

# Full-Year and Q4 2015 Results

4 February 2016



# Forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement:

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; effects of patent litigation in respect of IP rights; exchange rate fluctuations; the risk that R&D will not yield new products that achieve commercial success; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the impact of competition, price controls and price reductions; taxation risks; the risk of substantial product liability claims; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing; the risks associated with manufacturing biologics; the risk of delay to new product launches; the difficulties of obtaining and maintaining regulatory approvals for products; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; the risk that new products do not perform as we expect; failure to achieve strategic priorities or to meet targets or expectations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the risk of misuse of social media platforms and new technology; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the risks from pressures resulting from generic competition; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; economic, regulatory and political pressures to limit or reduce the cost of our products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the impact of failing to attract and retain key personnel and to successfully engage with our employees; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.



# Agenda

**Overview**

Pascal Soriot



**Growth Platforms**

Luke Miels



**Finance**

Marc Dunoyer



**Pipeline**

Sean Bohan



**Closing**

Pascal Soriot



# Highlights

- **Total Revenue \$24.7bn, +1%**
  - Growth Platforms: Now 57% of total<sup>1</sup>, +11%
- **Core EPS \$4.26, +7%**
  - Underpinned by Core SG&A cost reduction; 2% in FY 2015 and 11% in Q4
- **Pipeline progress continued: Two approvals and two regulatory submissions in Q4**
- **2016 Guidance (CER)**
  - Total Revenue: A low to mid single-digit percent decline
  - Core EPS: A low to mid single-digit percent decline

1. As a percentage of Total Revenue and includes New Oncology as a sixth Growth Platform  
Absolute values at actual exchange rates. Growth rates at Constant Exchange Rates (CER)



# Strong Q4 pipeline newsflow

## Regulatory approvals

- **Zurampic** (lesinurad) - gout (US)
- **Tagrisso** - lung cancer (US, EU)

## Regulatory submission acceptances

- **brodalumab** - psoriasis (US, EU)
- **ZS-9** - hyperkalaemia (EU)

## Other key developments

- CHMP positive opinions (EU):
  - **Zurampic, Brilique** - prior MI (PEGASUS trial), **Tagrisso**

On track to deliver 7-8 potential regulatory submissions for new medicines in 2015-2016

CAZ AVI (CEPH/BLI) serious infections	✓	
cediranib (VEGFR) ovarian cancer (EU)	✓	
selumetinib (MEK) uveal melanoma	X	
<b>Tagrisso</b> (EGFR) NSCLC 2L T790M	✓	
brodalumab (IL17R) psoriasis	✓	
PT003 (LAMA/LABA) COPD	✓	
<b>2015</b>		
		acalabrutinib (BTK) blood cancer
		tremelimumab (CTLA-4) mesothelioma
		roxadustat (HIF-PHI) anaemia (CN)
		benralizumab (IL-5R) severe asthma
		<b>2016</b>



# Leveraging top-line growth down the P&L

	FY 2015 \$m	% change	% Total Revenue	Q4 2015 \$m	% change
<b>Total Revenue</b>	24,708	+1	100	6,399	+2
<i>Of which Growth Platforms</i>	14,003	+11	57	3,588	+11
<b>Core EPS</b>	\$4.26	+7	-	\$0.94	+22

Absolute values at actual exchange rates. Growth rates at CER








# Growth Platforms

## Luke Miels

EVP, Global Product & Portfolio Strategy, Global Medical Affairs and Corporate Affairs



# Strong performance across all areas

	FY 2015 \$m	% change	% Total Revenue	Q4 2015 \$m	% change
<b>Growth Platforms</b>	13,885	+10	56	3,531	+10
 <b>Respiratory</b>	4,987	+7	-	1,289	+4
 <b>Brilinta/Brilique</b>	619	+44	-	174	+43
 <b>Diabetes</b>	2,224	+26	-	585	+24
 <b>Emerging Markets</b>	5,822	+12	-	1,428	+10
 <b>Japan</b>	2,020	+4	-	541	+8







Absolute values at actual exchange rates. Growth rates at CER





# New Oncology further strengthens Growth Platforms

## *Lynparza, Iressa (US), Tagrisso and future medicines*

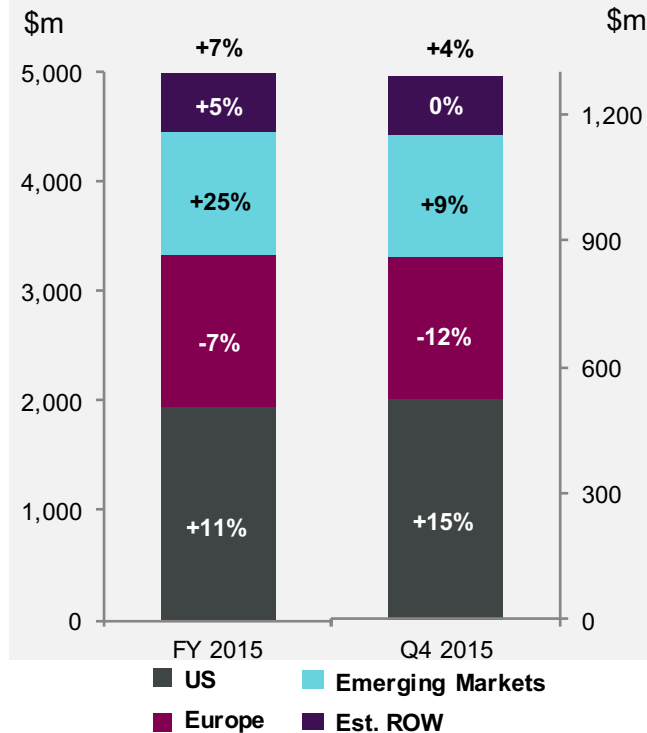
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 <b>New Oncology</b>	119	n/m	-	57	n/m

