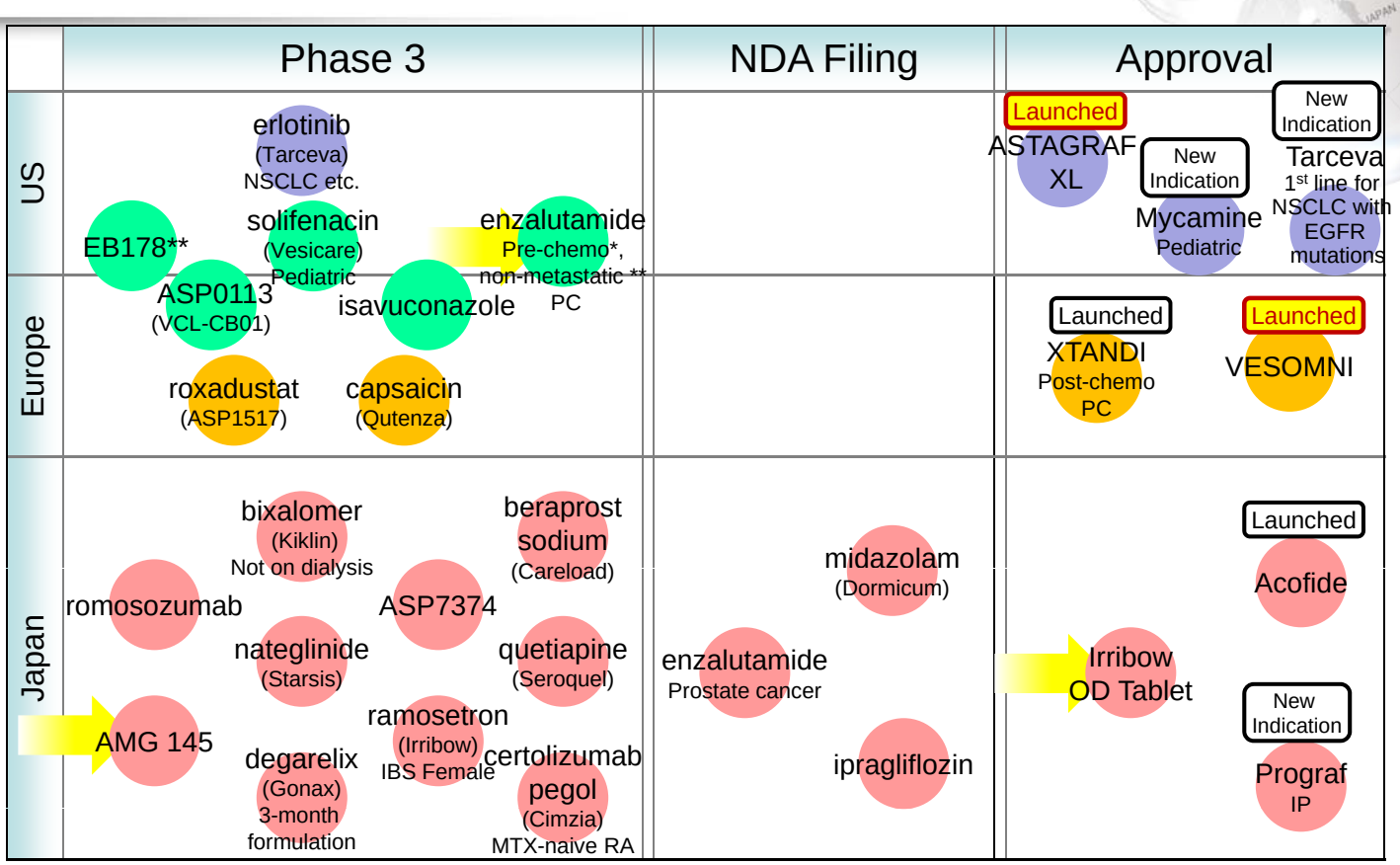
Japan P2b monotherapy

Summary	Target disease	Moderate-to-severe rheumatoid arthritis
	Design	Double-blind, placebo-controlled, dose-finding study
	Treatment arms	4 dose groups of oral QD ASP015K and placebo group
	Duration	12 Weeks
	Number of subjects	281
	Primary endpoint	Percentage of subjects achieving ACR 20 response at Week 12/End of Treatment

・For the primary endpoint, percentage of subjects achieving ACR20 response, ASP015K demonstrated a statistically significant difference from placebo in the higher three dose groups.
・ASP015K was well tolerated and the results support progression to Phase 3 development.

MTX: Methotrexate

FY2013 Progress of Late Phase Compounds



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

Initiatives to Build Resilience for Sustainable Growth

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Initiatives in 2013

Maximizing the value of new products

- Further enhancement of oncology franchise(XTANDI sales growth/additional indications)
- Maximization of OAB franchise (Vesicare, mirabegron)
- Strategic alliance with Amgen in Japan
- Co-promotion arrangement with MSD for ipragliflozin

Enhancing ability to generate innovative drugs

- Reshaping research framework and introduction of new initiatives
  Establishment of Astellas Innovation Management ("AIM")
- Regenerative Medicine: full commitment to cell therapy
- Collaborations with Cytokinetics and Mitokyne
- Introduction of next-generation ADC technology from Ambrx

Achieving Operational Excellence

- Succession of Fuji Plant Business of Astellas Pharma Tech to Nichi-Iko
- Business Process Outsourcing to Accenture in multiple business areas
- Consolidation to Nihonbashi for Development and QA&RA at Hasune office (in Itabashi-ku), and its close

Organizational and personnel requirements are changing due to these business structure transformations

