Financial Results for the First Nine Months of FY2012

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Financial Results for the First Nine Months of FY2012

Fiscal year: From April through March.

(Billion YEN)

	FY11 Apr. –Dec. Actual	FY12 Apr. –Dec. Actual	Change	FY12 Forecasts#	Progress per FY12 Forecasts
Net Sales	763.8	755.1	-1.1%	972.0	77.7%
COGs as % of sales	241.5 31.6%	245.6 32.5%	- +0.9ppt		
SG&A Excluding R&D as % of sales	240.2 31.5%	240.3 31.8%	+0.0%		
R&D Expenses as % of sales	135.5 17.7%	134.1 17.8%	-1.0%	184.0	72.9%
Operating Income as % of sales	146.5 19.2%	135.0 17.9%	-7.8%	147.0	91.9%
Ordinary Income	149.9	136.4	-9.0%	149.0	91.5%
Net Income	98.6	84.6	-14.2%	98.0	86.4%
Comprehensive Income	30.0	112.3	274.1%		

Total amortization for OSI and Agensys
-FY11 Apr. –Dec. 19.8 bn YEN (OSI: 14.6, Agensys: 5.1)
-FY12 Apr. –Dec. 18.1 bn YEN (OSI: 12.9, Agensys: 5.1)

-Special gain and loss (net) -13.9 bn YEN
-Decrease in income tax burden rate (35.3%→30.9%)

Revised forecasts disclosed at 2Q/FY2012 financial announcement in November 2012

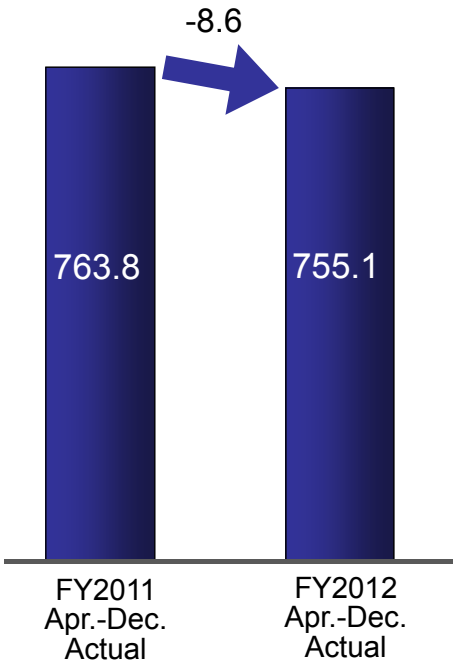
◆Exchange Rates (YEN)

[Average for terms]	Apr. -Dec. FY11	Apr. -Dec. FY12	Change	Forecasts for FY12
USD	79	80	1 weakening of YEN	80
EUR	111	102	8 strengthening of YEN	100

[End of terms]	End of Mar. 2011	End of Dec. 2011	Change	End of Mar. 2012	End of Dec. 2012	Change
USD	83	78	5 strengthening of YEN	82	87	4 weakening of YEN
EUR	118	101	17 strengthening of YEN	110	115	5 weakening of YEN

Results for the First Nine Months of FY2012: Analysis of Change in Sales

(Billion YEN)



[Sales vs. Previous Year] -8.6 (Billion YEN)

- Major positive factors
  - Global/ Vesicare +6.6
    - Funguard/Mycamine +3.1
    - Betanis/Myrbetriq +3.1
    - XTANDI (US) +5.7
  - Japan/ Micardis [Family] +3.7
    - Growth of New Product Group +18.8
      - Celecox, Symbicort, Geninax, Bonoteo etc.
  - Americas/ Scan +1.8
    - Tarceva +1.0
- Major negative factors
  - Global/ Prograf -1.8
    - Harnal -7.4
  - Japan/ Lipitor [Family] -23.0
    - Gaster -6.1
  - Americas/ Absence of DPP-IV royalty of the previous year (due to sale of DPP-IV related assets) -2.2

[Forex impact: -9.8]
[Impact of NHI drug price reduction in Japan: -21.4]

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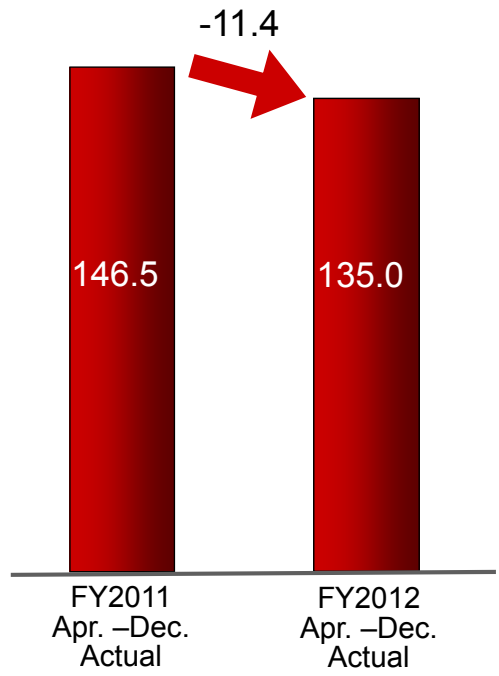
Keep the current full-year forecast for FY2012 (972.0 billion YEN) as it is, expecting increase in sales

Results for the First Nine Months of FY2012: Analysis of Change in Operating Income (OP)

(Billion YEN)



[OP vs. Previous Year] -11.4 (Billion YEN)

- Decrease in gross profit: -12.7 <negative factor>
  - Decrease in gross profit along with decrease in sales
  - Increase in COGs ratio: +0.9ppt
    Increasing factor: Forex impact on elimination of unrealized gain, etc.
- Decrease in R&D expenses: -1.3 <positive factor>
  - Impact from change in depreciation method: Approx. -3.9 etc.
- Same level of SG&A excluding R&D expenses as the previous year
  - Decrease in cost for VESIcare business in the US
  - Increase in cost for oncology business in the US
    -Co-promotion fee payment for XTANDI in the US
    -Increase in sales force etc.

