

Q2/FY2017 FINANCIAL RESULTS

ENDED SEPTEMBER 30, 2017



Yoshihiko Hatanaka
President and CEO
Astellas Pharma Inc.
October 31, 2017

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

In this material, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas Pharma. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this material is not intended to constitute an advertisement or medical advice.

AGENDA

3

I

Q2/FY2017 Financial Results

II

Initiatives to Build Resilience for Sustainable Growth

III

Profit Distribution Policy

Q2/FY2017 FINANCIAL RESULTS (CORE BASIS)

4

On-track toward FY2017 FCST

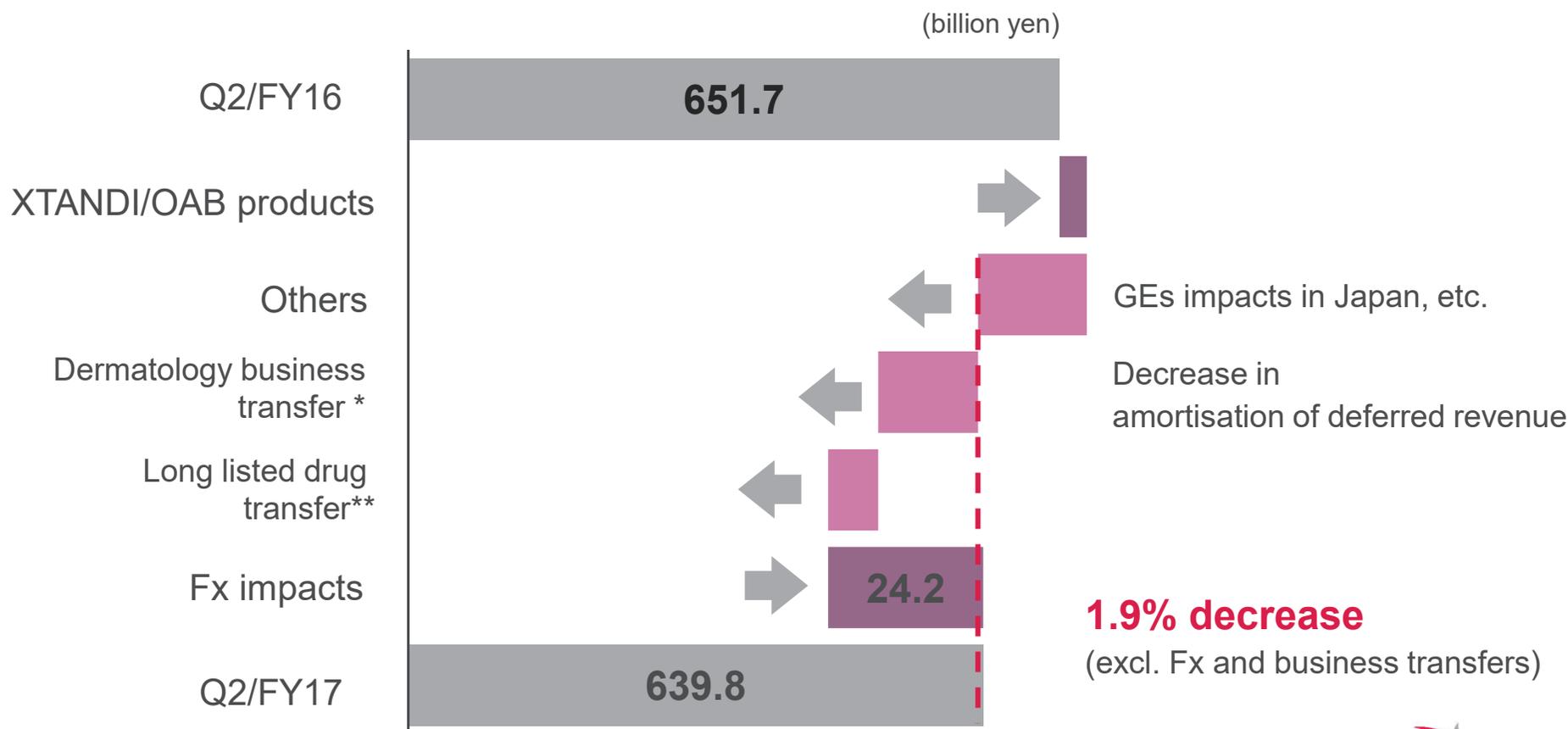
(billion yen)	Q2/FY16	Q2/FY17	Change	FY17 FCST*	Achievement	Excl impacts from Fx and business transfer
Net sales	651.7	639.8	-1.8%	1,279.0	50.0%	-1.9%
Cost of sales	146.2	148.8	+1.8%			
% of sales	22.4%	23.3%				
SG&A expenses	220.8	228.3	+3.4%			
% of sales	33.9%	35.7%				
R&D expenses	99.7	107.5	+7.8%	218.0	49.3%	
% of sales	15.3%	16.8%		17.0%		
Amortisation of intangible	17.7	17.9	+1.3%			
Share of associates/JVs losses	- 0.8	- 0.9	-			
Core operating profit	166.5	136.4	-18.1%	254.0	53.7%	-2.7%
Core profit for the period	120.6	106.6	-11.6%	195.0	54.7%	



*Announced in April 2017

SALES ANALYSIS (YEAR ON YEAR)

**Growth drivers in good shape,
slight decrease in net sales due to GEs impacts in Japan**



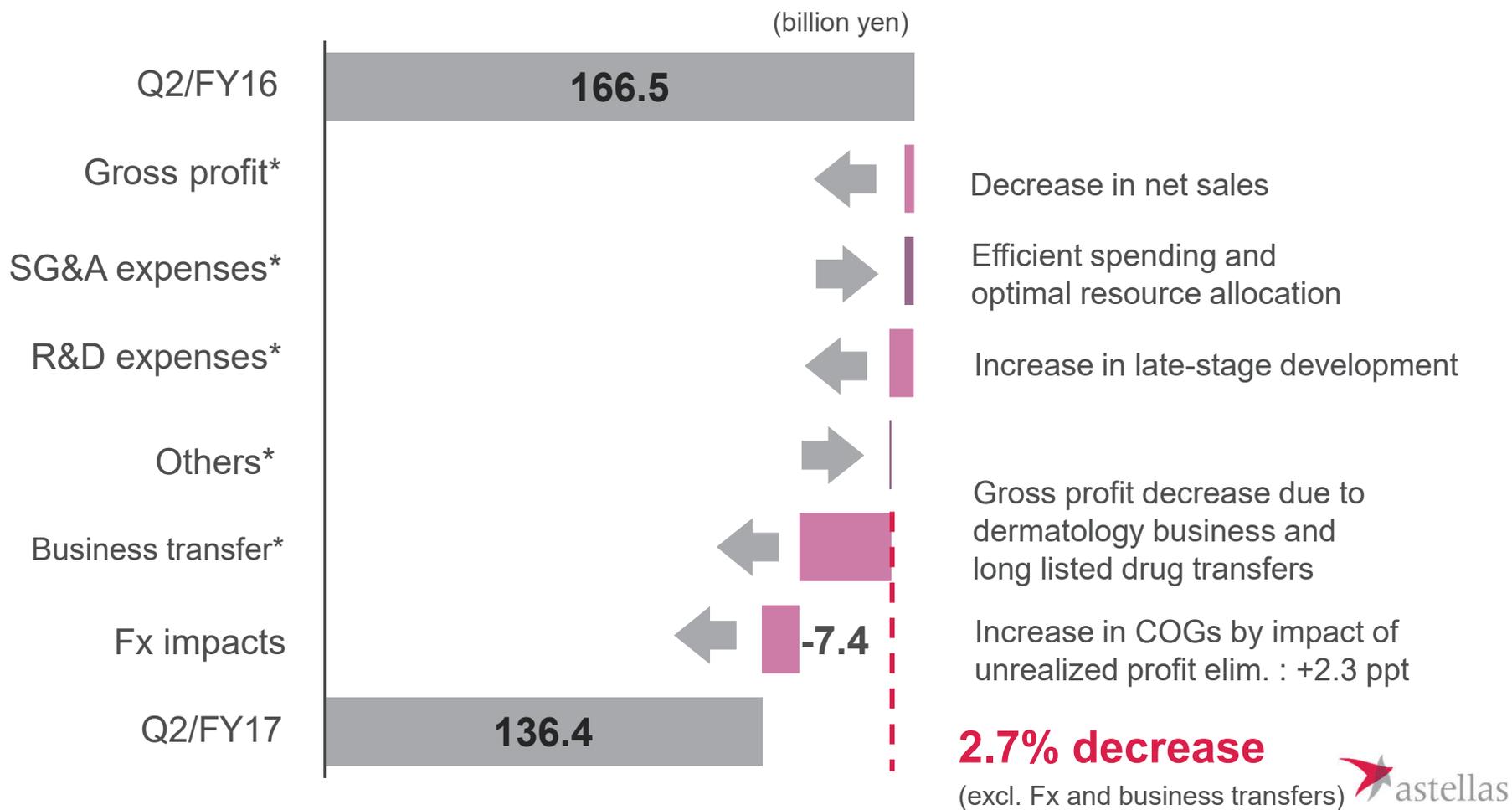
*Dermatology business transfer: Decrease in amortisation of deferred revenue