Absolute values at actual exchange rates. Growth rates at CER



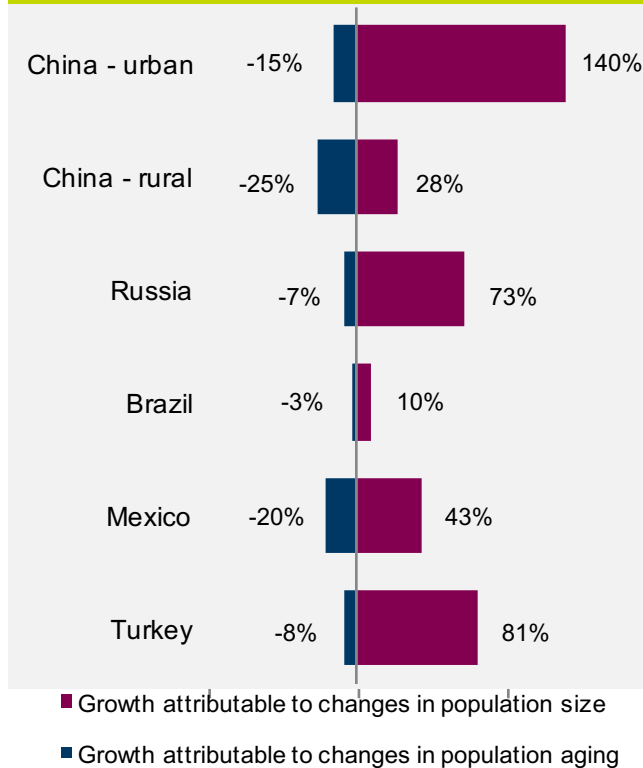
# Respiratory: Strength in Emerging Markets

## Growth supported by new medicines



Absolute values at actual exchange rates. Growth rates at CER

## Expected growth of active diagnosed prevalent asthma cases (2010-2026)



Source: Decision Resources 2015

## Particular strength in Emerging Markets

### US +11%

- *Symbicort* +1%, driven by higher market share within growing market
- *Tudorza* and *Daliresp*: Good uptake

### EU (7)%

- *Symbicort* lower due to analogues
- Portfolio enhanced by *Eklira*, *Duaklir* and Takeda transaction from 2016

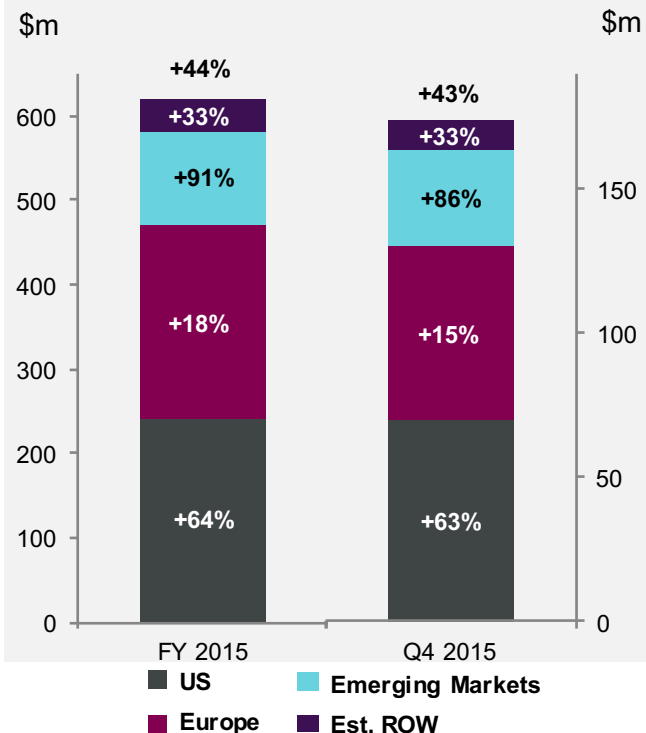
### Emerging Markets +25%

- China +38%
- *Pulmicort* strength +35%; China +43%



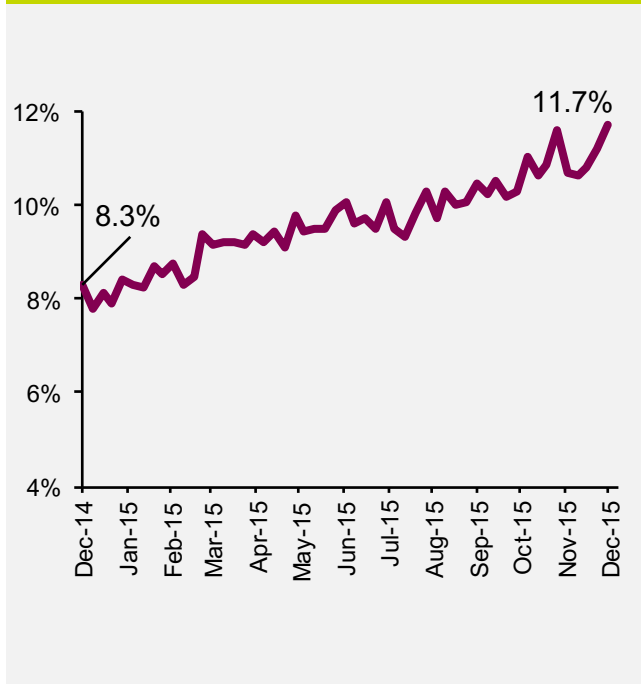
# Brilinta/Brilique: Growth in all markets