[Forex impact: -11.3]

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Keep the current full-year forecast for FY2012 (147.0 billion YEN) as it is, expecting increase in OP

Sales by Region (Local Currency Basis)

*Calculated based on the location of the seller

Increases in US/Europe/Asia, Decreases in Japan

Japan

FY12 Apr. –Dec. Revenue (Billion YEN)	YoY (%)	Progress per FY12 Forecasts (%)
432.4	-2.8	77.1

Sales in Japanese market: 416.5 bn YEN (-3.0% YoY)
-Contribution of major growing products and new products
-Impact of NHI drug price reduction and generic products

Europe

FY12 Apr. –Dec. Revenue (Million EUR)	YoY (%)	Progress per FY12 Forecasts (%)
1,416	+3.6	76.5

-Growth in Vesicare, Mycamine and Eligard
-Continuous contribution of bendamustin revenues and other products: 429M EUR (+13% YoY)

Americas

FY12 Apr. –Dec. Revenue (Million USD)	YoY (%)	Progress per FY12 Forecasts (%)
1,840	+3.4	78.9

-Growth in VESIcare, Scan and Tarceva
-Contribution of XTANDI and Myrbetriq
-Absence of DPP-IV royalty of the previous year: -27M USD

Asia

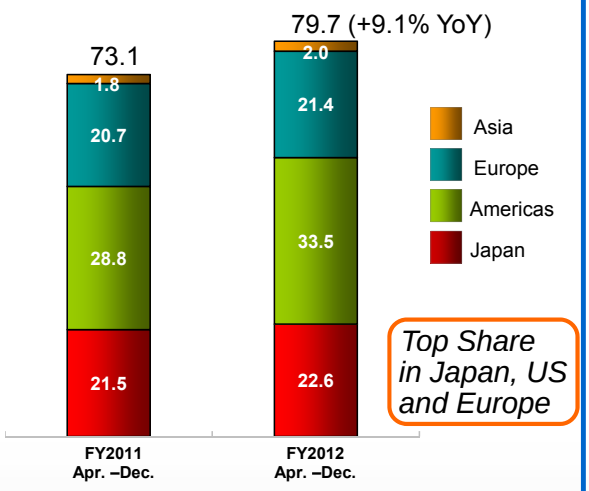
FY12 Apr. –Dec. Revenue (Billion YEN)	YoY (%)		Progress per FY12 Forecasts (%)
30.7	+14.1	+12.7 excluding forex impact	78.1

-Growth in all major products

Urology: Vesicare, Betanis/Myrbetriq and Harnal

Growth of Vesicare and Betanis/Myrbetriq

Vesicare

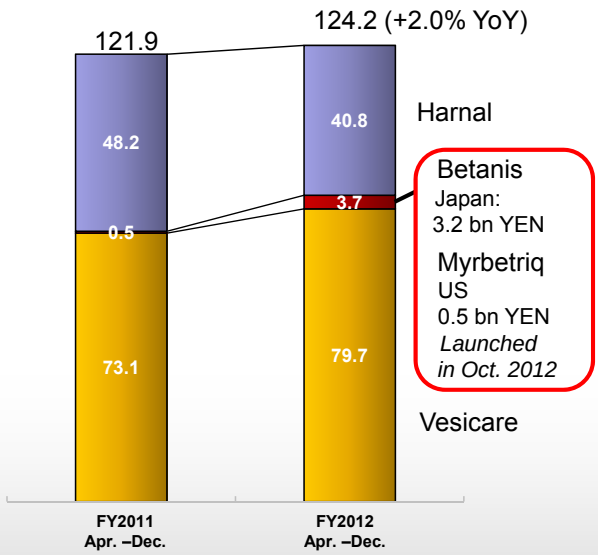


Top Share in Japan, US and Europe

[YoY]

- Japan: +5%
- Americas: +15% (USD basis)
- Europe: +12% (EUR basis)
- Asia: +9% (excluding forex impact)

Three Urology Products

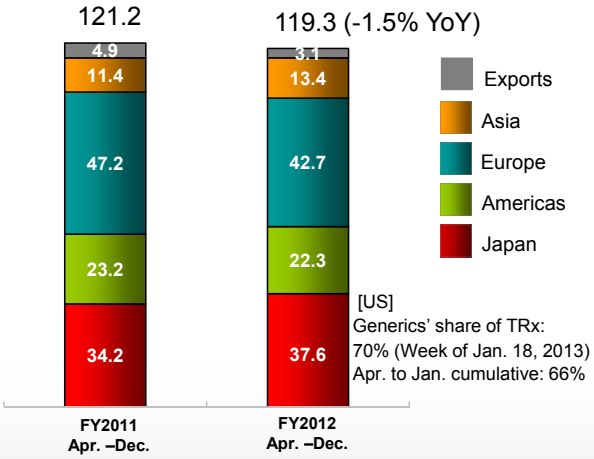


Immunology (including Transplantation) and Infectious Diseases:

Prograf and Funguard/Mycamine

Softening of decreasing trend in Prograf, Growth in Funguard/Mycamine

Prograf

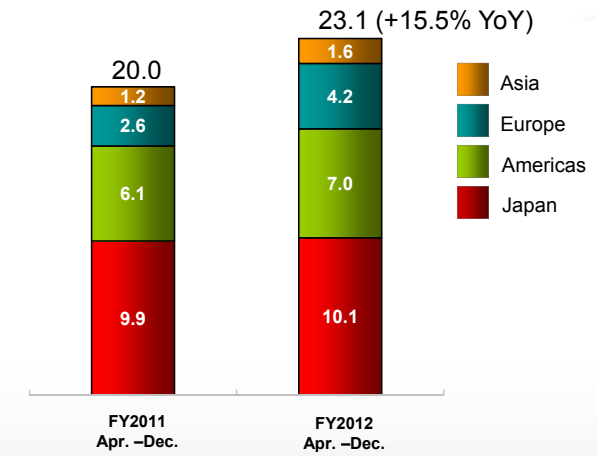


[US]
Generics' share of TRx:
70% (Week of Jan. 18, 2013)
Apr. to Jan. cumulative: 66%

[YoY]

- Japan: +10%
- Americas: -5% (USD basis)
- Europe: -2% (EUR basis)
- Asia: +15% (excluding forex impact)