**Long listed drug transfer: Amortisation of deferred revenue in Q2/FY17 – Sales of transferred products in Q2/FY16

OAB: Overactive bladder,
OAB products: Vesicare+
Betanis/Myrbetriq/BETMIGA

CORE OP ANALYSIS (YEAR ON YEAR)

Development costs for late-stage projects increased



*Fx impacts excluded from each item



Q2/FY2017 FINANCIAL RESULTS (FULL BASIS)

7

Other expenses due to wind-down of Agensys research operations

(billion yen)	Q2/FY16	Q2/FY17	Change	FY17FCST*	Achievement
Core operating profit	166.5	136.4	-18.1%	254.0	53.7%
Other income	0.4	10.0	-		
Other expenses	9.8	50.3	+414.4%		
Operating profit	157.1	96.1	-38.8%	254.0	37.8%
Financial income	2.4	5.6	+135.5%		
Financial loss	1.7	0.5	-71.0%		
Profit before tax	157.8	101.2	-35.8%	260.0	38.9%
Profit for the period	115.1	82.1	-28.6%	198.0	41.5%
EPS (yen)	54.16	39.97	-26.2%	95.88	41.7%

Q2/FY17 main items

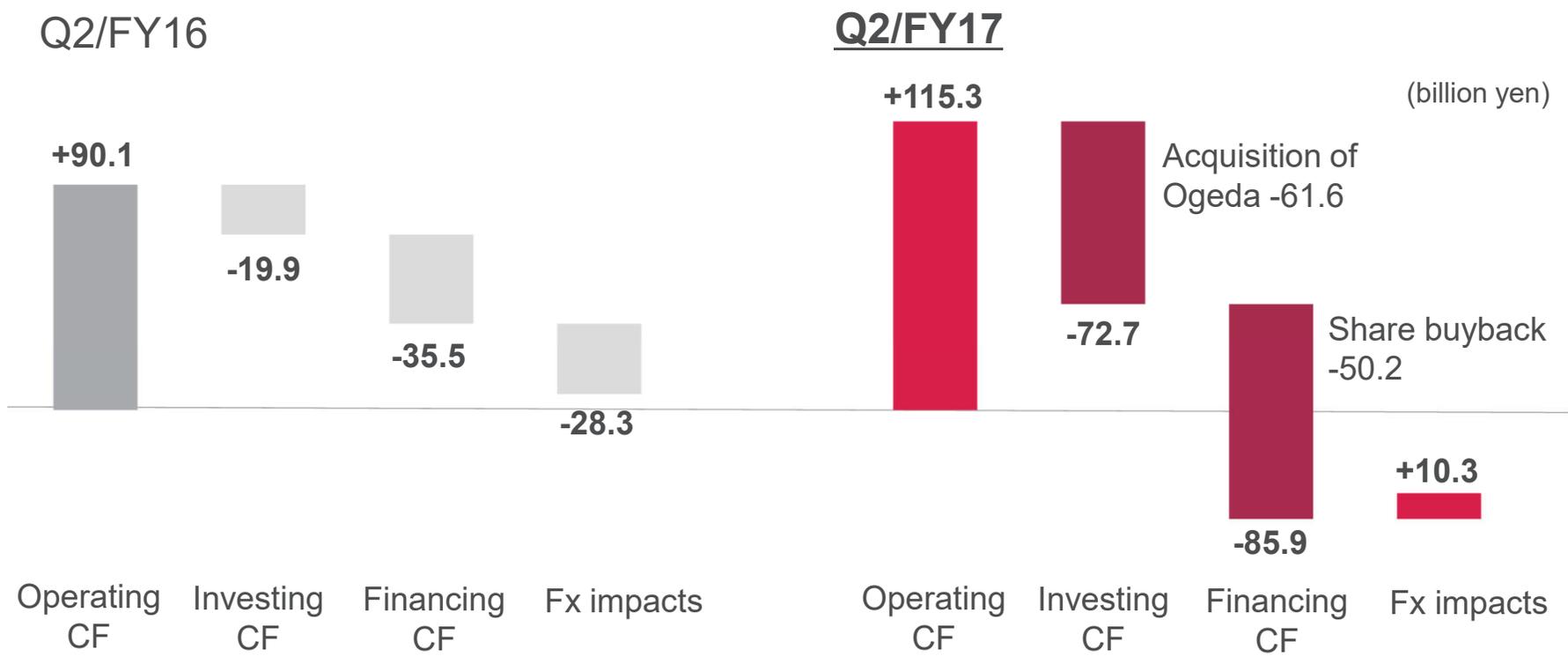
Other expenses	Wind-down of Agensys research operations: 13.0 billion yen (incl. impairment loss: 9.9)
----------------	---



*Announced in April 2017

CASH FLOW ANALYSIS

Cash flows from operating business increased by 28% (YoY)
Implemented active business investment and flexible shareholder return



SALES IN THREE KEY AREAS

9

XTANDI increase on a global basis

(billion yen)	Q2/FY16	Q2/FY17	Change	CER growth
Oncology	153.9	167.8	+9.1%	+3%
XTANDI	126.0	140.3	+11.4%	+6%
OAB in Urology	105.5	107.3	+1.7%	-3%
Vesicare	59.8	49.7	-16.9%	-20%
Betanis/Myrbetriq/BETMIGA	45.7	57.6	+26.0%	+21%
Transplantation	94.2	99.3	+5.4%	+1%



Oncology: XTANDI, Tarceva, Eligard and Gonax
 Transplantation: Prograf, Advagraf/Graceptor/ASTAGRAF XL

CER: Constant Exchange Rate

REVISED FORECASTS FOR FY2017 (CORE BASIS)

10

Revision of initial forecasts based on Q2/FY2017 results and Fx trend

(billion yen)	FY2017 Initial Forecasts	FY2017 Revised Forecasts	Change
Net sales	1,279.0	1,297.0	+18.0
R&D expenses	218.0	218.0	-
as % of sales	17.0%	16.8%	
Core operating profit	254.0	258.0	+4.0
Core profit for the year	195.0	201.0	+6.0

Exchange rate (yen) Average for the period	Initial Forecasts	Revised Forecasts
USD	110	111
EUR	120	128

Fx impacts

(billion yen)

- Sales: +20.2
- Core operating profit: +3.8

REVISED FORECASTS FOR FY2017 (FULL BASIS)

11

Revision of initial forecasts based on other income and expenses booked in Q2/FY2017

(billion yen)	FY2017 Initial Forecasts	FY2017 Revised Forecasts	Change
Net sales	1,279.0	1,297.0	+18.0
R&D expenses	218.0	218.0	-
as % of sales	17.0%	16.8%	
Operating profit	254.0	222.0	-32.0
Profit before tax	260.0	228.0	-32.0
Profit for the year	198.0	180.0	-18.0
EPS (YEN)	95.88	88.15	

