ASTRAZENECA PLC
Form 6-K
February 04, 2016

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Report of Foreign Issuer

Pursuant to Rule 13a-16 or 15d-16 of
the Securities Exchange Act of 1934

For the month of February 2016

Commission File Number: 001-11960

AstraZeneca PLC

2 Kingdom Street, London W2 6BD

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F X Form 40-F __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes __ No X

If “Yes” is marked, indicate below the file number assigned to the Registrant in connection with Rule 12g3-2(b): 82-_____

4 February 2016

Full-Year and Q4 2015 Results

Financial Summary

	FY 2015			Q4 2015		
	$m	% change		$m	% change	
		CER1	Actual		CER1	Actual
Total Revenue2	24,708	1	(7)	6,399	2	(5)
Core3 Op. Profit	6,902	6	(1)	1,556	28	31
Core EPS	$4.26	7	-	$0.94	22	26
Reported Op. Profit	4,114	100	93	1,088	n/m4	n/m4
Reported EPS	$2.23	137	128	$0.63	n/m4	n/m4

- Core EPS in the year up by 7% and by 22% in Q4 2015
- Total Revenue growth of 1% in the year, with the gross margin on Product Sales up by 1% point
- Top-line and gross-margin growth underpinned continued investment in R&D. Core R&D costs up by 21% in the year, reflecting the investment in the pipeline
- Core SG&A costs down by 2% in the year (Q4 2015: down by 11%), in line with commitments
- Reported EPS in the year up by 137%, at $0.63 in Q4 2015 (Q4 2014: loss per share of $0.25)
- A second interim dividend of $1.90 per share, bringing the dividend for the full year to $2.80; the Board reaffirms its commitment to the progressive dividend policy
- FY 2016 CER guidance - a low to mid single-digit percentage decline in Total Revenue and a low to mid single-digit percentage decline in Core EPS; includes dilutive effects from recent transactions

FY 2015 Commercial Highlights

The Growth Platforms grew by 11% in the year, representing 57% of Total Revenue. ‘New Oncology’ is included for the first time, reflecting its long-term importance for the Company’s future growth:

1. Respiratory: +7%, before completion of the acquisition of Takeda’s Respiratory business
2. Brilinta/Brilique: +44%, underpinned by a recently-extended US label and positive CHMP opinion
3. Diabetes: +26%, including +76% in Emerging Markets. Global Farxiga/Forxiga growth of 137%
4. Emerging Markets: +12%, including China and Latin America each growing by 15%
5. Japan: +4%, including +8% in Q4 2015
6. New Oncology: Contributed $119m, comprising Lynparza, Iressa (US) and Tagrisso

Achieving Scientific Leadership: Progress since the last results announcement

Regulatory Approvals	Zurampic (lesinurad) - gout (US) Tagrisso (osimertinib, formerly AZD9291) - 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

Pascal Soriot, Chief Executive Officer, commenting on the results said:

“We delivered a strong pipeline and financial performance in 2015 as we begin the next phase in our strategic journey. The Growth Platforms delivered an 11% rise in Product Sales that, along with the 7% increase in Core EPS, demonstrated the underlying strength of our business. Our culture of innovation continued to drive R&D productivity, with six regulatory approvals in the year. This momentum will continue in 2016 as we anticipate six regulatory

submissions and around ten major data readouts. We strengthened the strategic importance of Oncology, bringing to patients next-generation therapies such as Tagrisso in lung cancer and Lynparza in ovarian cancer, as well as a promising immuno-oncology pipeline. Alongside this organic progress, we also continued to invest in our main therapy areas through key agreements with Acerta Pharma, ZS Pharma, and Takeda.

As we face the transitional period of patent expiry for Crestor in the US, we're confident that our strong execution on strategy, combined with the benefits of focused investments and new launches, keeps us on track to return to sustainable growth in line with our targets."

FY 2016 Guidance
All guidance is shown at CER1.

Total Revenue	A low to mid single-digit percentage decline
Core Earnings Per Share	A low to mid single-digit percentage decline

The above guidance incorporates the dilutive effects arising from the Acerta Pharma and ZS Pharma transactions announced in 2015.