Funguard/Mycamine

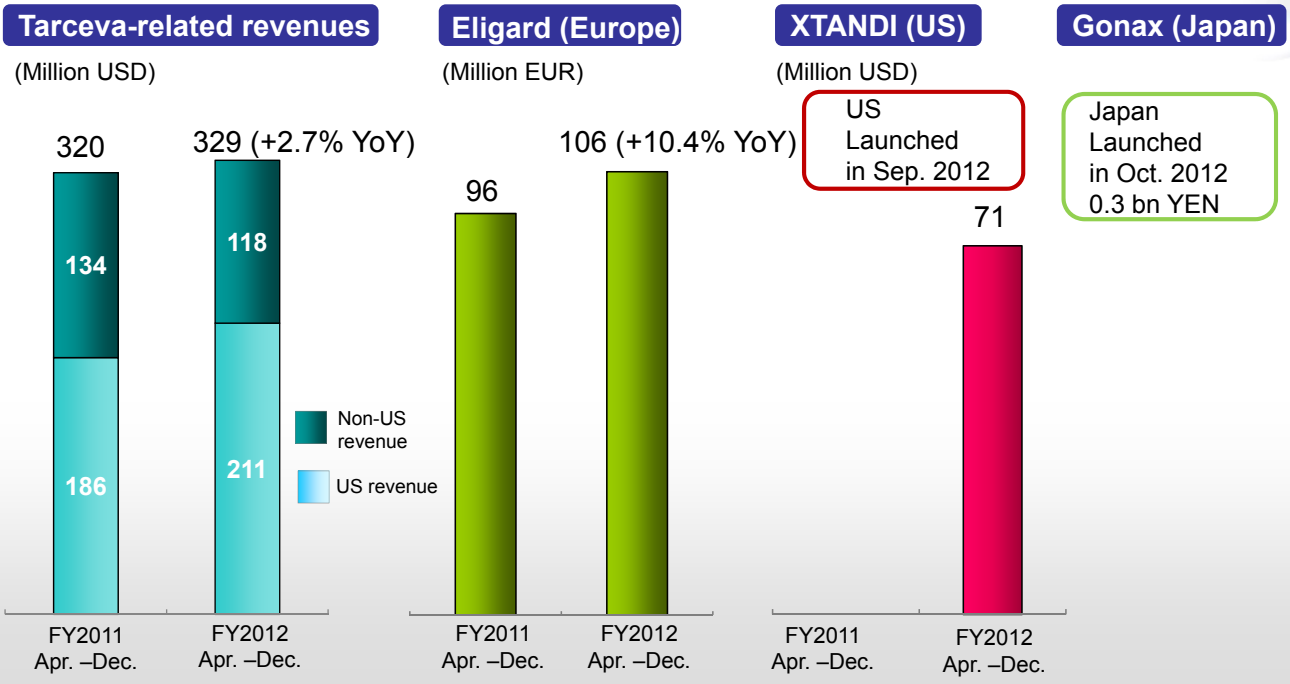


[YoY]

- Japan: +2%
- Americas: +13% (USD basis)
- Europe: +72% (EUR basis)
- Asia: +34% (excluding forex impact)

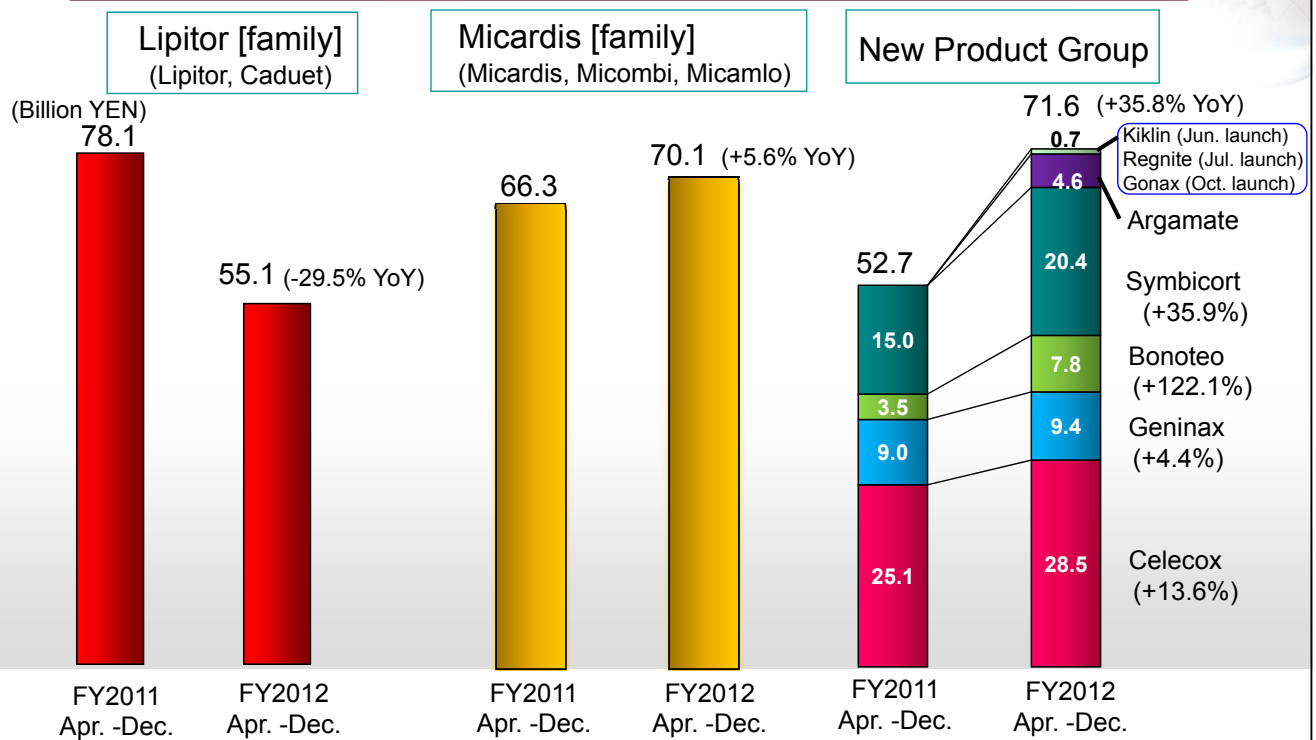
Oncology: Tarceva, Eligard, XTANDI and Gonax

Combined Tarceva, Eligard, XTANDI and Gonax revenues grew to 43.3 billion YEN



Major Products in Japan (Excluding Global Products)