## Consistent growth across markets



Absolute values at actual exchange rates. Growth rates at CER

## US oral anti-platelet class market share new-to-brand prescriptions



Source: IMS Health NPA, weekly data to 1 January 2016

## Global execution of lifecycle management

### US

- Launch of post-MI indication

### EU

- CHMP positive opinion
- Indication leadership across EU markets

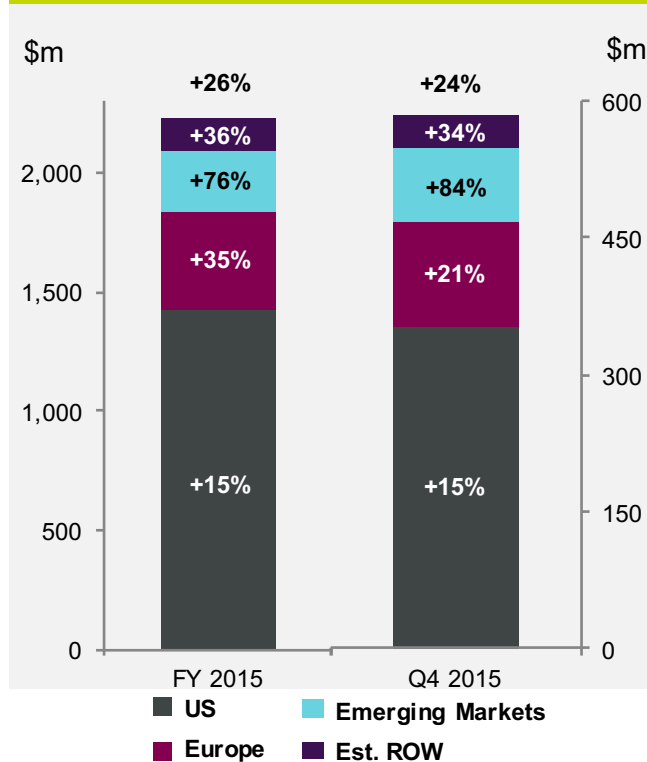
### Emerging Markets

- China largest EM market (+160%)



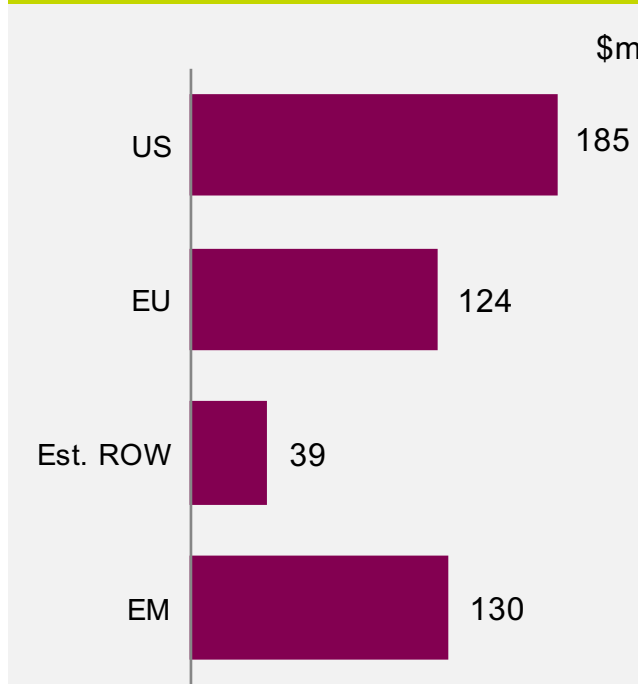
# Diabetes: Global franchise growth continues

## Quarterly growth continues at >20%



Absolute values at actual exchange rates. Growth rates at CER

## Absolute FY 2015 growth of Diabetes franchise by geography



Absolute values at constant exchange rates in bar chart above

## Strong growth in all markets

### US +15%

- Benefit from full suite of medicines, led by *Farxiga*

### EU +35%

- Increasing Diabetes footprint; growth across portfolio

### Emerging Markets +76%

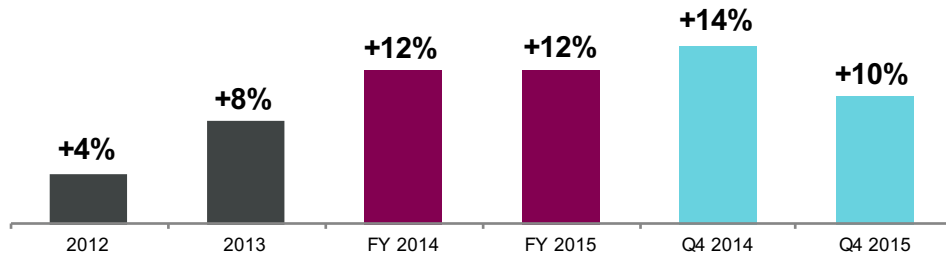
- Strong growth, *Forxiga* launch, *Onglyza* uptick



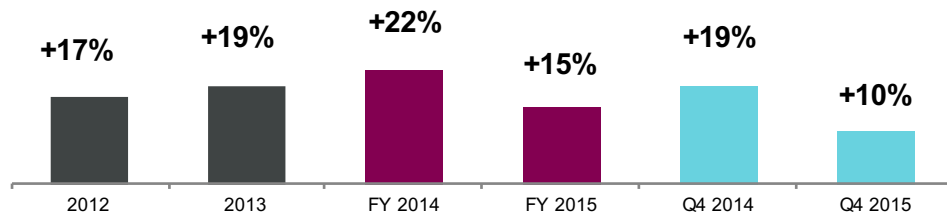
# Emerging Markets: Continued high growth