AGENDA

12

I

Q2/FY2017 Financial Results

II

Initiatives to Build Resilience for
Sustainable Growth

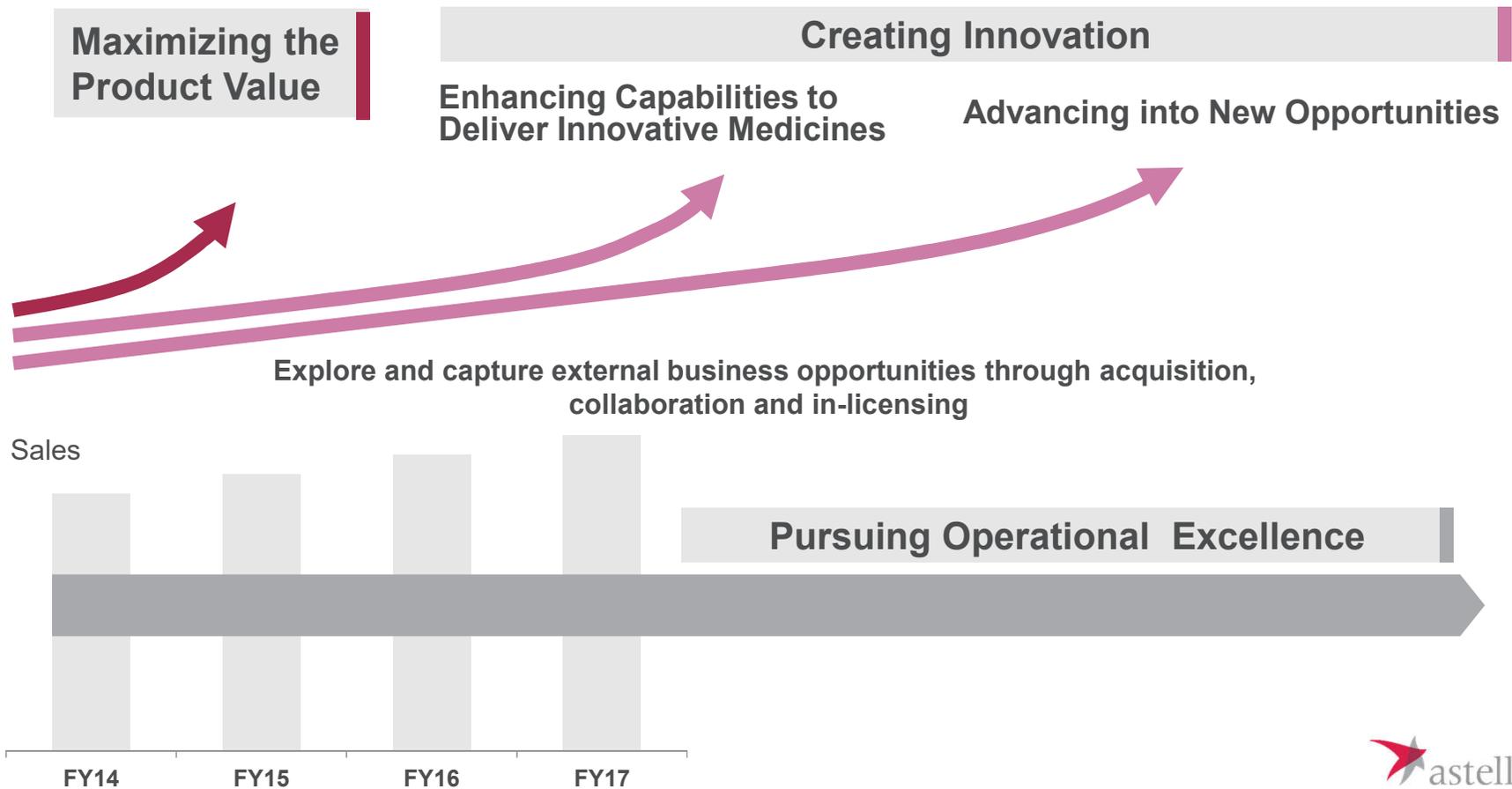
III

Profit Distribution Policy

ACHIEVING SUSTAINABLE GROWTH

(same as Strategic Plan 2015-2017 slide)

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

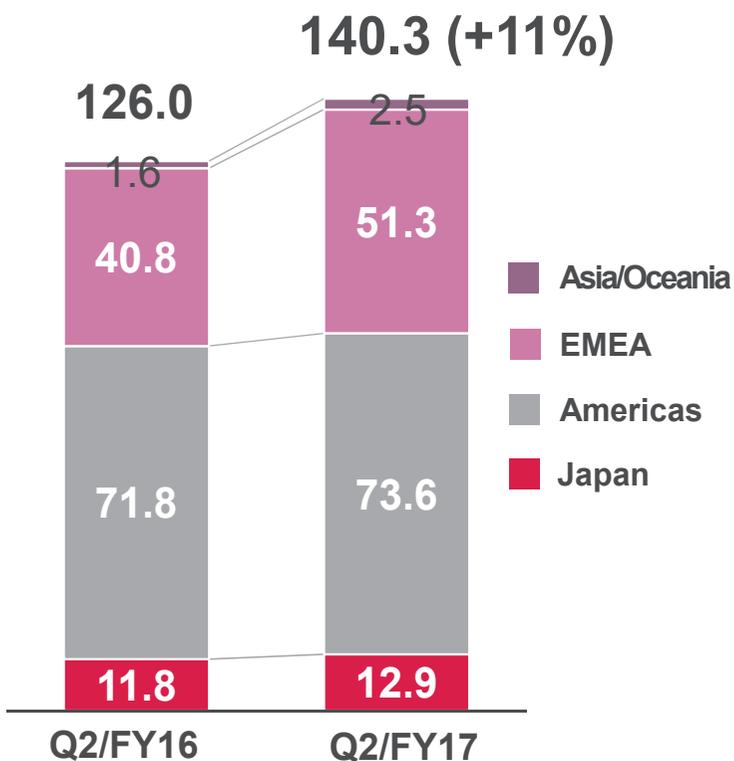




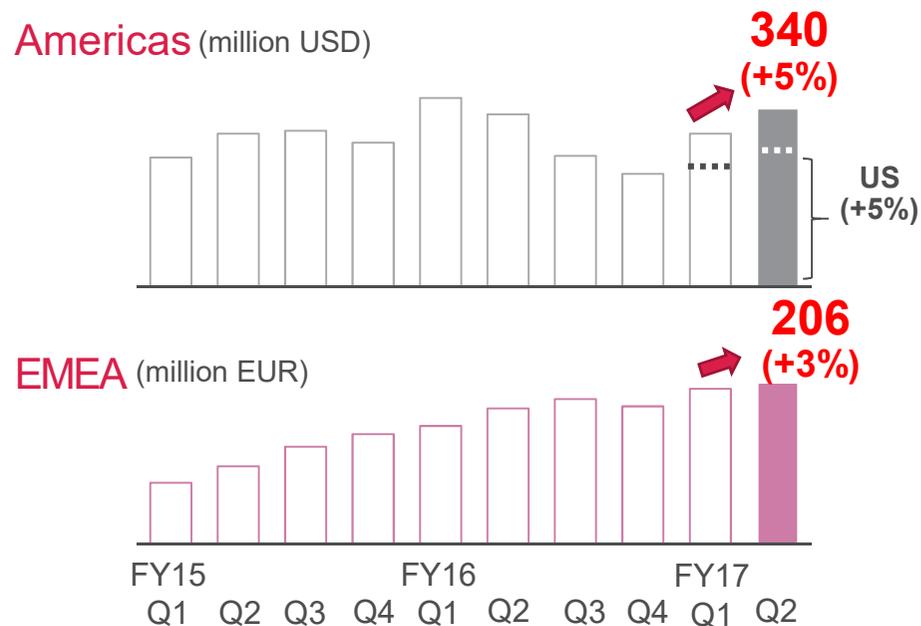
MAXIMIZE THE PRODUCT VALUE

Global sales steadily grew

Sales by region



Quarterly sales (local currency)



- Further penetration in earlier treatment within current indications
- Expansion to new markets: launched in >70 countries

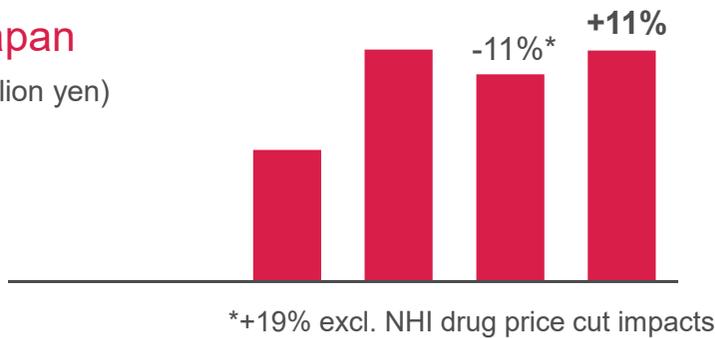
XTANDI

Upward revision of initial forecasts “277.7 → 291.3 billion yen”
Growth in more profitable ex-US markets such as EMEA

Sales since launch by region

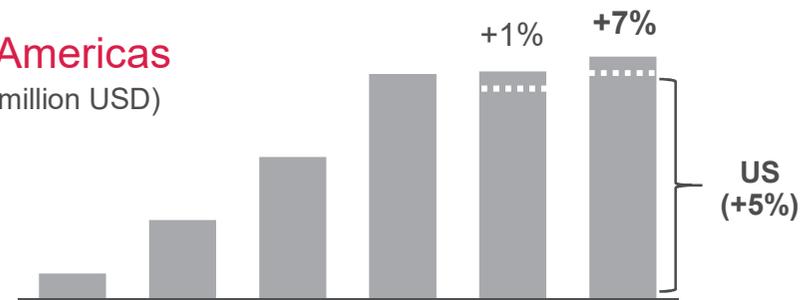
Japan

(billion yen)



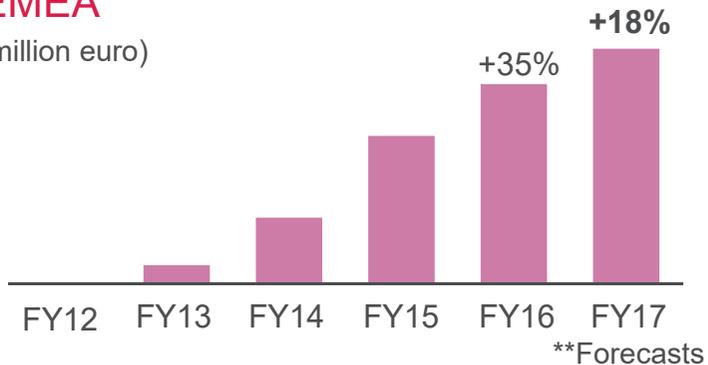
Americas

(million USD)



EMEA

(million euro)



Asia&Oceania

(billion yen)