Growth of major products and new product group



Continuous Introduction of New Products

Continuous approval and launch of new products in each area

➢JP/US/EU

- May EU — DIFICLIR launch (Clostridium difficile infections)
- Jun. JP — Symbicort new dosage and administration (Adult bronchial asthma, as-needed use in addition to maintenance therapy)
- Jun. JP — Kiklin launch (Hyperphosphatemia)
- Jul. JP — Regnite launch (Restless legs syndrome)
- Aug. JP — Symbicort new indication (Chronic obstructive pulmonary disease)
- Sep. US — XTANDI launch (MCRPC, post-chemotherapy)
- Oct. US — Myrbetriq launch (Overactive bladder)
- Oct. JP — Gonax launch (Prostate cancer)
- Oct. JP — Launch of Quattrovac Subcutaneous Injection Syringe Combined vaccine
- Dec. JP — Micamlo BP approval (Hypertension)
- Dec. JP — Cimzia approval (Rheumatoid arthritis not responding to conventional therapy)
- Dec. EU — BETMIGA approval (Overactive bladder)
- Jan. 2013 JP — ARGAMATE Granule launch (Hyperkalemia)

➢Asia and Oceania

- ➢May Taiwan -Feburic (febuxostat) launch
- ➢Aug. Hong Kong -Feburic launch
- ➢Aug. Singapore -Advagraf launch
- ➢Oct. Hong Kong -Eligard approval
- ➢Nov. Malaysia -Advagraf approval

MCRPC: Metastatic castration-resistant prostate cancer

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/tamsulosin (EU)	solifenacin (Pediatric, EU/US)	solifenacin/mirabegron (EU) ASP3652 (CP/CPPS etc., EU)	ASP7035, ASP0306 ASP4901 (AKP-002) ASP3652 (JP), ASP6432
Immunology (including Transplantation) and Infectious Diseases	tacrolimus extended release capsules (US) micafungin (pediatric, US) amoxicillin (Helicobacter pyroli eradication, JP)	certolizumab pegol (MTX-naive RA, JP) isavuconazole (Aspergillosis, candidemia, EU/US) ASP0113 (CMV reactivation in HSCT, EU/US) ASP7374 (Influenza, JP)	ASKP1240 (Transplant, US) ASP015K (RA, JP) ASP7373 (Influenza, JP) ASP0113 (SOT, EU/US)	ASKP1240 (JP) ASP2408 ASP2409 fidaxomicin (JP)
Oncology	enzalutamide (PC, Post-Chemo, EU) tivozanib (RCC, US) erlotinib (1st line for NSCLC with EGFR mutation, US)	enzalutamide (PC, Pre-Chemo etc., EU/US/JP/Asia) erlotinib (NSCLC etc., US) tivozanib (RCC, EU)	enzalutamide (PC, Post-Chemo, JP) linsitinib (OC, NSCLC, US) sepantronium (NHL, EU/US) quizartinib (AML, EU/US) OSI-027 (RCC, US) degarelix (3M, JP) tivozanib (BC, CRC, EU/US)	sepantronium (JP) AGS-16M8F/AGS-16C3F ASG-5ME, ASG-22ME ASP1707(PC, EU) ASP3026 ASP9603 enzalutamide (BC) ASP9853, quizartinib (JP)
Neuroscience		quetiapine (BPD, JP) capsaicin (PDN, EU)	quetiapine (MDD, JP)	ASP0777, ASP8477 ASP9226
DM Complications and Kidney Diseases, Others	acotiamide (FD, JP) ramosetron (IBS OD, JP)	ipragliflozin (Diabetes, 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)	ASP1517 (Anemia associated with CKD, JP) YM311 (Renal anemia, EU) linaclotide (IBS, JP) ASP1707 (Endometriosis, EU/JP)	ASP7991 YM311 (JP) ASP8232

OAB: Overactive bladder, CP/CPPS: Chronic prostatitis/Chronic pelvic pain syndrome, MTX: Methotrexate, CMV: Cytomegalovirus, HSCT: Hematopoietic stem cell transplant, SOT: Solid organ transplant, DGF: Delayed graft function, RA: Rheumatoid arthritis, PC: Prostate cancer, OC: Ovarian cancer, NSCLC: Non-small cell lung cancer, RCC: Renal cell carcinoma, BC: Breast cancer, NHL: Non-Hodgkin's lymphoma, AML: Acute myeloid leukemia, CRC: Colorectal cancer, FD: Functional dyspepsia, 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 November 2012 <Approved>

Product Name (Generic Name)	Target Disease	Area	Stage	Changes
Cimzia (certolizumab pegol)	Treatment of rheumatoid arthritis not responding to conventional therapy (including inhibition of progression of bone structural damage)	Japan	Approved	Approved in Japan in December 2012.
BETMIGA (mirabegron)	Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder syndrome	Europe	Approved	Approved in Europe in December 2012.

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Changes in Pipeline Status Since November 2012 <Filed >

Code No. Generic Name	Target Disease	Area	Stage	Changes
FK506 tacrolimus	Prophylaxis of organ rejection in adult patients receiving kidney transplants and in adult male patients receiving liver transplants [Extended release capsules]	US	Filed	NDA accepted in US in November 2012. PDUFA date is July 21, 2013.
FK463 micafungin	Candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses, esophageal candidiasis, prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation [Pediatric patients >= 4 months through 16 years of age]	US	Filed	sNDA accepted in US in November 2012. Priority review granted. PDUFA date is March 27, 2013.
ASP4130 tivozanib	Advanced renal cell carcinoma	US	Filed	NDA accepted in US in November 2012. PDUFA date is July 28, 2013.
erlotinib	First-line treatment of patients with locally advanced or metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor activating mutations	US	Filed	sNDA submitted in US in November 2012 [New indication]. sNDA accepted in January 2013. Priority review granted. PDUFA date is Q2 2013.