- Aligning human resources with new business structure by offering early retirement incentive program to 300 employees in FY 2014

Optimization of Resource Allocation

Initiative for enhancing ability to generate innovative drugs

Collaboration with Mitokyne

Expanding research to new frontier, by utilizing external resource

Mitochondria-related Diseases

astellas ⟷ Mitokyne

R&D Collaboration (5 years)

Lead clinical development

Lead research and drug discovery

Exclusive right to acquire Mitokyne

Dispatching researchers
Bearing a part of research cost

Equity investment with other VCs
($45M in total)

astellas INNOVATION MANAGEMENT AIM

Agile research framework will be constructed with bio-venture companies, academia, CROs and KOLs, etc. to enhance open innovation drug discovery

Initiatives for Achieving Operational Excellence

Succession of Fuji Plant Business of ATEC* to Nichi-Iko

- Actively strengthen corporate function and tie up with partners in the areas of production and technology as well
- Promote the establishment of a stable production system that would efficiently realize “steady supply of high-quality drugs” in changing environment



*Astellas Pharma Tech

Business Process Outsourcing to Accenture in multiple business areas

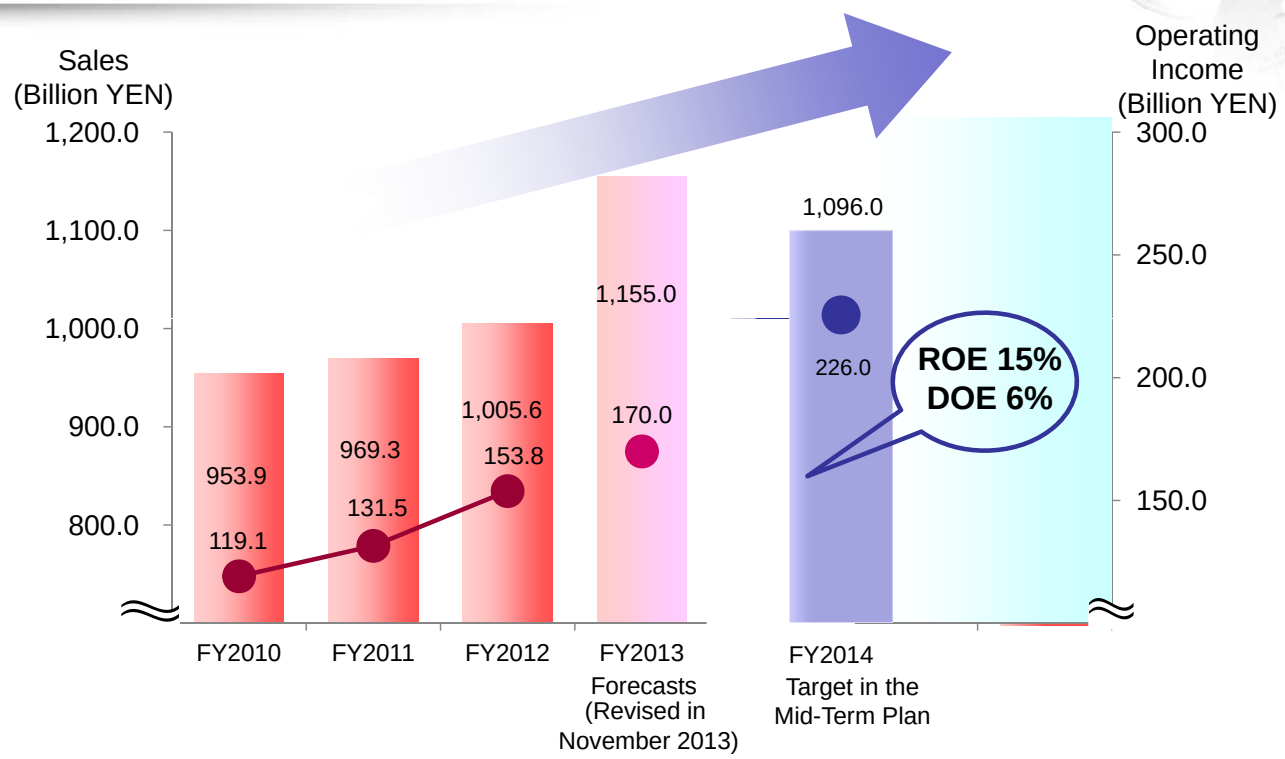
- Aim to obtain high quality services and promote efficiency by working with a specialist external partner
- Allocate own resources to businesses that contribute to competitive advantage

Business Process Outsourcing (BPO)

astellas ⇄ accenture

Offering Services

Resiliently Respond to the Changing Environment and Aim for Sustainable Growth



Revised full year forecasts for FY2013
➢No change in forecast for operating income announced in May 2013, but downward revision of sales forecasts.

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	221.63 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)

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

Interim dividend for FY13: 65 yen per share

** Not reflected the acquisition of own shares announced on Nov. 1, 2013 (up to 5.3 million shares)

Acquisition of Own Shares

Improve capital efficiency and shareholder return

At the meeting of the Board of Directors on November 1, 2013
a resolution was adopted to acquire the Company's own shares.

- Reasons for the acquisition of own shares:

  To improve capital efficiency and shareholder return.

- Class of shares to be acquired: Common stock of the Company
- Total number of shares to be acquired: Up to 5.3 million shares

  (The percentage compared to the total number of shares outstanding: 1.17%)
- Aggregate amount of acquisition cost: Up to 30 billion YEN
- Period of acquisition: From November 5, 2013 to December 16, 2013

* The status of treasury stock as of September 30, 2013:

Total number of shares outstanding:	451,217,914 shares
Number of treasury stock:	5,746,721 shares

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