## Growth continued at double digits

### Emerging Markets



### China



Growth rates at CER

## Broad-based performance

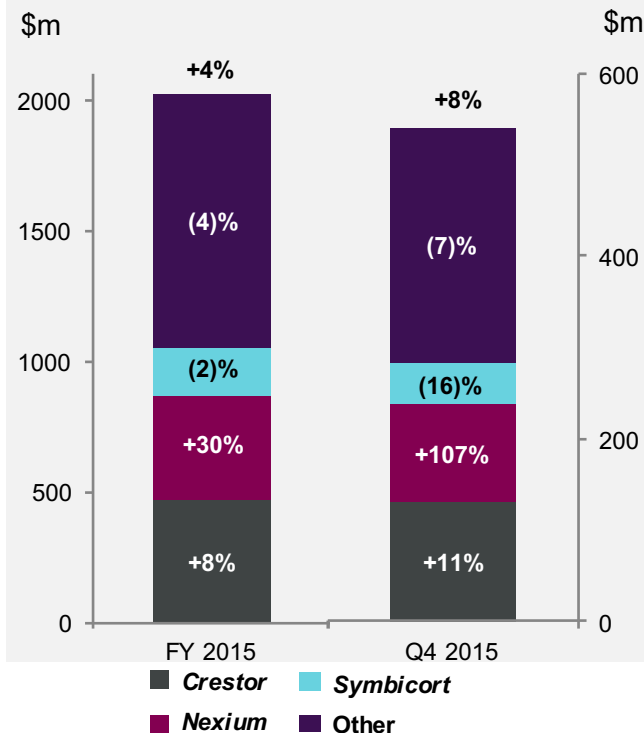
- Strong growth driven by established portfolio
- Balanced presence: ~40% China, ~60% ex-China (Brazil +16%, Russia +21%)
- New medicines and pipeline well-positioned for growing patient needs
- Performance currently exceeding long-term targets

**Long-term target: Mid-to-high single-digit growth**



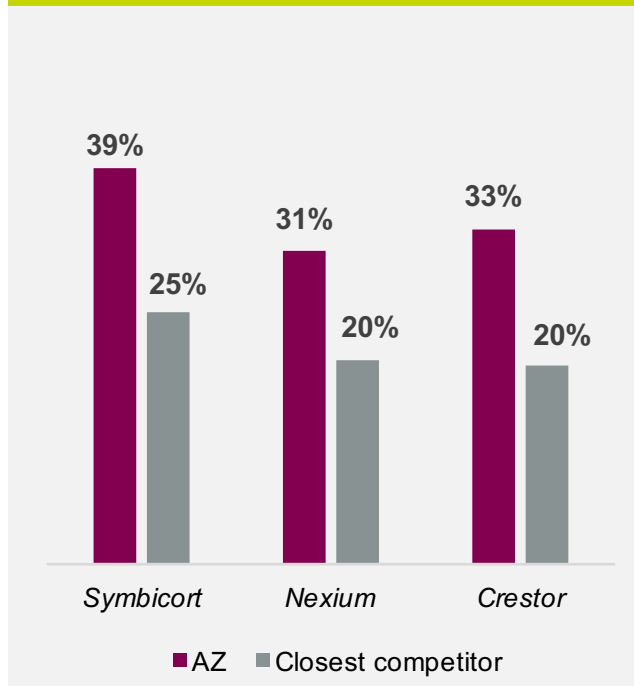
# Japan: Continued solid growth

## Growth supported by new products



Absolute values at actual exchange rates. Growth rates at CER

## Leading dynamic patient share



Source: IMS, November 2015

## Established products to be augmented by new opportunities

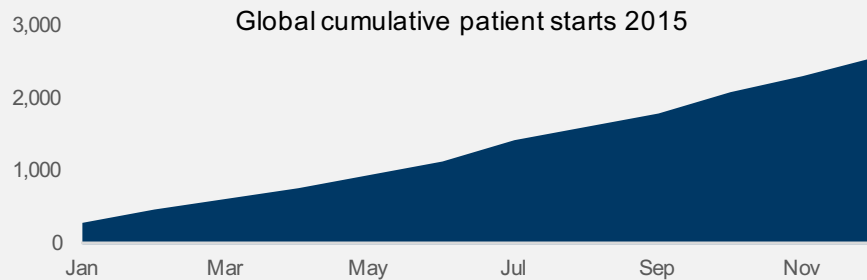
- Strong market share, Product Sales growth from key medicines despite challenging external environment
- *Brilinta* regulatory decision for ACS and post-MI indications expected H1 2016
- *Tagrisso* priority review, regulatory decision expected H1 2016

**Long-term target:**  
Low single-digit growth



# New Oncology: Fundamental to future growth

## Lynparza (ovarian cancer)

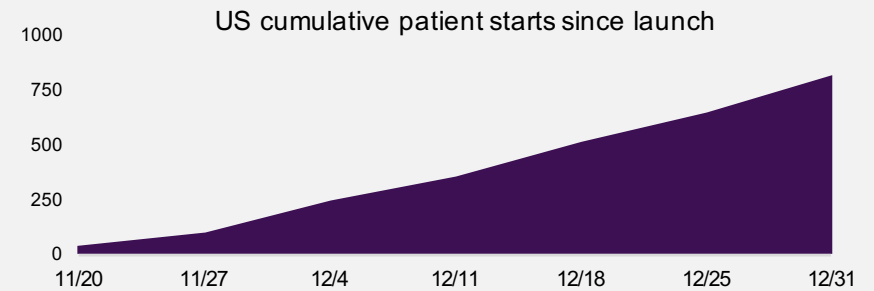


- Global Product Sales \$94M
- Approved in 24 countries, launched in 15



Absolute values at actual exchange rates

## Tagrisso (lung cancer)



- Product Sales \$19M (launched 13 November 2015)
- NCCN<sup>1</sup> treatment guideline inclusion one week after approval