NDA: New drug application, sNDA: supplemental NDA

Changes in Pipeline Status Since November 2012 <Stage Up/New>

■ Stage up

Code No. Generic name	Target Disease	Area	Stage	Changes
ASP7374	Prophylaxis of seasonal influenza	Japan	P3	Entered into P3 in Japan.
ASP1517 (FG-4592)	Anemia associated with chronic kidney disease in patients not on dialysis and on dialysis	Europe Japan	P3 P2	Entered into P3 in US/Europe. P3 study was initiated in US. Entered into P2 in Japan. (Licensed territory: EU, Japan etc.)
AC220 quizartinib	Acute myeloid leukemia	US/Europe Japan	P2 P1	Entered into P1 in Japan.

■ New P1

Code No.	Target Disease	Stage	Changes
ASP8232	Diabetic nephropathy	P1	Entered into P1.
fidaxomicin	*Clostridium difficile* associated diarrhea	P1	Entered into P1 for Japanese development.

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Changes in Pipeline Status Since November 2012 <Discontinued>

Code No. Generic name	Target Disease	Area	Stage	Reason for Discontinuation
PSN821	Type 2 diabetes, Obesity	Europe	P2	We received a notice from AstraZeneca not to exercise an exclusive option to acquire the asset of PSN821. We have decided to discontinue the development based on the strategic priority among focused therapeutic areas and pipeline at Astellas.
ASP8597 diannexin	Prevention of delayed graft function in kidney transplantation	US	P2	We have decided to discontinue the development based on the recent findings in the preclinical study conducted during P2/3 study.

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Mirabegron (YM178): Development Progress

- Japan: Launched on September 16, 2011
- US: NDA approved on June 28, 2012
  Launched on October 22, 2012
- EU: MAA filed on August 24, 2011
  MAA approved on December 20, 2012
- Asia: Multinational P3 completed
  (China/Korea/Taiwan/India)
  NDA filed:
  Australia in August 2012, Taiwan in October 2012,
  Korea in November 2012

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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/Japan/Asia (EU: Filed)			
				PC: Pre-chemo EU/US/Japan/Asia			
				BC:US			
	Tivozanib ASP4130	Renal cell carcinoma (RCC), Colorectal cancer (CRC), Breast cancer (BC),	Potent, selective, long half-life inhibitor of VEGF receptors 1, 2 and 3	RCC: EU/US (US: Filed)			
				CRC, BC: EU/US			
	Quizartinib AC220	Acute myeloid leukemia	Potent and selective 2nd generation FLT3 kinase inhibitor	EU/US/JP			
	Degarelix (Gonax)	Prostate cancer	1st GnRH antagonist in Japan	3M: JP			
	Sepantronium YM155	Non-Hodgkin's lymphoma	First-in-class survivin suppressant	EU/US/JP			
	ASP1707	Prostate cancer*	Oral GnRH antagonist				
	ASP3026	Cancer	ALK tyrosine kinase inhibitor				
	ASP9603	Prostate cancer					
	ASP9853	Cancer					
OSI	Erlotinib (Tarceva)	NSCLC (1st line for patients with EGFR mutation, adjuvant, combination with MetMab), CRC, Pediatric ependymoma	HER1/EGFR tyrosine kinase inhibitor	1st line for NSCLC with EGFR mutations: US			
				Others: US			
	Linsitinib ASP7487 (OSI-906)	Ovarian cancer, NSCLC	IGF-1R/IR tyrosine kinase inhibitor	US			
	OSI-027	Renal cell cancer	mTOR kinase inhibitor	US			
Antibody	AGS-16M8F/ AGS-16C3F	Renal cancer	Antibody utilizing ADC (target: ENPP3)				
	ASG-5ME	Prostate cancer, Pancreatic cancer	Antibody utilizing ADC (target: SLC44A4)				
	ASG-22ME	Solid tumors	Antibody utilizing ADC (target: Nectin-4)				

*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 Patients with metastatic castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy	Placebo-controlled, n=1,199	Study completed. -US Approval: Aug. 31, 2012 Launch: Sep. 13, 2012 -EU MAA filed: June 26, 2012			
P3 EU/US/JP/Asia [PREVAIL study]	ADT failure Chemotherapy-naive patients with progressive metastatic prostate cancer who have failed ADT	Placebo-controlled, n=1,680	Completed enrollment: May 2012			
P2 EU/US [TERRAIN study]	LHRH analogue failure Advanced prostate cancer patients who have progressed while on LHRH analogue therapy or following surgical castration	To compare with bicalutamide, n=370	Ongoing			
P2 EU	Hormone-naive Hormone-naive prostate cancer	Open-label, n=60	Results will be presented. Analysis ongoing			
P1/2 JP	Post-chemo Patients with progressive castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy	Open-label, n=46	Analysis ongoing			
P1 US	Breast Cancer Breast cancer patients who have failed prior hormonal therapy	Open-label, n=27	First Patient In: April 2012			

The results for P2 study with hormone-naive patients will be presented at ASCO-GU in Feb. 2013.

ADT: Androgen deprivation therapy, LHRH: Lutenizing hormone-releasing hormone
ASCO-GU: American Society of Clinical Oncology- Genitourinary Cancers Symposium

Tivozanib: Development Progress

Study	Target	Design	P1	P2	P3	Filed
P3 EU/US [TIVO-1 study] Pivotal	Renal cell carcinoma Monotherapy (Patients with advanced renal cell carcinoma)	Comparing the efficacy and safety of tivozanib with sorafenib, n=500	Completed -US NDA filed: Sep. 28, 2012 NDA accepted: Nov. 2012 PDUFA date: Jul. 28, 2013 -EU Preparing for MAA filing			
P1b US	Renal cell carcinoma Combo with temsirolimus	Open-label, n=28	Completed			
P2 EU/US	Colorectal cancer Combo with mFOLFOX6 (versus mFOLFOX6 +bevacizumab)	Comparing the efficacy and safety of tivozanib with bevacizumab, n=252	Ongoing			
P2 EU/US	Breast cancer Combo with paclitaxel (Patients with triple negative breast cancer)	Comparing the efficacy and safety of tivozanib with placebo, n=147	First patient in: Dec. 2012			
P1b US	Breast cancer and Colorectal cancer Combo with capecitabine	Open-label, n=24	Ongoing			

Other studies in renal cell carcinoma:
-TAURUS study (P2 in EU/US): Study to compare patient preference of tivozanib compared to sunitinib in a 2-way crossover design (n=160). First patient in: Sep. 2012
-BATON-RCC study (P2 in US): Exploratory biomarker study (n=105). Recruitment completed.