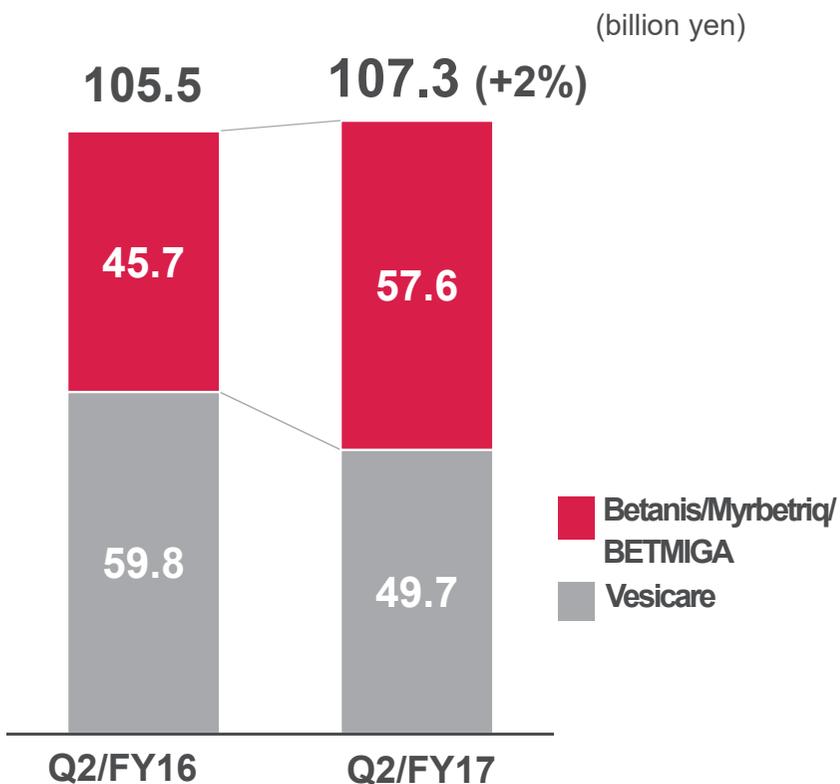


**As of Oct.2017

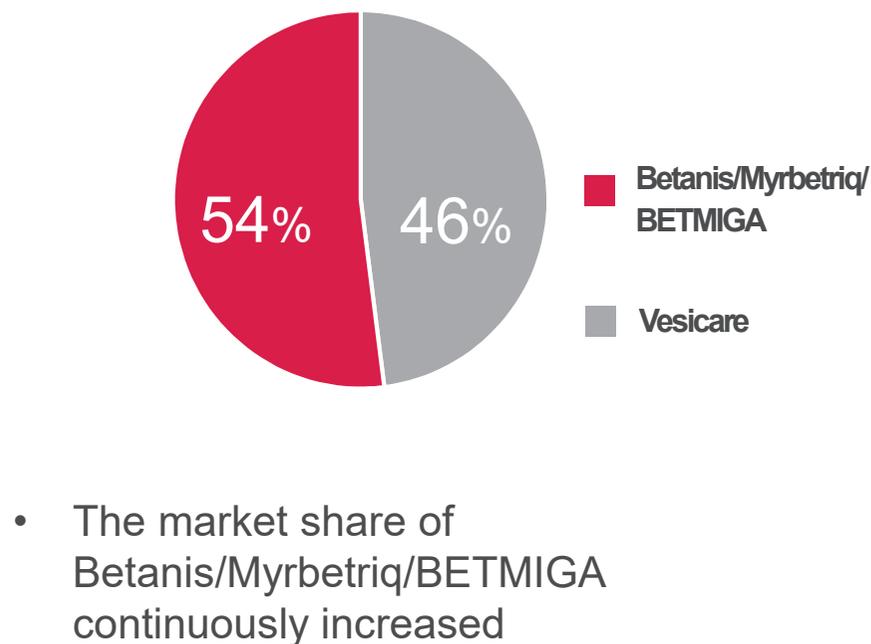
OAB FRANCHISE IN UROLOGY

Sales weight of Betanis/Myrbetriq/BETMIGA steadily expands

Sales by product



Sales composition ratio by product (yen basis)



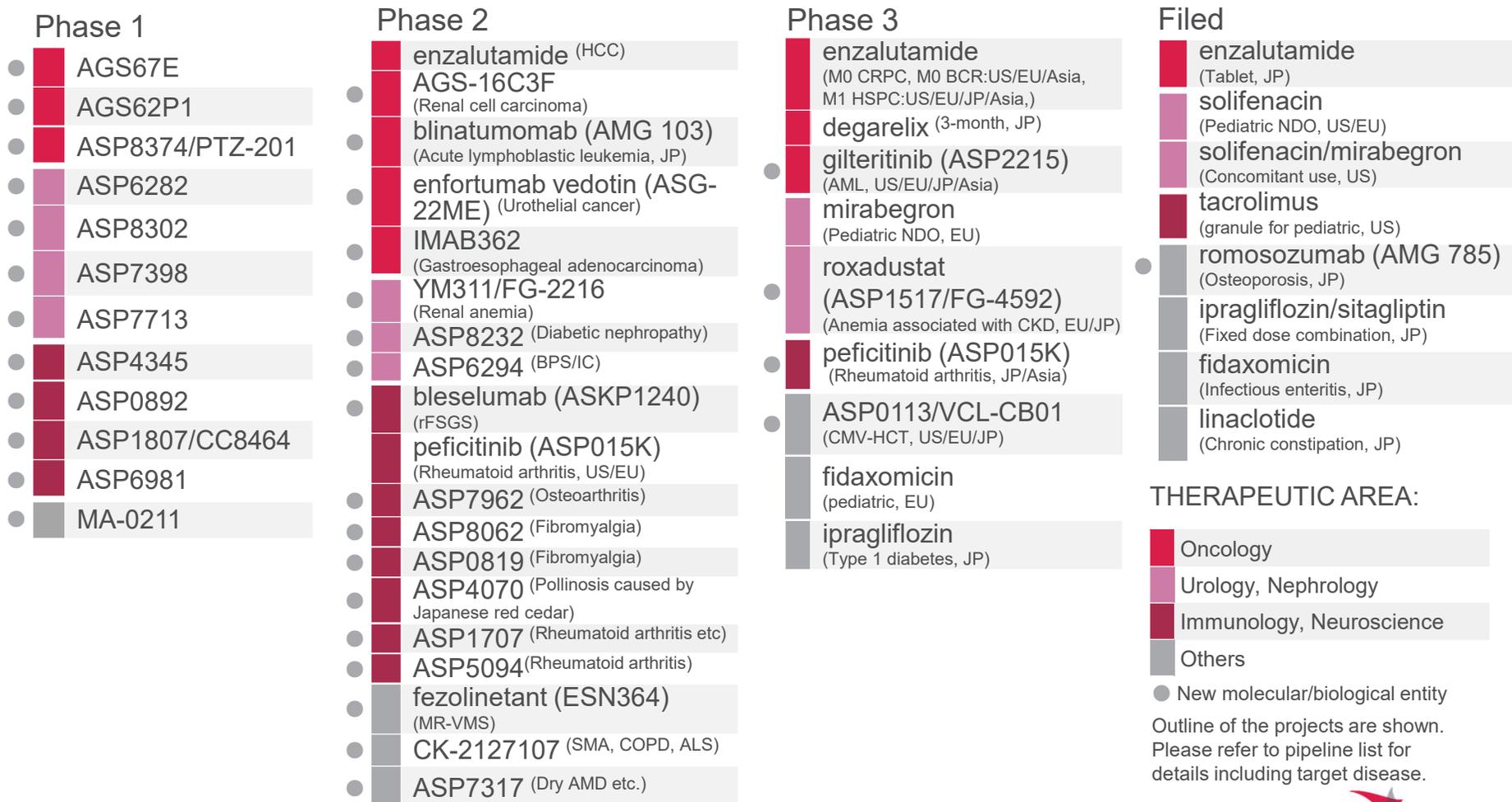


CREATE INNOVATION

PIPELINE

ROBUST PIPELINE OF ASTELLAS

Evaluating >30 new molecular/biological entities as potential drivers of future growth



HCC: Hepatocellular carcinoma, BPS/IC: Bladder pain syndrome/Interstitial cystitis, rFSGS: Recurrence of focal segmental glomerulosclerosis, MR-VMS: Menopause-related vasomotor symptoms, SMA: Spinal muscular atrophy, COPD: Chronic obstructive pulmonary disease, ALS: Amyotrophic lateral sclerosis, AMD: Age-related macular degeneration, M0 CRPC: Non-metastatic castration-resistant prostate cancer, M0 BCR: Non-metastatic biochemical recurrence, M1 HSPC: Metastatic hormone sensitive prostate cancer, AML: Acute myeloid leukemia, NDO: Neurogenic detrusor overactivity, CKD: Chronic kidney disease, CMV: Cytomegalovirus, HCT: Hematopoietic cell transplant

STEADY PROGRESS IN DEVELOPMENT

SUMMARY OF PROGRAM PROGRESS FROM JULY 2017 TO OCT 2017

20

Steady progression of pipeline



ASP8374/PTZ-201

Cancer

fidaxomicin

Filed in Jul. 2017

Infectious enteritis
(bacterial target:
Clostridium difficile) (JP)

solifenacin

NDO for pediatric (US)

- Granted for 6-months exclusivity in US
- Received Complete Response Letter from FDA in Aug 2017

linaclotide

Filed in Sep. 2017

Chronic constipation (JP)

enzalutamide tablet

Approved in Sep. 2017

metastatic CRPC (EU)

Discontinuation
(in a part of
indications) etc.