The guidance also assumes the loss of exclusivity for Crestor in the US from May 2016. Externalisation Revenue is expected to be ahead of that in FY 2015, including an increasing element of recurring income arising from prior agreements. This is in line with the Company's long-term business model.

Core R&D costs are expected to be at a similar level to FY 2015. The Company is also committed to materially reducing Core SG&A costs in FY 2016. These measures are based on constant exchange rates.

Currency Impact
The weakness of key trading currencies against the US dollar has continued. Based on average exchange rates in January 2016 and the Company's published currency sensitivities, an adverse impact of around 3% from currency movements on Total Revenue and Core EPS in FY 2016 would be anticipated. Further details on currency sensitivities are contained within the Operating and Financial Review.

Pipeline: Forthcoming Major Newsflow
Innovation is critical to addressing unmet medical need and is at the heart of the Company's growth strategy. The focus on research and development at AstraZeneca is anticipated to yield a productive year for the pipeline, particularly in Oncology:

H1 2016

Zurampic: Regulatory decision (EU)
PT003 - COPD: Regulatory decision (US)
benralizumab - severe asthma: Data readout

Brilinta/Brilique - stroke: Data readout, regulatory submission
saxagliptin/dapagliflozin - type-2 diabetes: Regulatory submission (US)
ZS-9: Regulatory decision (US)

	Tagrisso: Regulatory decision (JP) tremelimumab - mesothelioma: Data readout Lynparza - gastric cancer: Data readout
	benralizumab - severe asthma: Regulatory submission (US, EU)
	Brilinta/Brilique - peripheral arterial disease: Data readout saxagliptin/dapagliflozin: Regulatory decision (EU) roxadustat - anaemia: Rolling regulatory submission (CN)
H2 2016	Lynparza - ovarian cancer: Data readout Lynparza - breast cancer: Data readout tremelimumab - mesothelioma: Regulatory submission cediranib - ovarian cancer: Regulatory decision (EU) durvalumab - head & neck cancer: Data readout acalabrutinib - blood cancer: Data readout, regulatory submission (US) selumetinib - lung cancer: Data readout
	CAZ AVI - serious infections: Regulatory decision (EU)

Notes

1. All growth rates and guidance are shown at constant exchange rates (CER) unless specified otherwise.
2. Total Revenue defined as Product Sales and Externalisation Revenue.
3. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
4. Q4 2014 results reflected a Reported Operating Loss of $349m and a Reported Loss Per Share of $0.25; a percentage comparison to the Reported results in Q4 2015 is not meaningful.

The performance shown in this announcement covers the twelve and three month periods to 31 December 2015 (the year and the quarter respectively) compared to the twelve and three month periods to 31 December 2014 (the prior year and the prior quarter respectively).

Results Presentation
A presentation and accompanying live webcast for investors and analysts, hosted by management, will begin at midday GMT today. Details can be accessed via www.astrazeneca.com/investors.

Reporting Calendar
The Company intends to publish its first-quarter financial results on 29 April 2016.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Respiratory, Inflammation and Autoimmunity (RIA), Cardiovascular and Metabolic Disease (CVMD) and Oncology – as well as in Infection and Neuroscience. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit: www.astrazeneca.com.

Contacts at AstraZeneca

Media Enquiries

Esra Erkal-Paler	UK/Global	+44 20 7604 8030
Neil Burrows	UK/Global	+44 20 7604 8032
Vanessa Rhodes	UK/Global	+44 20 7604 8037
Karen Birmingham	UK/Global	+44 20 7604 8120
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Enquiries

UK

T	Thomas Kudsk Larsen		+44 7818 524185
E	Eugenia Litz	RIA	+44 7884 735627
Ni	Nick Stone	CVMD	+44 7717 618834
C	Craig Marks	Finance	+44 7881 615764
C	Christer Gruvris	Consensus Forecasts	+44 7827 836825

US

Li	Lindsey Trickett	Oncology, ING	+1 240 543 7970
M	Mitchell Chan	Oncology	+1 240 477 3771
T	Toll-Free		+1 866 381 7277

Key: RIA - Respiratory, Inflammation & Autoimmunity, CVMD - Cardiovascular & Metabolic Disease, ING - Infection, Neuroscience & Gastrointestinal