Overall survival data in TIVO-1 study will be presented at ASCO-GU in Feb. 2013.

Quizartinib: Development Progress in AML

	Study	Target	Design	Status and plan
Monotherapy	**P2b** EU/US	Relapse/refractory FLT3-ITD (+)	Dose range finding, open-label, once daily oral dosing (2 different doses) in 28-day cycles, n=70	Ongoing (First patient in: May 2012)
	P2 EU/US	Relapse/refractory FLT3-ITD (+) FLT3-ITD (-)	Open-label, single-arm, once daily oral dosing in 28-day cycles, n=333	Summary results obtained
	P1 JP	Relapse/refractory FLT3-ITD (+) FLT3-ITD (-)	Dose escalation, open-label, once daily oral dosing in 28-day cycles, n=18	Initiated
Combination +Maintenance	**P1** US	Newly diagnosed, untreated	Safety and PK in combination with first-line chemotherapy followed by maintenance therapy, open-label, dose escalation, n=58	Ongoing
	P1 US	Post-HSCT	Safety and PK as maintenance therapy after HSCT, open-label, dose escalation, n=30	Ongoing

The results of P2 study was presented at ASH in December 2012.

FLT3: FMS-like tyrosine kinase-3 , ITD: Internal Tandem Duplication
HSCT: Hematopoietic stem cell transplant, ASH: American Society of Hematology

Quizartinib: Results of P2 Study Presented at ASH -Study Design-

*Excerpt and partly modified from 2 presentations at ASH on Dec. 9 and 10, 2012 by Jorge Cortes, M.D., The University of Texas M.D. Anderson Cancer Center, and Mark Levis, M.D., Ph.D., Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins)

Patients with AML or AML secondary to MDS (n=271)
(Included FLT3-ITD[+] and [-] patients with a 10% allelic ratio cutoff by a central laboratory)

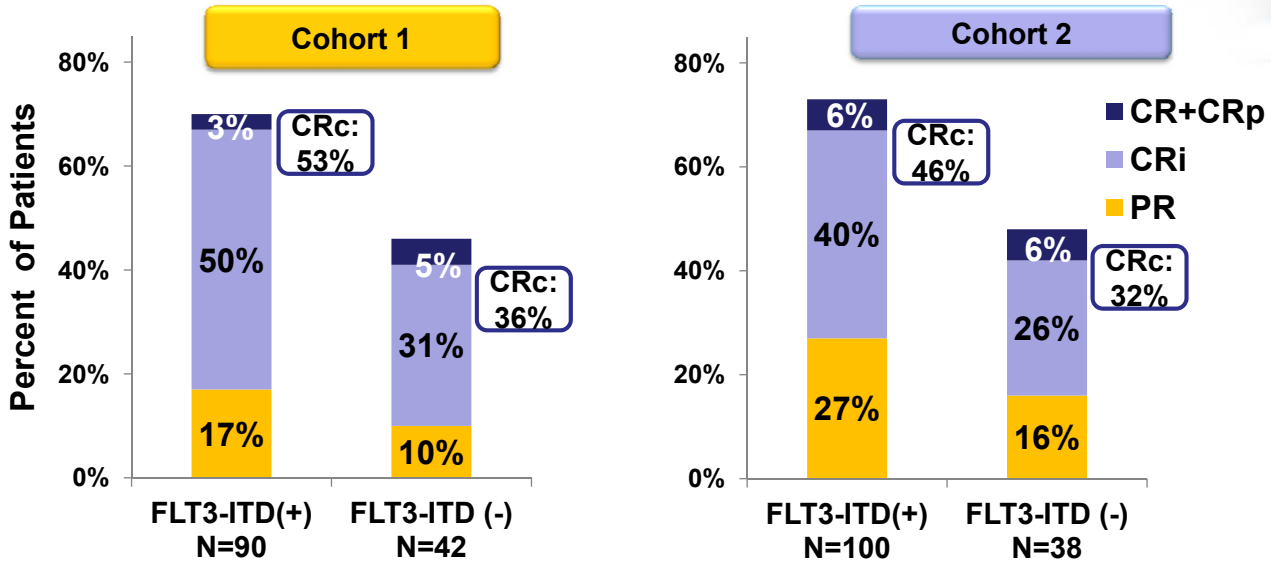
- **Cohort 1 (n=133)**
  ≥60 years, 1st relapse within 1 year, or refractory to 1st line treatment
  - **FLT3-ITD(+) (n=90)**
  - **FLT3-ITD(-) (n=42)**
- **Cohort 2 (n=138)**
  ≥18 years, relapsed after, or refractory to 2nd line treatment or HSCT
  - **FLT3-ITD(+) (n=100)**
  - **FLT3-ITD(-) (n=38)**

- 333 patients enrolled in Phase 2 (first 62 in an exploratory phase)
- Primary endpoint: Composite CR (CRc = CR + CRp + CRi)

CR=complete remission, CRp=complete remission with incomplete platelet recovery, CRi=complete remission with incomplete hematologic recovery

Quizartinib: Results of P2 Study Presented at ASH -Efficacy (Response Rate)-

*Excerpt and partly modified from 2 presentations at ASH on Dec. 9 and 10, 2012 by Jorge Cortes, M.D., The University of Texas M.D. Anderson Cancer Center, and Mark Levis, M.D., Ph.D., Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins)