1. National Comprehensive Cancer Network;  
a US cancer guideline-setting organisation



# Finance

**Marc Dunoyer**  
Chief Financial Officer





# FY 2015: Finance highlights

- **Total Revenue \$24.7bn, +1%**
  - Growth Platforms: Now 57% of total<sup>1</sup>, +11%
- **Core R&D investment underpinned by**
  - Core Gross Margin on Product Sales up by 1% point
  - Core SG&A cost reduction of 2% and 11% in Q4
  - Externalisation Revenue ~\$1b; Other Operating Income ~\$1.5bn
- **Core EPS \$4.26, +7%; +22% in Q4 2015**
- **Commitment to the progressive dividend policy**
  - A second interim dividend of \$1.90 per share
  - An unchanged full-year dividend per share
- **2016 Guidance (CER)**
  - Total Revenue: A low to mid single-digit percent decline
  - Core EPS: A low to mid single-digit percent decline
- **Future capital-allocation priorities outlined**

1. As a percentage of Total Revenue and includes New Oncology as a sixth Growth Platform  
Absolute values at actual exchange rates. Growth rates at CER



# Profit & Loss

## Leveraging top-line resilience

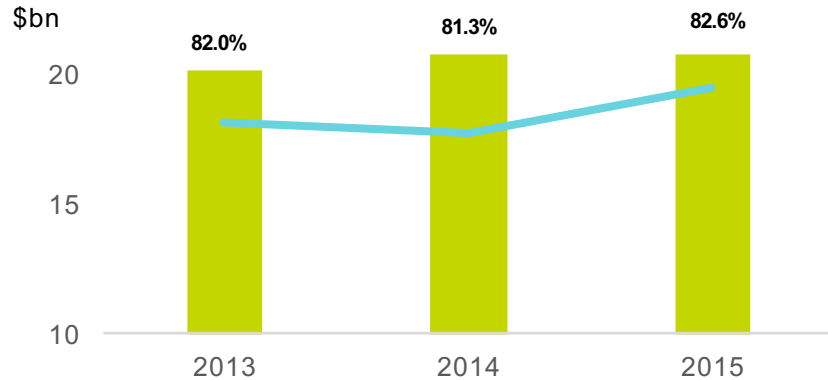
	FY 2015 \$m	% change	% Total Revenue	Q4 2015 \$m	% change
<b>Total Revenue</b>	<b>24,708</b>	<b>+1</b>	100	<b>6,399</b>	<b>+2</b>
Product Sales	23,641	(1)	96	6,207	-
Externalisation Revenue	1,067	+140	4	192	+490
Core Cost of Sales	(4,119)	(6)	17	(1,209)	+3
Core Gross Profit	20,589	+2	83 <sup>1</sup>	5,190	+2
Core R&D	(5,603)	+21	23	(1,567)	+21
Core SG&A	(9,265)	(2)	37	(2,461)	(11)
Core Tax Rate	16%	-	-	14%	3% points
<b>Core EPS</b>	<b>\$4.26</b>	<b>+7</b>		<b>\$0.94</b>	<b>+22</b>

1. Gross Profit as % of Total Revenue reflects Gross Profit derived from Product Sales, divided by Product Sales.  
Absolute values at actual exchange rates. Growth rates at CER

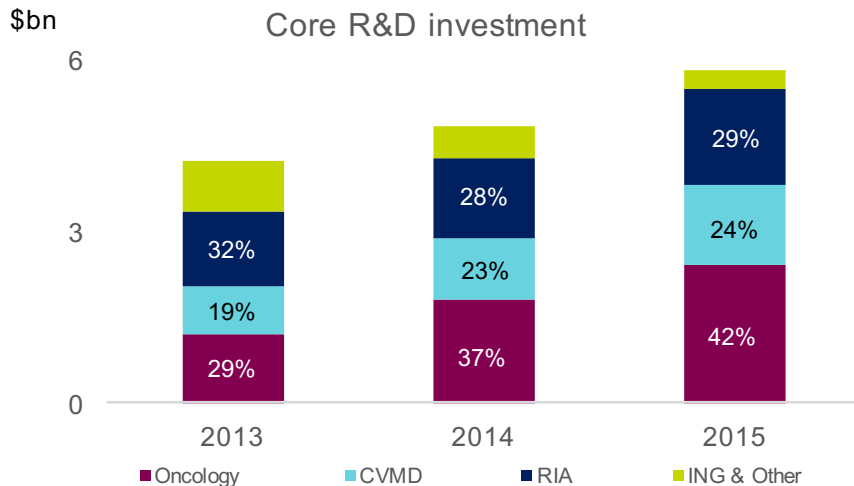


# R&D investment underpinned by strong Core Gross Profit

Core Gross Profit & Margin



- Manufacturing efficiencies
- Focus on supply chain
- Evolving mix of Product Sales from pipeline