Operating and Financial Review

All narrative on growth and results in this section relates to Core performance, based on constant exchange rates (CER) unless stated otherwise. Financial figures are in $ millions ($m). The performance shown in this announcement covers the twelve and three-month periods to 31 December 2015 (the year and the fourth quarter respectively) compared to the twelve and three months to 31 December 2014. Core measures, which are presented in addition to Reported financial information, are non-GAAP measures provided to enhance understanding of the Company's underlying financial performance. Core financial measures are adjusted to exclude certain significant items, such as:

– amortisation and impairment of intangibles, including impairment reversals but excluding any charges relating to IT assets

– charges and provisions related to our global restructuring programmes (this will include such charges that relate to the impact of our global restructuring programmes on our capitalised IT assets)
– other specified items, principally comprising legal settlements and acquisition-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration on business combinations

More detail on the nature of these measures is given on page 72 of the 2014 Annual Report and Form 20-F Information.

Total Revenue
Total Revenue increased by 1% to $24,708m in the year, comprising Product Sales of $23,641m (down by 1%) and Externalisation Revenue of $1,067m (up by 140%). Based on actual exchange rates, Total Revenue declined by 7% in the year, reflecting the particular weakness of key trading currencies against the US dollar.

Product Sales
The decline in Product Sales was primarily driven by the US market entry of Nexium generic products from February 2015, as well as full-year adverse impacts from Synagis guideline changes in 2014 and the change in accounting for the US Branded Pharmaceutical Fee, following issuance of final regulations in 2014.

Within Product Sales, the Growth Platforms grew by 11% in the year, representing 57% of Total Revenue. ‘New Oncology’ is included for the first time, given its long-term importance for the Company’s future growth:

	FY 2015		Q4 2015	
Growth Platform	Product Sales ($m)	% CER change	Product Sales ($m)	% CER change
Respiratory	4,987	7	1,289	4
Brilinta/Brilique	619	44	174	43
Diabetes	2,224	26	585	24
Emerging Markets	5,822	12	1,428	10
Japan	2,020	4	541	8
New Oncology	119	n/m	57	n/m
TOTAL1	14,003	11	3,588	11

1 Total Product Sales for Growth Platforms adjusted to remove duplication on a product and regional basis.

Externalisation Revenue
Externalisation Revenue of $1,067m for the year (Q4 2015: $192m) primarily reflected income generated from a strategic collaboration in haematology with Celgene Corporation (upfront receipt of $450m) and a co-development and co-commercialisation arrangement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) for Movantik in the US (upfront receipt of $200m). Other Externalisation Revenue reflected a number of collaboration agreements, including the acceleration of the development of brodalumab with Valeant Pharmaceuticals International, Inc. (upfront receipt of $100m) and the co-commercialisation of Nexium in Japan (milestone income of $123m) with Daiichi Sankyo.

Product Sales
_____

The performance of a selection of key medicines is shown below. A geographical split of the performance is shown in Notes 8 and 9.