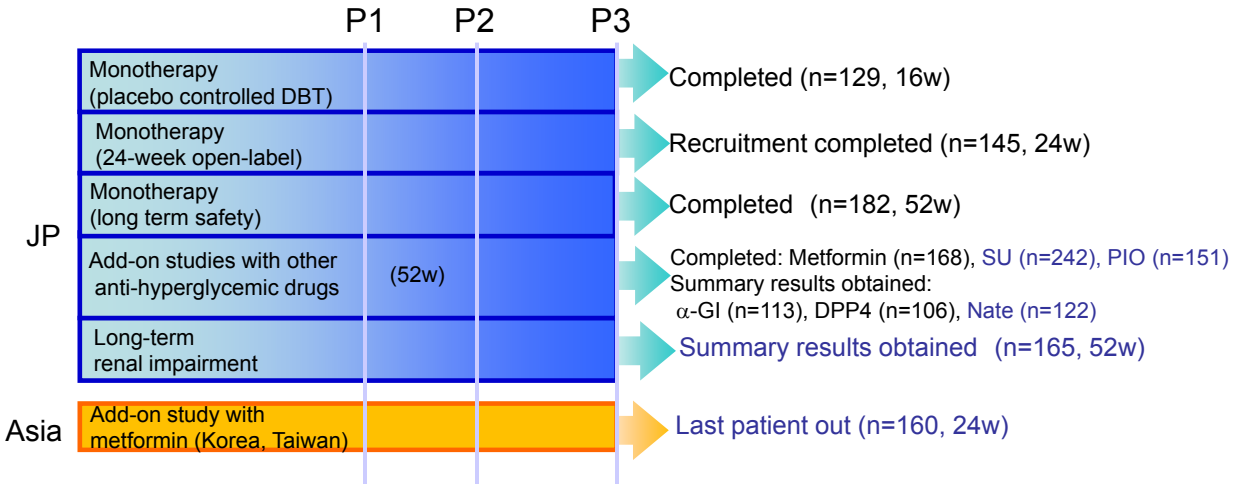


-Approx. 50% of FLT3-ITD (+) patients achieved a CRc.
-Approx. 1 in 3 FLT3-ITD (+) patients received a potentially curative HSCT in Cohort 2.

Ipragliflozin (ASP1941): Development Progress

Recent update of development status

- Japan: Add-on studies with other anti-hyperglycemic drugs:
  Study completed in SU, PIO and summary results obtained in Nate.
  Long-term renal impairment: Summary results obtained
- Asia: Add-on study with metformin (Korea, Taiwan): Last patient out



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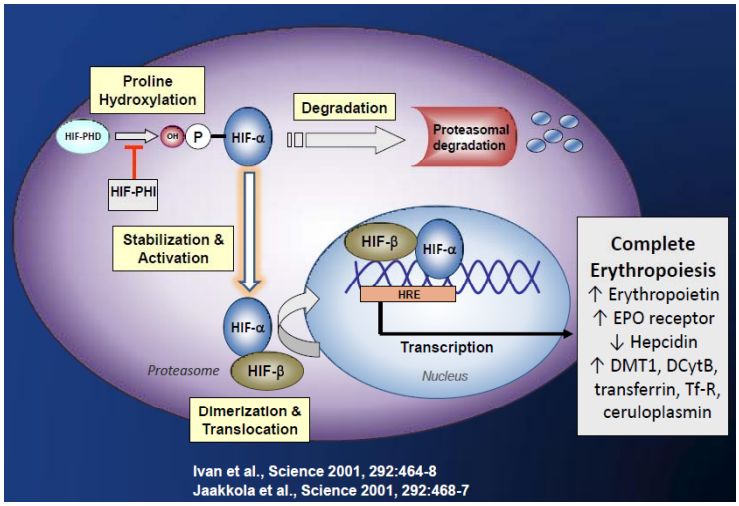
Preparing for filing in Japan

SU: sulfonylureas, PIO: pioglitazone, α-GI: α-glucosidase inhibitor, DPP4: DPP4 inhibitor, Nate: nateglinide

ASP1517 (FG-4592): Development Progress

Entered into P3 in US/Europe and P2 in Japan

- **Target disease:** Anemia associated with chronic kidney disease (CKD) in patients not on dialysis and on dialysis
- **Status:** Entered into P3 in US/Europe and P2 in Japan. (Licensed territory: EU, Japan etc.)
  -The first clinical study in P3 joint development program was initiated in US in November 2012. P2 in Japan is under preparation
- **Mechanism of action:** Inhibitor of hypoxia-inducible factor prolyl hydroxylase



-An orally administered agent

-New class of anemia therapeutic agent:
-Transient elevation of endogenous EPO within physiologic range

-P2 study demonstrated:
-Anemia correction and maintenance in treatment-naïve CKD patients not on dialysis and on dialysis

-P2 study results suggested the following:
-Effective without intravenous iron supplementation
-Cholesterol reduction
-No adverse effect on blood pressure, unlike ESAs

Hb: Hemoglobin, EPO: Erythropoietin, ESAs: Erythropoiesis-stimulating agents

ASP7374: Development Progress

Entered into P3 in Japan

- Target disease: Prophylaxis of seasonal influenza
- Status: Entered into P3 in Japan.
  The administration of the vaccine was completed in a P3 study with elderly volunteers in Dec. 2012
- Characteristics: Recombinant influenza vaccine produced by a cell-culture manufacturing method employing the Baculovirus Expression Vector System (BEVS), a next-generation technology platform