ASP4132: Cancer (P1)

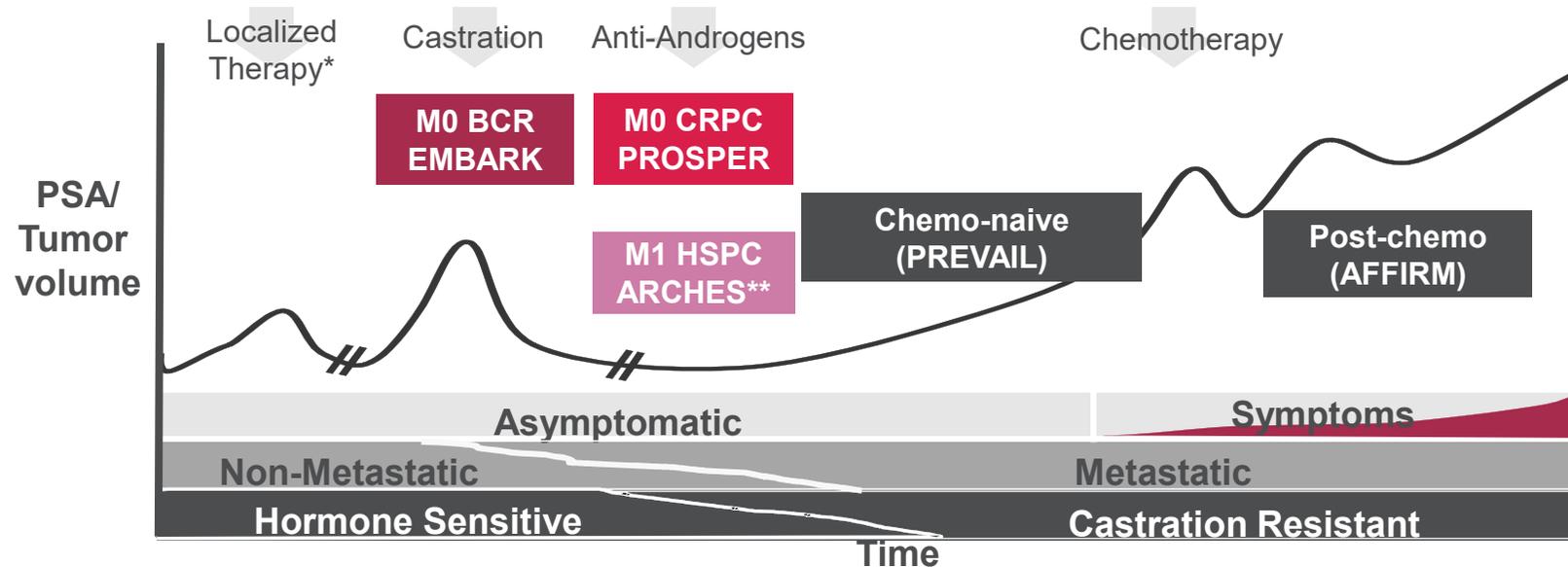
ASG-15ME: Urothelial cancer (P1)



Note: Phase 1 entry is defined as confirmation of IND open. Phase transition is defined by approval of company decision body for entering to next clinical phase. Filing is defined as submission of application to health authorities. Discontinuation is defined by the decision of company decision body.

ENZALUTAMIDE: MAXIMIZE THE VALUE FOR PROSTATE CANCER PATIENTS

Positive TLR obtained for PROSPER study



PROSPER study P3	M0 CRPC Non-metastatic CRPC	Placebo-controlled, combination with ADT, n=1,440	<u>TLR: Sep 2017</u>
EMBARK study P3	M0 BCR Non-metastatic prostate cancer, biochemical recurrence	To compare with ADT and combination, n=1,860	First Patient In: Jan. 2015
ARCHES study P3	M1 HSPC Metastatic hormone-sensitive prostate cancer	Placebo-controlled, combination with ADT, n=1,100	First Patient In: Mar. 2016

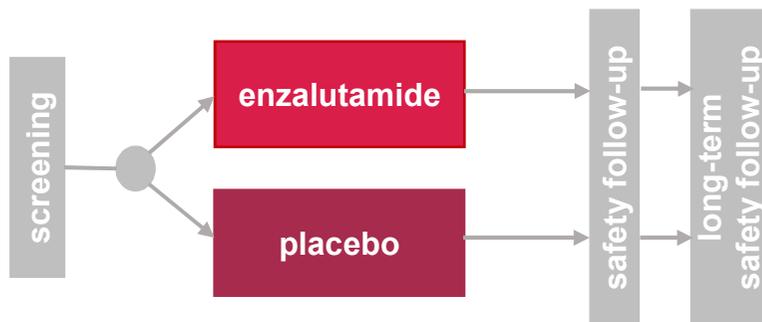


P. Mulders *et al.* EAU2012, modified by Astellas * Radiotherapy, prostatectomy, ** Metastatic at the time of diagnosis, PSA: Prostate-specific antigen

ENZALUTAMIDE: PROSPER STUDY IN M0 CRPC

Positive TLR obtained for PROSPER study

Study design



Top line results

- The study met the primary endpoint (Metastatic Free Survival: MFS).
- The preliminary analysis appears consistent with the safety profile of XTANDI in previous clinical trials.

Next step

- Detail analysis are in progress.
- Proceed preparation for filing.

Non-metastatic CRPC (M0 CRPC)

Disease background

Prostate cancer progressed despite of ADT, but no detectable radiographic evidence of cancer spreading to other part of body.

Current treatment option

After failed with ADT, no FDA/EMA approved treatment available until the disease state progressed to metastatic stage.

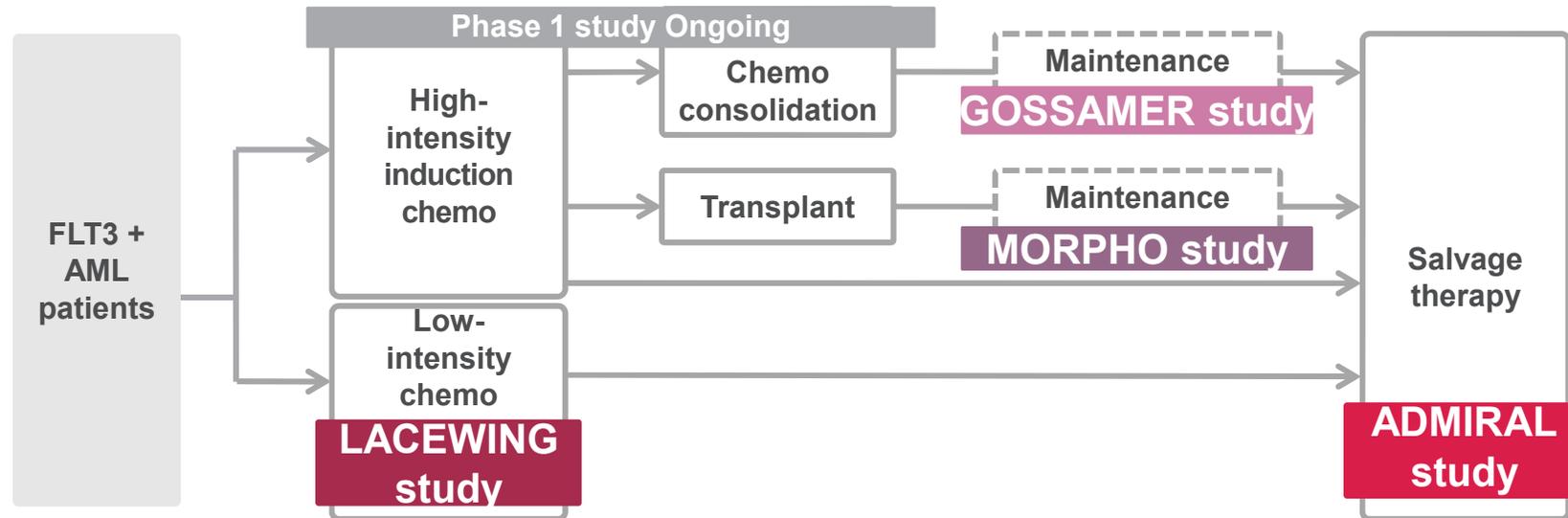
Unmet medical needs

Delaying of metastatic disease which has a poor prognosis.



GILTERITINIB: TREATMENT LANDSCAPE IN AML

Fast Track designation granted for gilteritinib development in relapsed or refractory FLT3 mutation positive AML patients



ADMIRAL study P3	Relapsed or refractory 1 st relapsed or refractory, FLT3 mutation positive	Open-label, randomized, monotherapy vs salvage chemo (2:1), n=369	First Patient In: Oct. 2015
LACEWING study P2/3	1st line intensive chemo ineligible Newly diagnosed, FLT3 mutation positive	Open-label, randomized, 3 arms (monotherapy, combo with azacitidine and azacitidine alone), n=528	First Patient in: Nov. 2016
GOSSAMER study P3	Post-chemo maintenance FLT3-ITD positive	Double-blind, randomized, monotherapy vs placebo (2:1), n=354	First Patient In: Apr. 2017
MORPHO study P3	Post-HSCT maintenance FLT3-ITD positive	Double-blind, randomized, monotherapy vs placebo (1:1), n=346	First Patient In: July 2017 Collaborating with BMT-CTN



ENFORTUMAB VEDOTIN: PLANNED/ON-GOING STUDIES

24

FPI achieved for P2 study in metastatic urothelial cancer patients with prior immune Check Point Inhibitor (CPI) treatment

Phase 2 study

Study design: single-arm, open-label, multicenter

Objective:

Efficacy and safety of enfortumab vedotin monotherapy in metastatic urothelial cancer patients who previously received CPI treatment.