	FY 2015			Q4 2015		
		% Change			% Change	
	$m	CER	Actual	$m	CER	Actual

Respiratory, Inflammation & Autoimmunity						
Symbicort	3,394	(3)	(11)	859	(6)	(12)
Pulmicort	1,014	15	7	274	9	2
Tudorza/Eklira	190	n/m	n/m	47	n/m	n/m
Daliresp	104	n/m	n/m	32	n/m	n/m
Duaklir	27	n/m	n/m	12	n/m	n/m
Others	258	(5)	(15)	65	(4)	(14)
TOTAL	4,987	7	(2)	1,289	4	(4)
Cardiovascular & Metabolic Disease						
Brilinta/Brilique	619	44	30	174	43	31
Onglyza	786	2	(4)	192	3	(4)
Bydureon	580	35	32	155	28	26
Farxiga/Forxiga	492	137	119	152	76	63
Byetta	316	2	(3)	72	10	4
Legacy:						
Crestor	5,017	(3)	(9)	1,322	-	(5)
Seloken/Toprol-XL	710	4	(6)	160	5	(8)
Atacand	358	(15)	(29)	86	(15)	(26)
Others	611	(10)	(18)	147	(9)	(17)
TOTAL	9,489	4	(3)	2,460	6	(1)
Oncology						
Iressa	543	(2)	(13)	129	(5)	(14)
Lynparza	94	n/m	n/m	36	n/m	n/m
Tagrisso	19	n/m	n/m	18	n/m	n/m
Legacy:						
Zoladex	816	7	(12)	198	4	(13)
Faslodex	704	9	(2)	185	12	2
Casodex	267	(6)	(17)	63	(7)	(15)
Arimidex	250	(5)	(16)	60	(1)	(12)
Others	132	6	(7)	27	(26)	(33)
TOTAL	2,825	7	(7)	716	9	(3)
Infection, Neuroscience & Gastrointestinal						
Nexium	2,496	(26)	(32)	564	(26)	(32)
Seroquel XR	1,025	(12)	(16)	241	(18)	(22)
Synagis	662	(26)	(26)	275	(32)	(32)
Losec/Prilosec	340	(10)	(19)	77	(23)	(30)
FluMist/Fluenz	288	-	(2)	191	46	43
Movantik/Moventig	29	n/m	n/m	15	n/m	n/m
Others	1,500	-	(12)	379	25	11

TOTAL	6,340	(16)	(23)	1,742	(13)	(18)
TOTAL PRODUCT SALES	23,641	(1)	(9)	6,207	-	(7)

FY 2015 Product Sales Summary

During 2014, final regulations relating to the US Branded Pharmaceutical Fee were issued, affecting how the fee is recognised. AstraZeneca accrues for the obligation as each sale occurs, and, as under the final guidelines the fee is based on actual Product Sales in the current year, the fee is recognised as a deduction from Product Sales rather than a charge to SG&A, impacting individual medicine sales in the US by an average of 2%.

Respiratory, Inflammation & Autoimmunity

Symbicort
FY 2015 sales declined by 3% to $3,394m.

In the US, sales of $1,520m represented growth of 1%, with lower net prices reflecting additional access and co-pay assistance. Strong volume growth was driven by higher market share within a growing market.

In Europe, sales declined by 14% to $1,076m with a modest volume decline and a significant price decline reflecting increased competition from recently-launched analogue medicines. In contrast, Emerging Markets sales grew by 22% to $394m with China sales growing by 38% to $124m, primarily reflecting volume growth.

Pulmicort
Pulmicort sales in the year were $1,014m, an increase of 15%. Growth was driven primarily by the performance of Pulmicort Respules in Emerging Markets, where Pulmicort sales grew by 35% to $609m. China sales increased by 43% to $485m, reflecting sustained investment in supporting asthma and chronic obstructive pulmonary disease (COPD) patients, both in hospitals and at home.

Tudorza/Eklira
Sales in the year were $190m; over half of the medicine’s sales were in the US, where the brand name is Tudorza. In March 2015, the Company completed the acquisition of the Actavis plc (Actavis) rights to the product.

Daliresp
Rights were acquired in March 2015 from Actavis for Daliresp in the US and Canada. Sales were $104m in the year.

Duaklir
Duaklir was successfully launched in the year, principally in Europe. Sales of $27m reflected good progress of this leading LAMA/LABA medicine, with an encouraging formulary uptake in the UK and a strong market-share performance in Germany.

The encouraging performances of Tudorza/Eklira, Daliresp and Duaklir under the Company’s ownership were in line with expectations.

Cardiovascular & Metabolic Disease

Brilinta/Brilique

Sales in the year were $619m, an increase of 44%. AstraZeneca announced in H2 2015 that the US Food and Drug Administration (FDA) had approved Brilinta tablets at a new 60mg dose to be used in patients with a history of heart attack beyond the first year of treatment.

FY 2015 sales in the US increased by 64% to $240m. The expanded indication launched in the second half of the year, underpinned ongoing new-to-brand prescription share growth, with share standing at 12% at the end of the year; this represented a four percentage point increase in the twelve-month period.

In Europe, Brilique continued to perform strongly, with an increase in full-year sales of 18% to $230m, reflecting indication leadership across a number of markets. Emerging Markets sales grew by 91% to $112m, with China representing the largest single market for the medicine, where sales were up by 160% to $38m.