- Increasing focus on main therapy areas
- Oncology now enjoys the largest share

Up-weighted 2015 investment in R&D

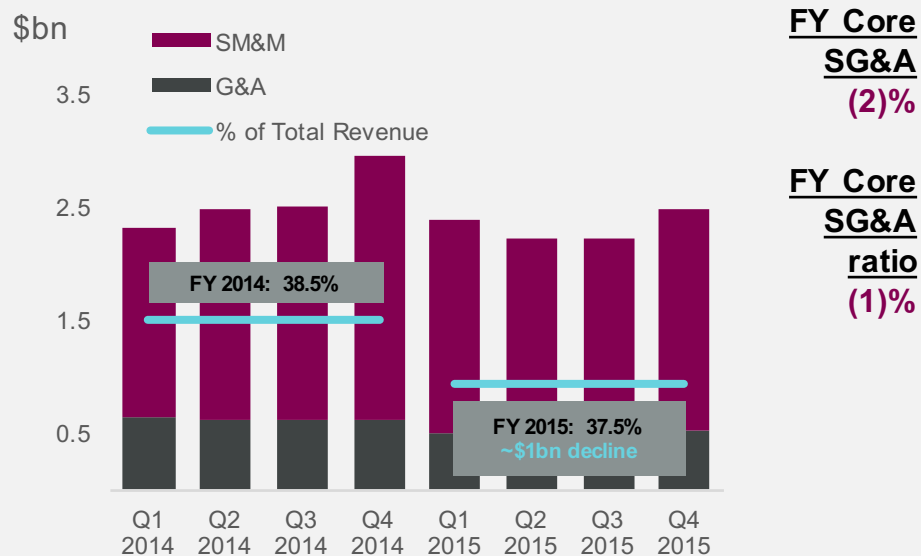
FY 2016 Core R&D costs are expected to be at a similar level to FY 2015 based on constant exchange rates

Absolute values at actual exchange rates. Growth rates at CER. Gross profit and margin here exclude the impact from Externalisation Revenue



# Continued focus on Core SG&A reduction

## 2015 Core SG&A cost reduction delivered



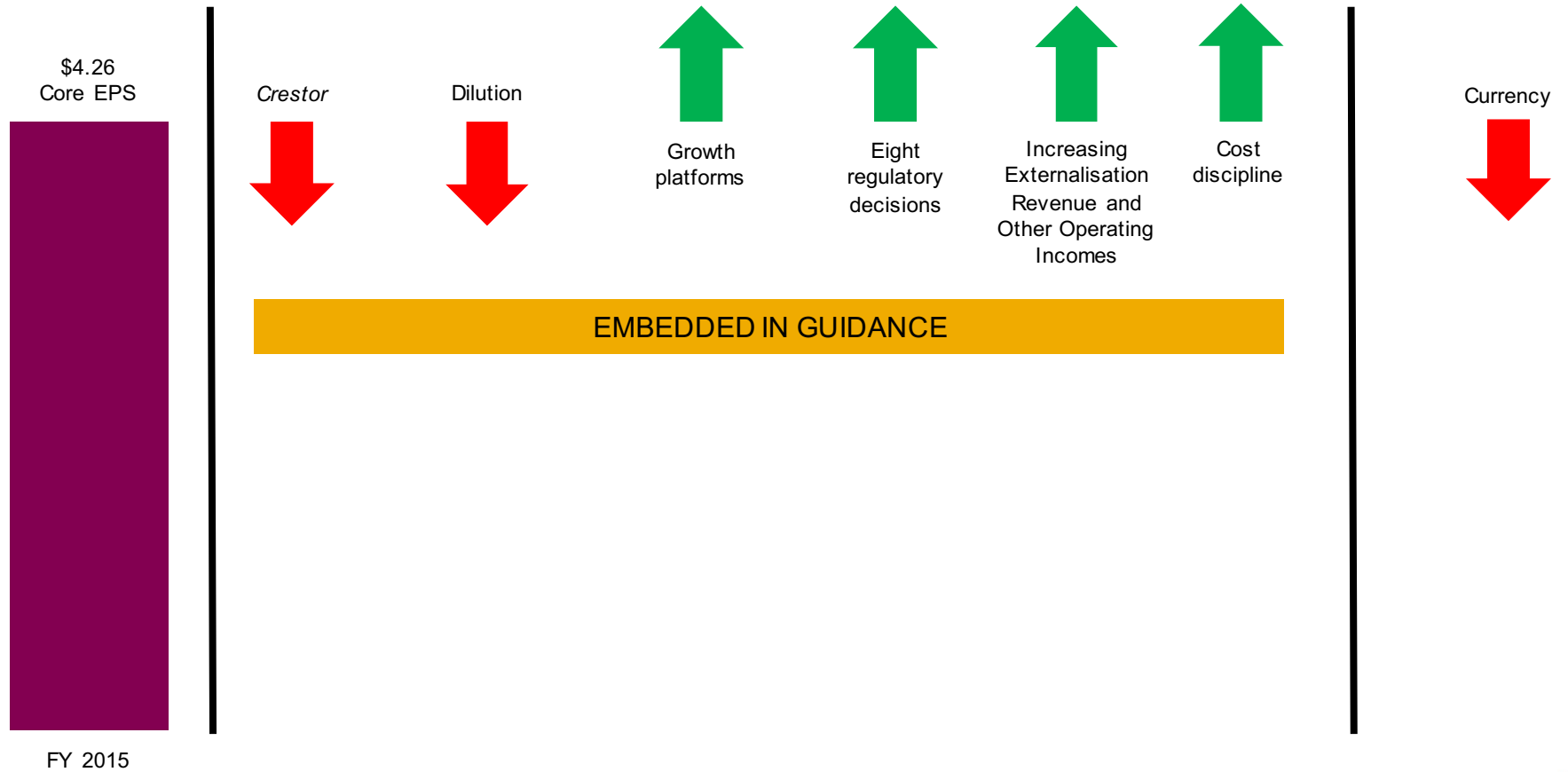
## Core SG&A commitment renewed

- The Company is committed to materially reducing Core SG&A costs in FY 2016 based on constant exchange rates
- Productivity programmes and progress
  - reducing third-party spend
  - optimising functions and processes
  - sales and marketing effectiveness