Patient population: Locally advanced or metastatic urothelial cancer who previously received CPI treatment.

Planned enrollment: approx. 120 patients

Primary endpoint: Objective response rate (ORR) by an independent review facility.

Phase 1b combination study

Study design: single-arm, open-label, multicenter, dose-escalation and dose-expansion

Objective:

Safety, tolerability and pharmacokinetics when enfortumab vedotin is combined with CPI in patients with urothelial cancer.

Patient population: Locally advanced or metastatic urothelial cancer

Planned enrollment: approx. 85 patients

Primary endpoint:

- Incidence of dose-limiting toxicity
- Type, incidence, severity, seriousness, and relatedness of adverse events
- Type, incidence, and severity of laboratory abnormalities

ROXADUSTAT: ROBUST PHASE 3 PROGRAM TO SUPPORT FILING AND REIMBURSEMENT IN EUROPE AND JAPAN

Positive TLR obtained for JP P3 study in peritoneal dialysis (PD) patients.

	Dialysis	Non-dialysis
Global	HIMALAYAS: Incident dialysis, vs epoetin alfa 	DOLOMITES , vs darbepoetin Enrollment completed 
	SIERRAS: Stable dialysis, vs epoetin alfa 	ALPS , vs placebo Enrollment completed Data readout planned in 1Q/2018 
	PYRENEES: Stable dialysis, vs epoetin alfa or darbepoetin Enrollment completed 	ANDES , vs placebo Enrollment completed 
Japan 	HD: Conversion , vs darbepoetin Enrollment completed	Conversion, vs darbepoetin
	HD: Conversion , long-term Enrollment completed Data readout planned in 1Q/2018	
	HD: Correction (ESA-naïve) Enrollment completed Data readout planned in 1H/2018	Correction
	PD: Study completed TLR obtained in Oct/2017	

ROXADUSTAT: JAPANESE PHASE 3 STUDY

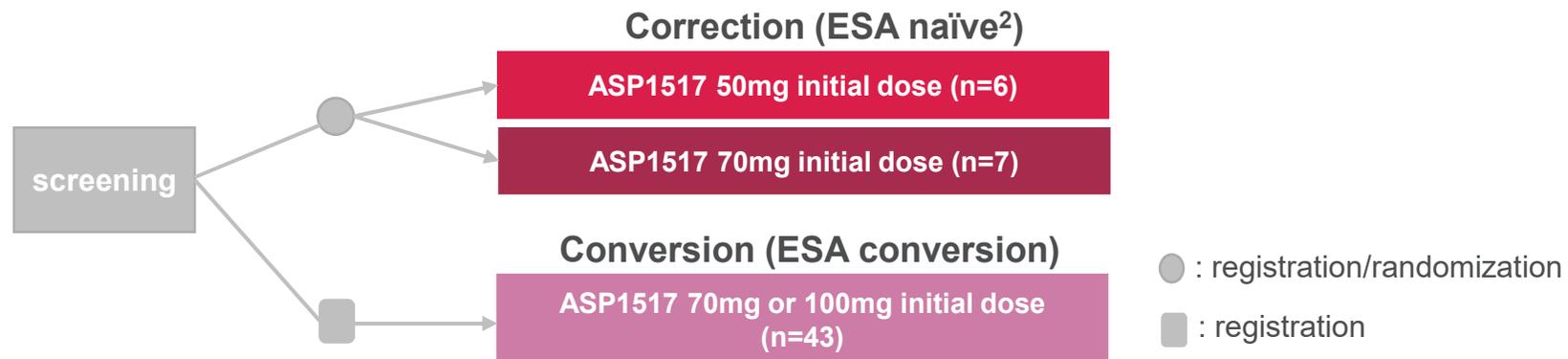
Positive TLR from the first Japanese Phase 3 study in PD patients

Study design: Phase 3, multi-center, open-label, randomized study

Patient population: Peritoneal dialysis chronic kidney disorder patients with anemia

Treatment: Three time a week, up to 24 weeks

Primary outcome measure: Hemoglobin(Hb) maintenance rate from week 18 to week 24¹



Top Line Result:

- Hb maintenance rate from week 18 to week 24 was 92.3% in ESA-naïve and 74.4% in ESA-conversion patients.
- roxadustat was well tolerated. The preliminary safety analysis is consistent with the safety profile of roxadustat in previous clinical studies.

Next Step: Detail analysis will be performed.

FIBROGEN



1: Proportion of subjects who achieve the target Hemoglobin (Hb) level (10.0 g/dL to 12.0 g/dL) from weeks 18 to 24 based on the average Hb level which was measured every two weeks. 2: ESA naïve: Subjects who have never been receiving ESAs after starting peritoneal dialysis, or subjects who have not received ESAs within 6 weeks before the screening assessment.

EXPECTED KEY PIPELINE EVENTS IN FY2017

Important milestones from POC through registration

*Subject to internal assessment, decision and regulatory consultation, as appropriate

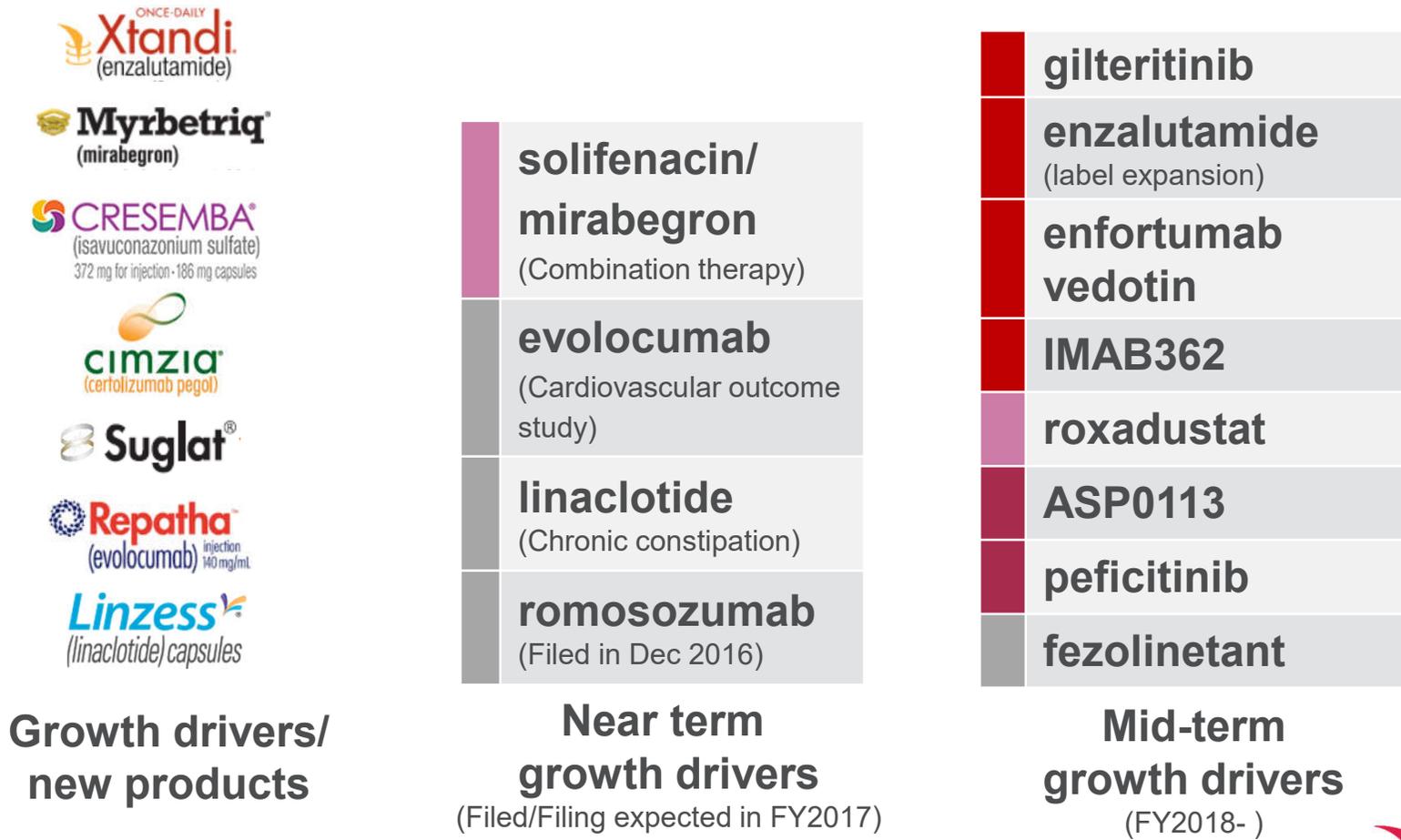
Data Readouts	Filing*	Regulatory Decisions
<p>Phase 2 (POC) study</p> <p>enzalutamide Breast Cancer (HER2+)</p> <p>ASP4070 (JRC2-LAMP-vax) Pollinosis caused by Japanese red cedar</p> <p>ASP1707 Rheumatoid Arthritis (MTX-IR)</p> <p>CK-2127107 Spinal Muscular Atrophy</p> <p>ASP7962 Osteoarthritis</p>	<p>Phase 3 study</p> <p>enzalutamide M0 CRPC (PROSPER)</p> <p>roxadustat Non-dialysis pts (ALPS) Hemodialysis: Conversion, long-term (Japan) Peritoneal dialysis (Japan)</p> <p>ASP0113 Hematopoietic Cell Transplantation</p> <p>peficitinib RA pts with MTX-IR RA pts with DMARD-IR</p>	<p>solifenacin/mirabegron Concomitant use of solifenacin and mirabegron (US)</p> <p>linaclotide Chronic constipation (Japan)</p> <p>evolocumab Cardiovascular outcome study (Japan)</p> <p>ipragliflozin/sitagliptin Fixed dose combination (Japan)</p> <p>enzalutamide Tablet (EU) Tablet (Japan)</p> <p>romosozumab Osteoporosis (Japan)</p> <p>quetiapine BP-D (Japan)</p> <p>solifenacin Pediatric NDO (US) Pediatric NDO (EU)</p>