Onglyza
Sales were up 2% in the year to $786m, with sales in Q4 2015 increasing by 3%.

US sales in the year declined by 13% to $420m as a consequence of a greater emphasis on the promotion of Farxiga. Competitive pressures in the DPP-4 class drove lower volumes and a decline in the net price.

Sales in Europe grew by 8% to $141m, while Emerging Markets sales increased by 41% to $159m.

Farxiga/Forxiga
Sales of Farxiga/Forxiga were up 137% in the year to $492m.

In the US, sales of $261m represented growth of 114%. Promotional activity underpinned increasing total-prescription market-share growth in the year; this was accompanied by overall growth in the market.

Sales in Europe reached $126m in the year, up by 126%. Launches of Forxiga in the year in a number of international markets, such as Australia, have been successful.

Bydureon/Byetta
Combined sales were $896m in the year, representing growth of 21%; Bydureon represented approximately 65% of total Bydureon/Byetta sales.

In the US, sales were $691m, up by 21%, with higher volumes driven by market growth and higher net prices. The majority of the remaining sales of Bydureon/Byetta were in Europe, totalling $143m; Bydureon sales in Europe grew by 65% to $81m, reflecting the Company’s ongoing effort to expand its Diabetes presence.

Legacy: Crestor
Sales of Crestor declined in the year by 3% to $5,017m; pricing was stable. The volume performance primarily reflected ongoing competition from generic statins.

In the US, Crestor sales declined by 3% to $2,844m, driven by lower market share and destocking, partially offset by favourable price movements.

In Europe, sales declined by 9% to $916m, reflecting prevailing competitive trends. Crestor consolidated its position as the leading statin in Japan, with sales growth in the year of 8% to $468m. Sales in China grew by 13% to $258m.

Oncology

Iressa

Sales of Iressa in the year declined by 2% to $543m, driven by the competitive environment in Europe where sales were down by 8% to $128m; Japan sales declined by 13% to $121m. Following the US launch in July 2015, Iressa saw an encouraging number of new-patient starts.

Emerging Markets sales grew by 4% to $272m, with China sales increasing by 5% to $146m and Latin America sales increasing by 17% to $11m.

Lynparza
Sales of Lynparza reached $94m in 2015. US sales of $70m followed the launch of the medicine in December 2014. Growth was driven by addressing the accumulated needs of eligible patients awaiting treatment, as well as patients newly tested for BRCA mutation. By the end of 2015, the medicine had been launched in 15 countries, including France and Germany.

Tagrisso
Sales of Tagrisso were $19m in 2015; the medicine was launched in November 2015 in the US with a strong performance in the number of new-patient starts.

Legacy: Zoladex
Sales increased by 7% to $816m, with a notable performance in China where sales reached $121m, reflecting growth of 29%.

Legacy: Faslodex
Sales were up 9% to $704m in 2015. US sales grew by 5% to $356m, accompanied by Europe sales of $207m, up by 2% in the year. The notable performance was in the Emerging Markets, where sales of $87m represented growth of 49%. Supported by the launch of 500mg Faslodex, China sales accelerated in the year to $11m (Q4 2015: growth of 100%, Q3 2015: growth of 50%). AstraZeneca Russia also achieved federal reimbursement for the medicine in the year.

Infection, Neuroscience & Gastrointestinal

Nexium
Sales of Nexium declined by 26% in the year to $2,496m.

US sales declined by 52% to $902m following the loss of exclusivity at the start of the year, directly impacting both pricing and volumes. Sales in Europe declined by 7% to $284m.

Nexium sales in Emerging Markets were up by 3% to $761m, with growth in Latin America of 18% to $127m. Japan sales increased by 30% in the year to $405m.

Seroquel XR
Sales declined by 12% in the year to $1,025m.

In the US, sales were down 3% at $716m. Sales in Europe declined by 30% to $202m, a function of generic-product competition.

Synagis
FY 2015 sales of Synagis declined by 26% to $662m.

A 43% decline in US sales in the year to $285m reflected the reduction in demand as a result of the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in 2014. These guidelines were more restrictive than the approved label, which further reduced patients eligible for preventative therapy with Synagis.