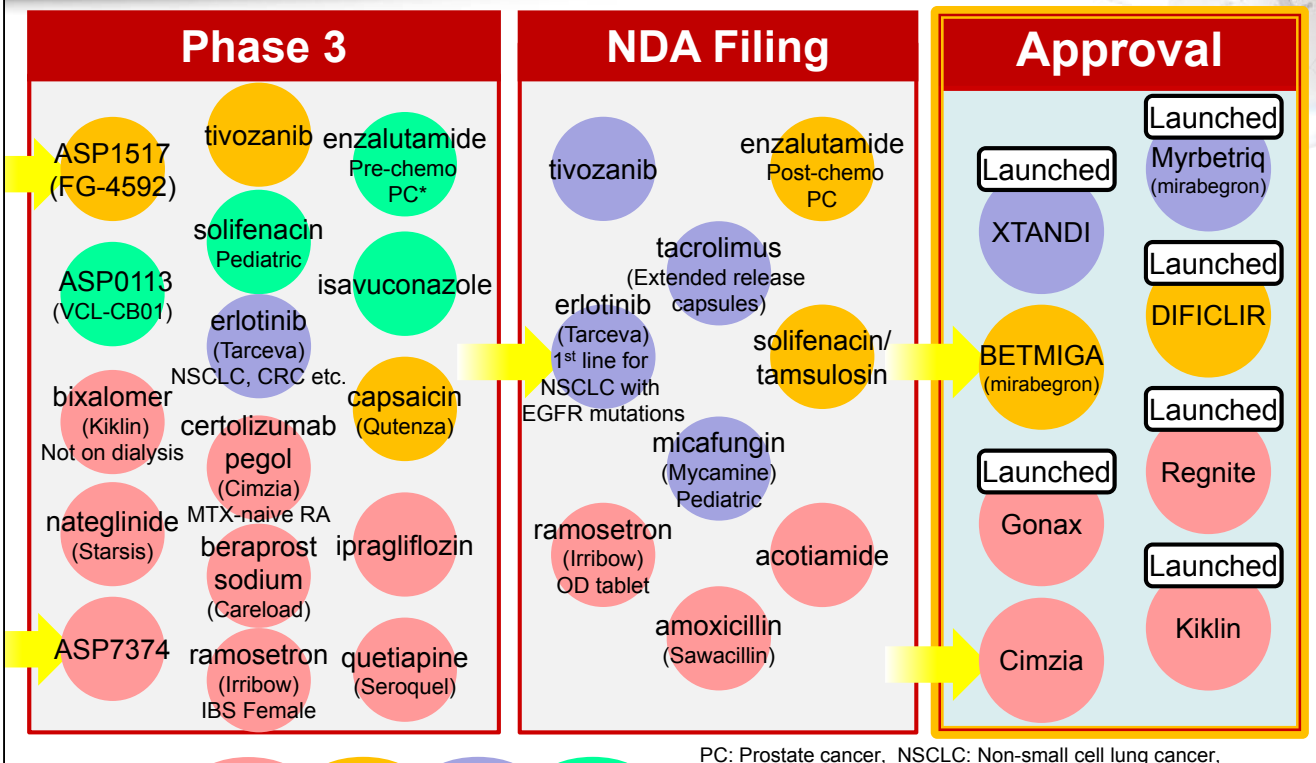
Outline of the P3 study

Target: Elderly volunteers
Treatment arm: 2 arms
(ASP7374 or egg-derived vaccine)
Administration: Single injection
Estimated number of subjects: 1,020
Primary endpoint: Hemagglutination inhibition (HI) antibody titer

*BEVS (Baculovirus Expression Vector System):
BEVS is a technology enabling to manufacture a recombinant protein in a large scale by integrating target gene information to baculovirus vector and transmitting the vector to insect cells.

Protein Sciences Corporation (PSC)* announced that the US FDA approved Flublok® (the brand name for ASP7374 in US) for people 18-49 years old in Jan. 2013.
*UMN Pharma, our partner, licensed the vaccine from PSC.

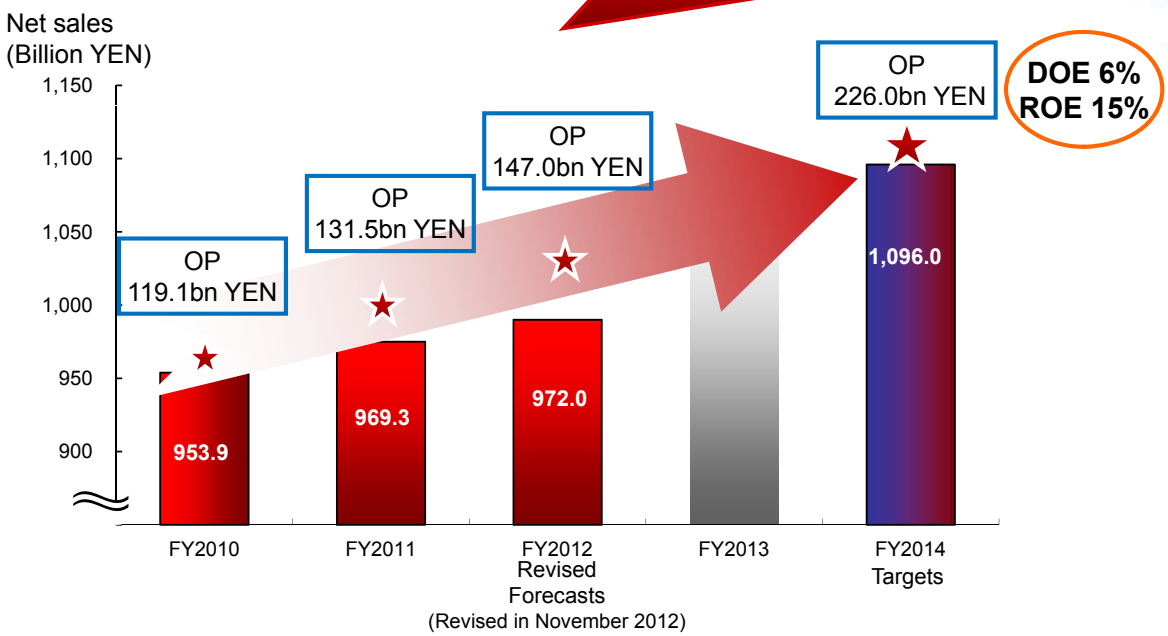
FY2012 Progress of Late Phase Compounds



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

Overcoming Patent Expiry of Major Products and Posting Sustained Growth

Continuous growth in sales and OP since the FY2010 low



(Revised in November 2012)

FY2012 full-year forecasts remain the same as one disclosed at financial announcement in November

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 (Forecast)
EPS	169.38 yen	213.04 yen*
Dividends per Share	125 yen	130 yen
ROE	7.7%	—
DOE	5.7%	—
Share Buybacks	—	Implemented in a flexible manner

*Updated calculation which reflected the acquisition of own shares from Nov. 5, 2012 to Dec. 10, 2012 (4.8 million shares). Not reflected the acquisition of own shares announced on Feb. 1, 2013 (up to 6 million shares)

Acquisition of Own Shares

Improve capital efficiency and shareholder return

Acquisition of own shares conducted in FY2012

- Period of acquisition: From Nov. 5, 2012 to Dec. 10, 2012
- Total number of shares acquired: 4.8 million shares
- Aggregate amount of acquisition cost: 19.5 billion yen

At the meeting of the Board of Directors held on Feb. 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 6 million shares
(The percentage compared to the total number of shares outstanding: 1.31%)
■Aggregate amount of acquisition cost: Up to 30 billion yen
■Period of acquisition: From Feb. 4, 2013 to Mar. 18, 2013

*The status of treasure stock as of Dec. 31, 2012
Total number of shares outstanding: 457,144,547 shares
Number of treasury stock: 10,820,088 shares

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