*Light gray items indicate completed events.
 MTX-IR: Methotrexate inadequate response, RA: Rheumatoid arthritis, DMARD-IR: Disease-modifying antirheumatic drugs inadequate response,
 BP-D: Depressive symptoms associated with bipolar disorder, NDO: Neurogenic detrusor overactivity

POTENTIAL GROWTH DRIVERS

Future growth driven by compounds that already have achieved POC



Subject to internal assessment, decision and regulatory consultation, as appropriate

POC; Proof of Concept

■ Oncology, ■ Urology, Nephrology, ■ Immunology, Neuroscience, ■ Others



CREATE INNOVATION

NEW INITIATIVES

INITIATIVES TO CREATE INNOVATION (1)

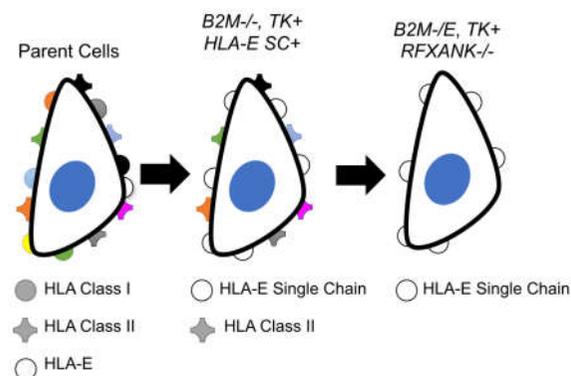
Exclusive worldwide license agreement to research, development and commercialization in collaboration with Universal Cells for a novel cell therapy



Utilizing Universal Cells' Universal Donor Cell technology

- Technology to create stem cell therapies that overcome immune rejection
- Universal Donor Cell technology can be administered to any recipient without the need for Human Leukocyte Antigen (HLA) matching

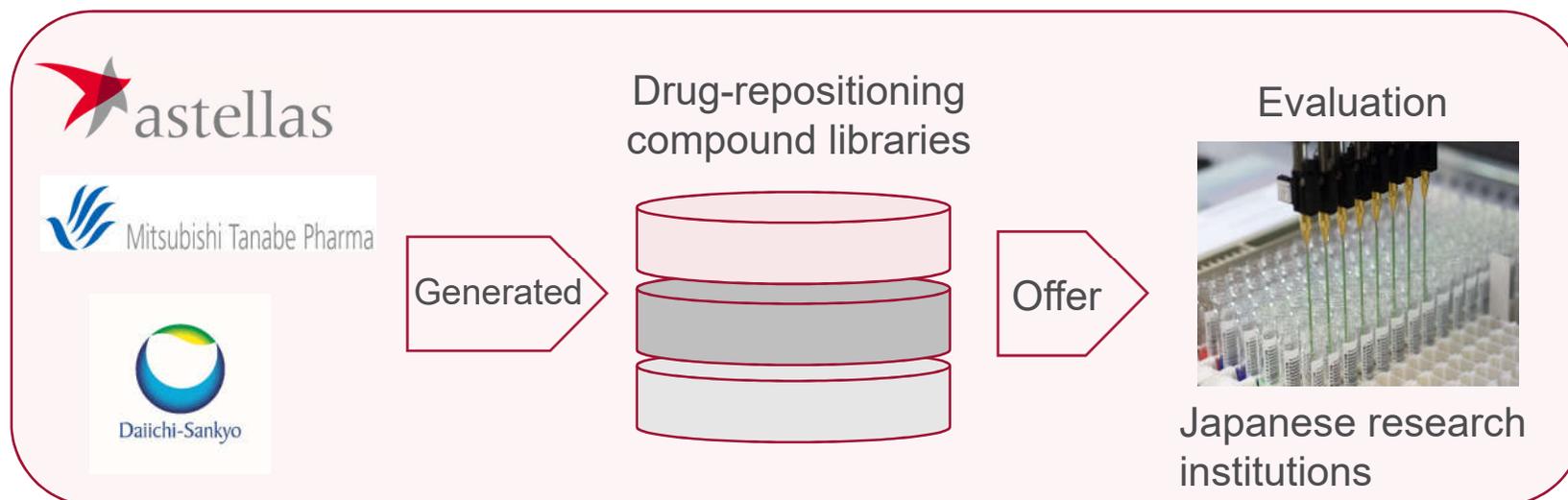
Process to create
Universal Donor Cell



INITIATIVES TO CREATE INNOVATION (2)

31

- Facilitating open innovation through a new drug discovery program called “JOINUS” using drug-repositioning compound libraries



- Investment in Tokyo Institute of Technology-related venture capital fund “MIRAI SOZO 1 Limited Partnership”



The fund invests in a wide variety of industries and areas such as big data analysis, sensors, semiconductors and healthcare

CREATE SOCIAL VALUE

32

Resolve social issues and enhance our enterprise value over the long-term

Initiatives for Access to Health



Participation in
Access Accelerated



Collaborative development
agreement for rice-based
oral vaccine



Support of Action on Fistula



Development of
pediatric formulation
for schistosomiasis

Recent activities

- New collaborative research agreement to discover anti- tuberculosis drugs

TB Alliance

- Screening collaboration agreement to discover antimalarial drugs

Medicines for
Malaria Venture

These two research programs will be funded by the
Global Health Innovative Technology Fund (“GHIT Fund”)



PURSUE OPERATIONAL
EXCELLENCE

INITIATIVES TO CONTINUOUS STRENGTHENING OF MANAGEMENT FOUNDATION

34

Resource allocation from scratch responding to environment changes

Investment priority

- Investment in growth areas and withdrawal from non-growth areas
- Sufficient investment to deal with new risks

Capability, organization / structure

- Optimal sales structure
- Optimization of manufacturing and research organization

Cost structure

- Cost reduction through strategic procurement activities
- Further focus on appropriate expenses use

Initiatives in 1H/FY2017

- ✓ Transfer of long-listed products
- ✓ Enhancement of global management structure
- ✓ Wind-down of Agensys research operations