FluMist/Fluenz
Sales in the year were stable at $288m. US sales declined by 6% to $206m, reflecting supply issues. In contrast, Europe sales increased by 16% to $76m.

Movantik/Moventig
Sales in the year totalled $29m (Q4 2015: $15m); the medicine was launched in March 2015. The majority of sales were in the US, where the Company announced a co-commercialisation agreement in 2015 with Daiichi Sankyo for Movantik.

Regional Product Sales

	FY 2015			Q4 2015		
		% Change			% Change	
	$m	CER	Actual	$m	CER	Actual
US	9,474	(6)	(6)	2,572	(3)	(3)
Europe	5,323	(6)	(19)	1,421	(7)	(17)
Established ROW1	3,022	-	(14)	786	4	(8)
Japan	2,020	4	(9)	541	8	-
Canada	533	4	(10)	134	2	(14)
Other Established ROW	469	(19)	(32)	111	(10)	(26)
Emerging Markets2	5,822	12	(1)	1,428	10	(4)
China	2,530	15	13	599	10	6
Ex. China	3,292	10	(9)	829	9	(10)
Total	23,641	(1)	(9)	6,207	-	(7)

1 Established ROW comprises Japan, Canada, Australia and New Zealand.
2 Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.

US
US sales declined in the year by 6% to $9,474m. The US Branded Pharmaceutical Fee was recognised as a deduction from Product Sales in the year rather than as a charge to SG&A, impacting individual medicine sales by an average of around 2%.

The decline in sales in the US also reflected the entry of Nexium generic products from February 2015; Nexium sales in the US declined by 52% to $902m in the year. Adverse Synagis guideline changes were reflected in a 43% decline in US Synagis sales to $285m in the year.

Favourable performances were delivered by Brilinta, Farxiga, Bydureon and Lynparza as well as the acquired Respiratory medicines Tudorza and Daliresp. Tagrisso, launched earlier than originally anticipated in the fourth quarter, delivered an encouraging number of new-patient starts.

Continued growth in demand for Farxiga was supported by a strong promotional programme. Bydureon benefitted from the launch of the Bydureon Pen as well as growth in demand in the overall GLP-1 class.

Europe

Sales in Europe declined by 6% to $5,323m in the year. Strong growth from the Diabetes portfolio was more than offset by continued generic competition facing Crestor and Seroquel XR. A 14% decline in Symbicort sales to $1,076m reflected adverse pricing movements driven by competition from analogues in key markets. Duaklir more than doubled its first-half sales in the final quarter, bringing the full-year total to $26m. Lynparza was launched in Europe in 2015, contributing sales of $23m in the year.

Established ROW

Sales in the Established Rest Of World (ROW) were stable in the year at $3,022m.

Japan sales in the year increased by 4% to $2,020m. Sales of Crestor continued to grow strongly in the full year, up 8% to $468m. This reflected a continued increase in the usage of the 5mg dosage. Nexium sales rose by 30% to $405m, flattered by the impact of a product recall in FY 2014. Symbicort sales in the year fell by 2% to $176m in Japan, with a Q4 2015 sales decline of 16%. The strong performance in Q4 2014 reflected restocking. Underlying Symbicort sales growth in the year was estimated at around 5%. The Established ROW market share of Symbicort was broadly stable in the fourth quarter and over the full year.

Canada sales grew by 4% to $533m in the year, driven by the performances of Onglyza with sales up 27% to $53m and Symbicort sales increasing by 8% to $149m.

Emerging Markets

The Company continues to focus on delivering innovative medicines by accelerating investment in its Emerging Markets capabilities, with a focus on China and other leading markets, such as Russia and Brazil.

Emerging Markets sales in the year increased by 12% to $5,822m, with contributions to growth generated from across the region. Around 60% of Emerging Markets sales were derived outside of China in the year. Emerging Markets sales in the final quarter increased by 10% to $1,428m, ahead of the Company’s long-term forecast of mid to high single-digit percentage growth in the region’s Product Sales.

China sales in the year increased by 15% to $2,530m, while Brazil sales grew by 16% to $381m and Russia sales grew by 21% to $231m.