Absolute values at actual exchange rates. Growth rates at CER



# A year of challenges and opportunities



# FY 2016 guidance & capital-allocation priorities

**FY 2016 guidance (CER)**

Total Revenue	Low to mid single-digit percentage decline
Core EPS	Low to mid single-digit percentage decline

**Capital allocation priorities**

- Investment in the business
- Progressive dividend policy
- Strong, investment-grade credit rating
- Earnings-accretive opportunities

Growth rates at CER



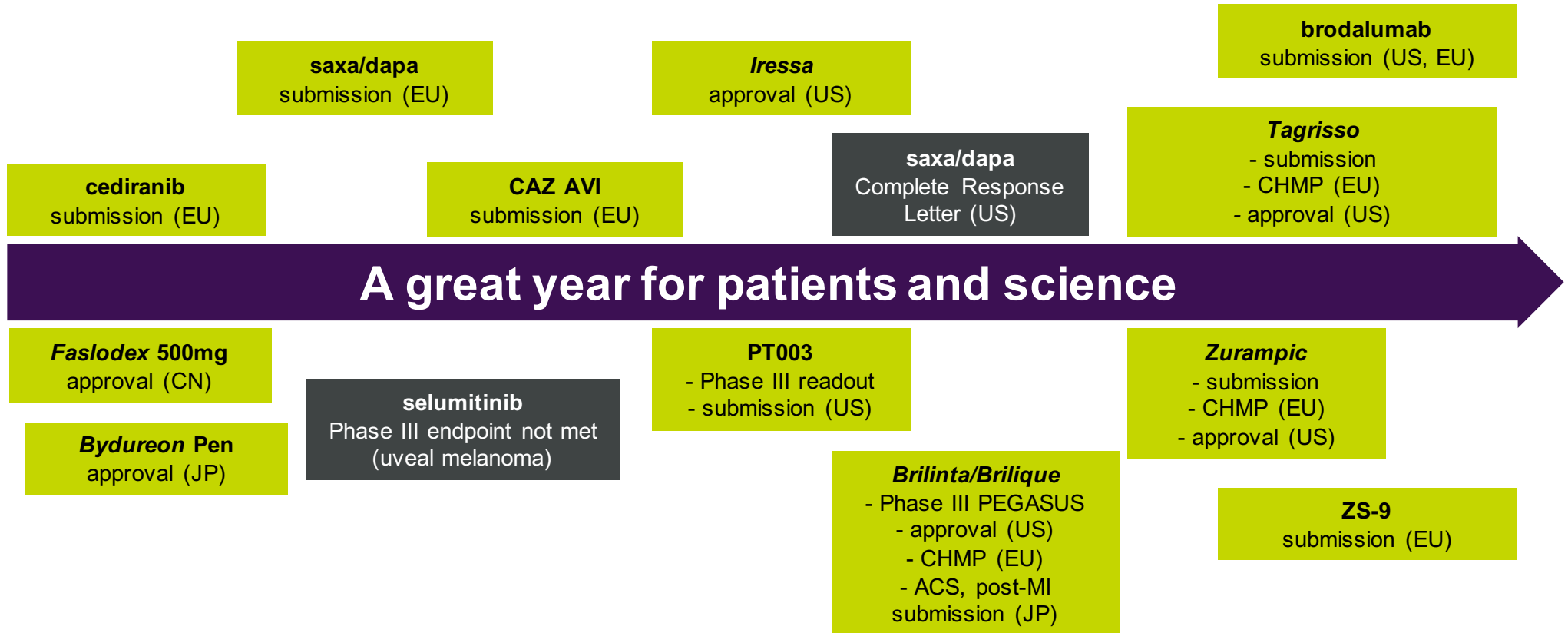
# Pipeline

**Sean Bohan**

EVP, Global Medicines Development & Chief Medical Officer



# 2015: Delivering the late-stage pipeline





# Q4 late-stage pipeline highlights

## Respiratory, Inflammation & Autoimmunity (RIA)

- **Symbicort** - asthma: LABA safety trial positive
- **Zurampic** - gout: Approval (US), CHMP positive opinion (EU)
- **brodalumab** - psoriasis: Regulatory submission (US, EU)
- **anifrolumab** - lupus (SLE): Phase II presentation



## Cardiovascular & Metabolic Disease (CVMD)

- **Brilique** - prior MI: CHMP positive opinion (EU)
- **ZS-9** - hyperkalaemia: Regulatory submission (EU)
- **saxa/dapa** - new US regulatory submission now expected H1 2016



## Oncology

- **Lynparza** - prostate cancer: Breakthrough Therapy (US)
- **Tagrisso** - lung cancer: Approval (US, EU), ADAURA (adjuvant) trial started
- **durvalumab** no reg. submission for monotherapy in PD-L1+ 3L NSCLC
- **durva + treme** trials started: NEPTUNE (1L NSCLC), EAGLE (2L SCCHN), KESTREL (1L SCCHN), DANUBE (1L bladder cancer), ALPS (2L pancreatic cancer)

Status since the prior results announcement on 5 November 2015



# 2016 key pipeline newsflow

## Regulatory decisions

### H1 2016

- **Zurampic** - gout (EU)
- **PT003** - COPD (US)
- **ZS-9** - hyperkalaemia (US)
- **Tagrisso** - lung cancer (JP)