AGENDA

35

I

Q2/FY2017 Financial Results

II

Initiatives to Build Resilience for Sustainable Growth

III

Profit Distribution Policy

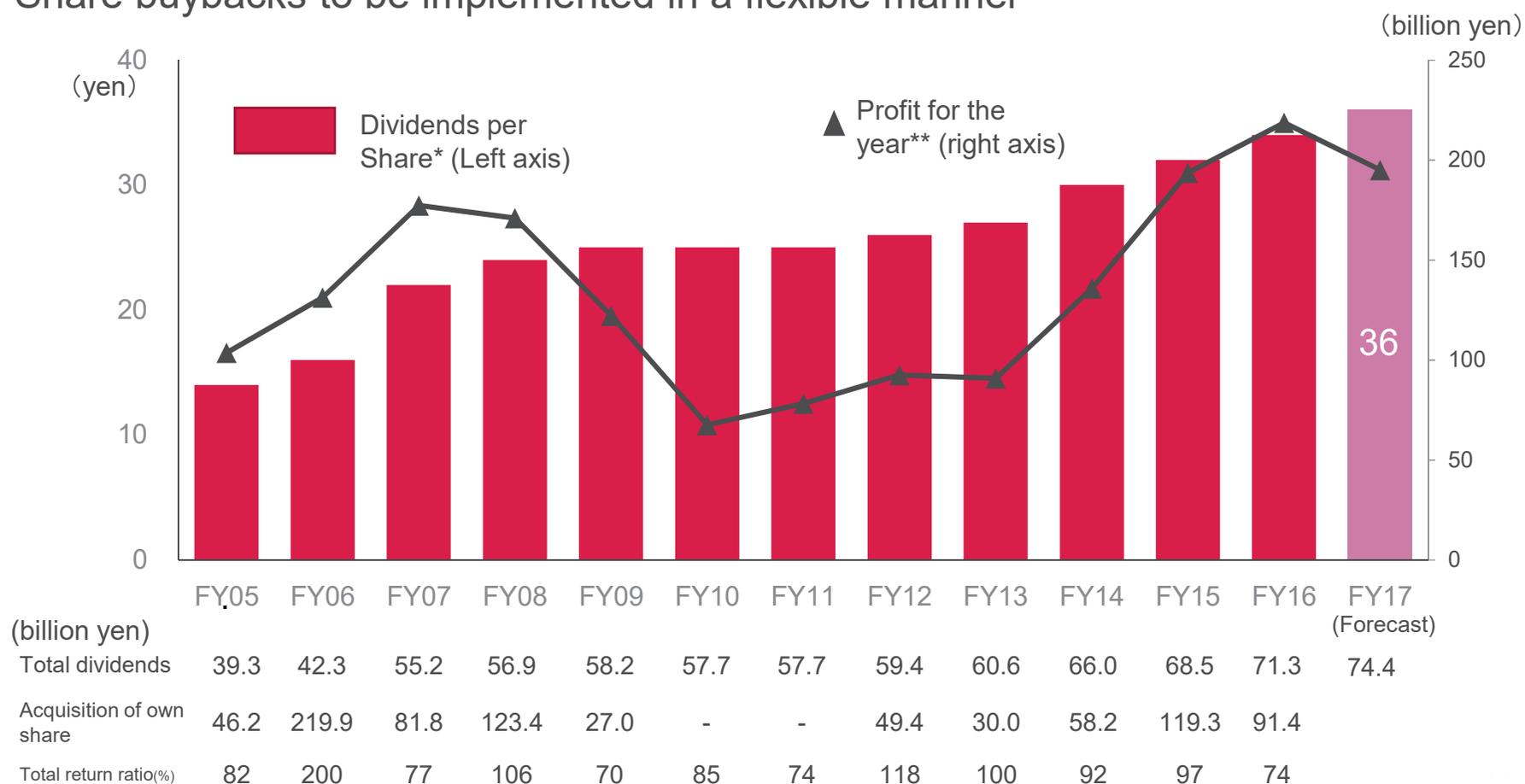
Profit Distribution Policy

36

Top priority on investment for growth business

Dividends to be increased continuously based on mid-and long-term growth

Share buybacks to be implemented in a flexible manner

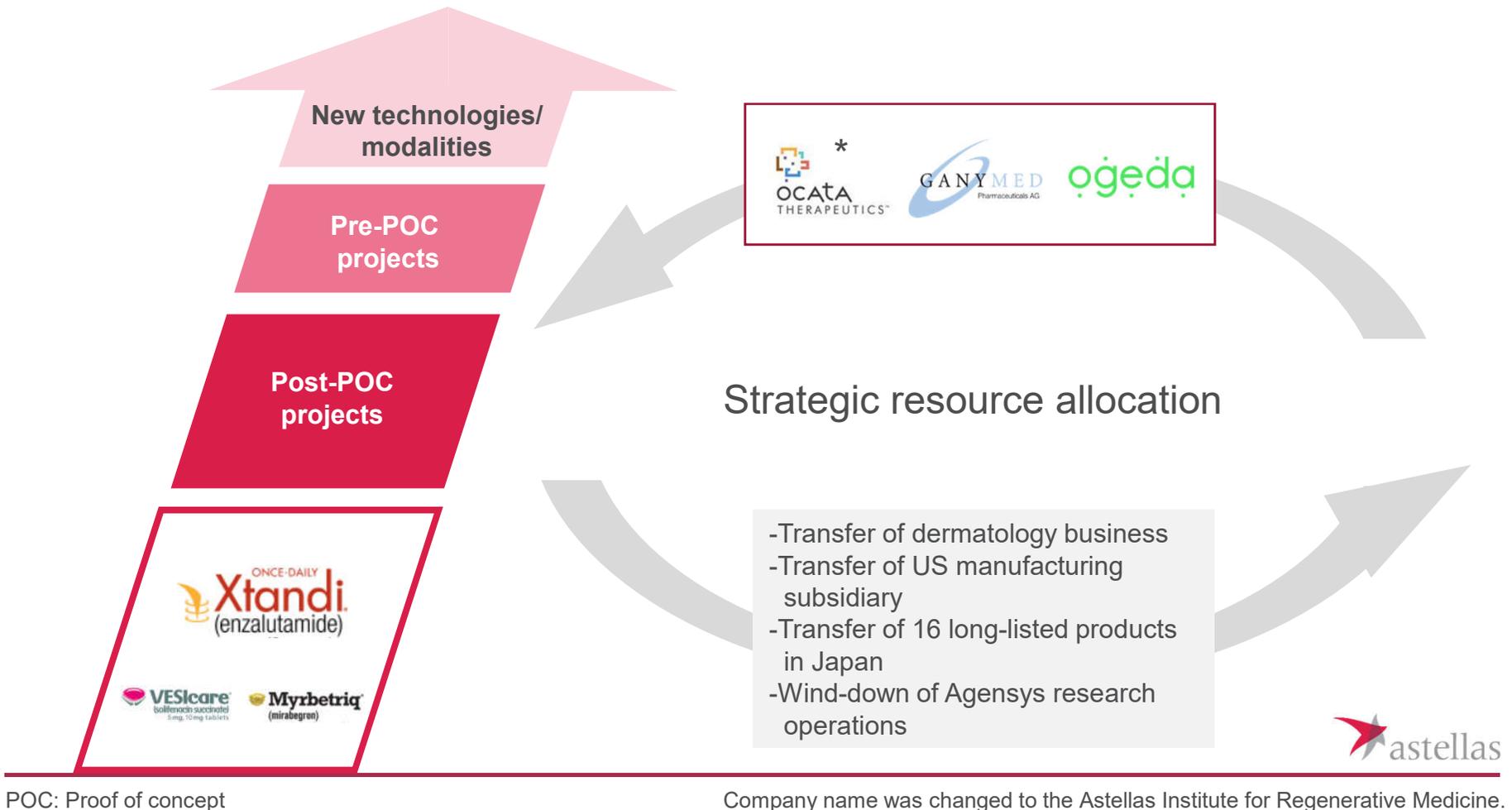


*The Company conducted a stock split of common stock at a ratio of 5 for 1 with an effective date of April 1, 2014, Figures are calculated based on the number of shares issued after the stock split (excluding treasury shares) on the assumption that the stock split was conducted at the beginning of fiscal 2005.

**From fiscal 2013, figures are in accordance with International Financial Reporting Standards (IFRS).

REALIZE SUSTAINABLE GROWTH

Turn innovative science into value for patients on the forefront of healthcare change





APPENDIX

Q2/FY2017: SALES BY REGION

39

	Q2/FY16	Q2/FY17	Change
Japan (billion yen)	237.2	213.0	-10.2%
of sales in Japanese market	221.8	194.1	-12.5%
Americas (million USD)	1,963	1,876	-4.4%
EMEA (million EUR)	1,406	1,339	-4.8%
Asia/Oceania (billion yen)	41.8	49.4	+18.1%

FX RATE (ACTUAL)

40

Average rate for the period

(yen)

Currency	Q2/FY16	Q2/FY17	Change
USD	105	111	+6
EUR	118	126	+8

Change in closing rate from PY end

Currency	Q2/FY16	Q2/FY17
USD	-12	+1
EUR	-14	+13

Exchange rate change +: Yen Weakening, - : Yen Strengthening

FY2017 FCST : FX SENSITIVITY

41

**Forecast rates from Q3/FY2017 onwards:
110 USD/yen, 130EUR/yen**

Estimated Fx sensitivity (Q3 and onward) of FY2017 forecasts by 1 yen appreciation*

Currency	Average rate 1 yen higher than assumption		Year-end rate 1 yen higher than assumption
	Net sales	Core OP	Core OP
USD	Approx. -2.4 bil yen	Approx. -0.6 bil yen	Approx. +0.6 bil yen
EUR	Approx. -1.3 bil yen	Approx. -0.5 bil yen	Approx. +0.3 bil yen



*Sensitivity to fluctuation of Fx rates used for consolidation of overseas affiliates' results compared to forecasted rates from Q3/FY2017 and onwards

BALANCE SHEET/CASH FLOW HIGHLIGHTS

42

(billion yen)	FY2016 end	Sep. 2017
Total assets	1,820.9	1,895.7
Cash and cash equivalents	340.9	307.9
Total net assets	1,271.8	1,350.9
Equity ratio (%)	69.8%	71.3%

(billion yen)	Q2/FY16	Q2/FY17	FY2016
Cash flows from operating business	90.1	115.3	235.6
Cash flows from investing activities	(19.9)	(72.7)	(73.4)
Free cash flows	70.2	42.6	162.2
Cash flows from financing activities	(35.5)	(85.9)	(166.2)
Acquisition of treasury shares	(0.8)	(50.2)	(92.2)
Dividends paid	(34.0)	(35.1)	(70.1)

PROFIT DISTRIBUTION

	FY2015	FY2016	FY2017 (forecast)
EPS (yen)	89.75	103.69	88.15
Divided per share (yen)	32	34	36 (forecast)
ROE	15.0%	17.3%	-
DOE	5.4%	5.6%	-
Share buyback	68 million shares 119.3 billion yen	60 million shares 91.4 billion yen	-
Treasury stock cancellation	38 million shares	68 million shares	85 million shares

ON THE FOREFRONT OF HEALTHCARE CHANGE