Financial Performance

FY 2015	Reported	Restructuring	Intangible Amortisation & Impairments	Diabetes Alliance	Other1	Core FY 2015	Core FY 20142	% Change CER	% Change Actual
Product Sales	23,641	-	-	-	-	23,641	26,095	(1)	(9)
Externalisation Revenue	1,067	-	-	-	-	1,067	452	140	136
Total Revenue	24,708	-	-	-	-	24,708	26,547	1	(7)
Cost of Sales	(4,646)	158	369	-	-	(4,119)	(4,888)	(6)	(16)
Gross Profit	20,062	158	369	-	-	20,589	21,659	2	(5)
Gross Margin3	80.3%					82.6%	81.3%	+0.8	+1.3

Distribution	(339)	-	-	-	-	(339)	(324)	17	5
% Total Revenue	1.4%					1.4%	1.2%	-0.2	-0.2
R&D	(5,997)	258	136	-	-	(5,603)	(4,941)	21	13
% Total Revenue	24.3%					22.7%	18.6%	-3.8	-4.1
SG&A	(11,112)	618	921	54	254	(9,265)	(10,216)	(2)	(9)
% Total Revenue	45.0%					37.5%	38.5%	+1.1	+1.0
Other Operating Income	1,500	-	178	-	(158)	1,520	759	104	100
% Total Revenue	6.1%					6.2%	2.9%	+2.9	+3.3
Operating Profit	4,114	1,034	1,604	54	96	6,902	6,937	6	(1)
% Total Revenue	16.7%					27.9%	26.1%	+1.3	+1.8
Net Finance Expense	(1,029)	-	-	409	115	(505)	(493)		
Joint Ventures	(16)	-	-	-	-	(16)	(6)		
Profit Before Tax	3,069	1,034	1,604	463	211	6,381	6,438	7	(1)
Taxation	(243)	(217)	(344)	(152)	(34)	(990)	(1,040)		
Tax Rate	8%					16%	16%		
Profit After Tax	2,826	817	1,260	311	177	5,391	5,398	7	-
Non-controlling Interests	(1)	-	-	-	-	(1)	(2)		
Net Profit	2,825	817	1,260	311	177	5,390	5,396	7	-
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,262		
Earnings Per Share	2.23	0.65	1.00	0.24	0.14	4.26	4.28	7	-

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 7) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 6).
2 2014 comparatives have been restated to reflect the reclassification of Externalisation Revenue from Other Operating Income.
3 Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales.
4 All financial figures, except Earnings Per Share, are in $ millions ($m). Weighted Average Shares are in millions.

Q4 2015	Reported	Restructuring	Intangible	Other1	Core	% Change

			Amortisation & Impairments	Diabetes Alliance		Q4 2015	Q4 20142	CER	Actual
Product Sales	6,207	-	-	-	-	6,207	6,683	-	(7)
Externalisation Revenue	192	-	-	-	-	192	33	490	482
Total Revenue	6,399	-	-	-	-	6,399	6,716	2	(5)
Cost of Sales	(1,269)	34	26	-	-	(1,209)	(1,359)	3	(11)
Gross Profit	5,130	34	26	-	-	5,190	5,357	2	(3)
Gross Margin3	79.6%					80.5%	79.7%	-0.7	+0.8
Distribution	(99)	-	-	-	-	(99)	(88)	23	13
% Total Revenue	1.5%					1.5%	1.3%	-0.3	-0.2
R&D	(1,746)	78	101	-	-	(1,567)	(1,360)	21	15
% Total Revenue	27.3%					24.5%	20.3%	-3.7	-4.2
SG&A	(2,668)	260	237	(270)	(20)	(2,461)	(2,953)	(11)	(17)
% Total Revenue	41.7%					38.5%	44.0%	+5.7	+5.5
Other Operating Income	471	-	22	-	-	493	228	100	116
% Total Revenue	7.4%					7.7%	3.4%	+3.2	+4.3
Operating Profit	1,088	372	386	(270)	(20)	1,556	1,184	28	31
% Total Revenue	17.0%					24.3%	17.6%	+4.8	+6.7
Net Finance Expense	(279)	-	-	104	25	(150)	(112)		
Joint Ventures	(7)	-	-	-	-	(7)	(4)		
Profit Before Tax	802	372	386	(166)	5	1,399	1,068	29	31
Taxation	6	(78)	(97)	(11)	(20)	(200)	(119)		
Tax Rate	(1)%					14%	11%		
Profit After Tax	808	294	289	(177)	(15)	1,199	949	22	26
Non-controlling Interests	-	-	-	-	-	-	-		
Net Profit	808	294	289	(177)	(15)	1,199	949	22	26
	1,264	1,264	1,264	1,264	1,264	1,264	1,263		