### H2 2016

- **saxa/dapa** - type-2 diabetes (EU)
- **cediranib** - ovarian cancer (EU)
- **CAZ AVI** - serious infections (EU)

## Key regulatory submissions

### H1 2016

- **Brilinta/Brilique** - stroke
- **saxa/dapa** - type-2 diabetes (US)

### H2 2016

- **benralizumab** - severe asthma (US, EU)
- **roxadustat** - anaemia (CN)<sup>1</sup>
- **tremelimumab** - mesothelioma
- **acalabrutinib** - blood cancer (US)

## Key data readouts

### H1 2016

- **benralizumab** - severe asthma
- **Brilinta/Brilique** - stroke
- **Lynparza** - gastric cancer
- **tremelimumab** - mesothelioma

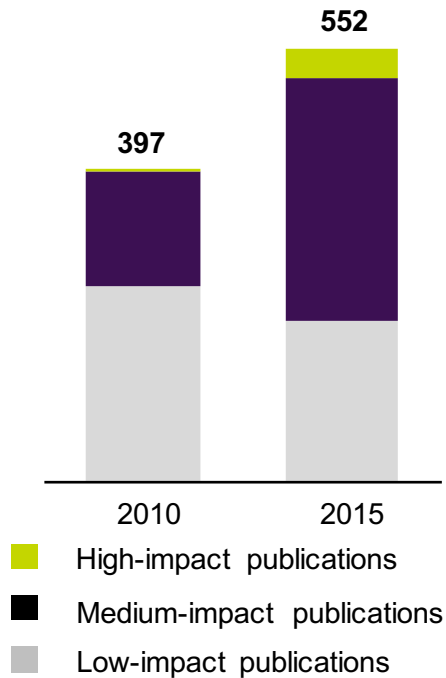
### H2 2016

- **Brilinta/Brilique** - PAD<sup>2</sup>
- **Lynparza** - ovarian, breast cancers
- **durvalumab** - H&N cancer
- **acalabrutinib** - blood cancer
- **selumetinib** - lung cancer

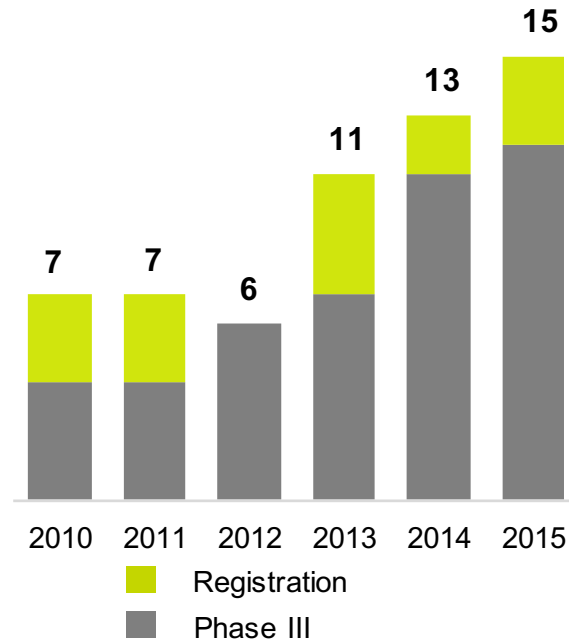


# Sustainable R&D productivity

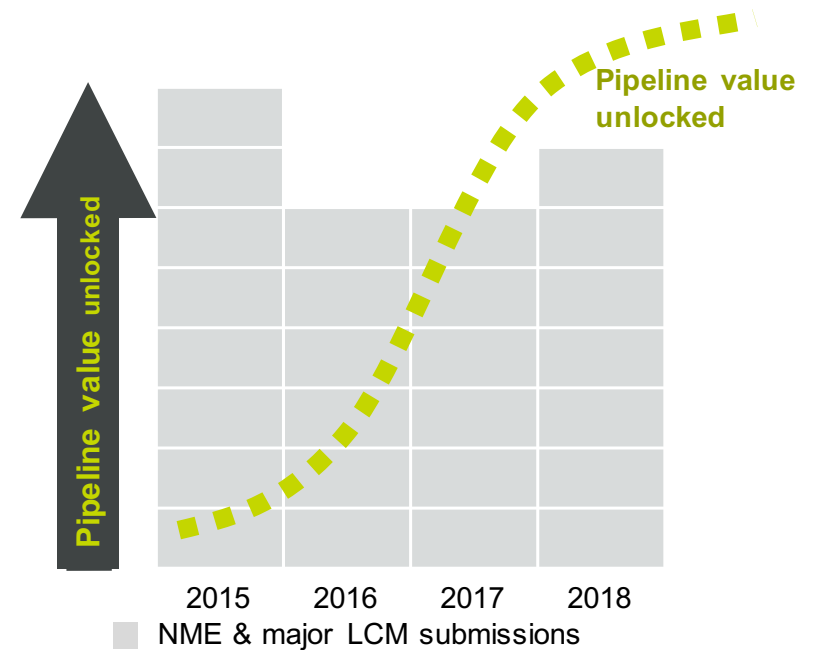
## Publications



## Phase III / Registration NMEs



## Unlocking pipeline value



## Delivering sustainable R&D productivity improvements

High-impact (rating > 15); medium-impact (rating > 5); low-impact (rating < 5)

Reflects Phase III / Registration volumes at year-end

Reflects expected regulatory submissions of key NMEs and major lifecycle management programmes



# Closing

**Pascal Soriot**

Chief Executive Officer



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# On track to deliver long-term goals



1. Target is at constant exchange rates (2013) which is equivalent to ~\$40bn at today's exchange rates



# Full-Year and Q4 2015 Results

4 February 2016