Weighted Average Shares									
Earnings Per Share	0.63	0.24	0.23	(0.15)	(0.01)	0.94	0.76	22	26

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 7) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 6).
2 2014 comparatives have been restated to reflect the reclassification of Externalisation Revenue from Other Operating Income.
3 Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales.
4 All financial figures, except Earnings Per Share, are in $ millions ($m). Weighted Average Shares are in millions.

Profit and Loss

Gross Profit
Core Gross Profit increased by 2% in the year to $20,589m. Excluding the impact of externalisation, the Core Gross-Profit margin increased by one percentage point. Drivers of the margin increase included the mix of Product Sales and manufacturing efficiencies.

Operating Expenses
Core R&D costs were up 21% in the year to $5,603m as the Company continued to focus on its pipeline. Oncology attracted over 40% of total Core R&D investment in the year, reflecting a number of active trials.

In line with commitments made in early 2015 to reduce Core SG&A costs for the full year, Core SG&A costs declined by 2% to $9,265m. Core SG&A costs also declined in the year by one percentage point as a proportion of Total Revenue. A number of ongoing programmes designed to address Core SG&A costs are progressing. These initiatives are focused on:

- Sales, marketing and medical-cost effectiveness
- Centralisation of selected functions and process improvements
- Reduced third-party spend
- Additional efficiencies gained across support functions and IT
- Continued footprint optimisation, including presence in the UK and US

Resources will continue to be deployed selectively to meet changing customer needs and the evolving portfolio, while driving top-line growth.

Other Operating Income
Core Other Operating Income of $1,520m in the year increased by 104% and included:

- $380m of income related to the disposal of the US rights to Entocort
- $322m of royalty income arising from a number of agreements
- $215m of income related to the disposal of the rest-of-world rights to Entocort
- $193m of income related to the disposal of Myalept
- $165m of income related to the disposal of Caprelsa

Operating Profit

Core Operating Profit increased by 6% to $6,902m in the year. The Core Operating Margin increased by one percentage point to 28% of Total Revenue. The increase reflected the decline in Core SG&A costs and the increase in Externalisation Revenue and Core Other Operating Income, while the Company continued to invest in the pipeline and the Growth Platforms.

Reported Operating Profit of $4,114m was $1,977m higher than FY 2014 principally due to the difference in Core adjustments between FY 2015 and FY 2014. Most significantly, fair value adjustments to contingent consideration relating to the Bristol-Myers Squibb Company (BMS) share of the global Diabetes alliance increased Reported Operating Profit by $378m in FY 2015, whereas fair value adjustments to contingent consideration reduced Reported Operating Profit by $529m in FY 2014. These fair value movements reflect estimates for future liabilities that can change materially over time. In addition, restructuring costs of $1,034m in FY 2015 were significantly lower than restructuring costs of $1,558m in FY 2014.

Finance Expense

The Core Net Finance Expense was $505m in the year, compared with $493m in FY 2014. The Reported Net Finance Expense of $1,029m included a charge of $524m relating to the discount unwind on contingent consideration liabilities recognised on business combinations, principally relating to the acquisition of the BMS share of the global Diabetes alliance.

Taxation

Excluding the previously disclosed one-off tax benefit of $186m following agreement of US federal tax liabilities of open years up to 2008, other net reductions in provisions for tax contingencies and non-Core revaluations of contingent consideration arising on business combinations, partially offset by the impact of internal transfers of intellectual property, the Core and Reported tax rates for the year ended 31 December 2015 were 21% and 22% respectively. Including the impact of these items, the Core and Reported tax rates for the year were 16% and 8% respectively. The cash tax paid for the year was $1,354m, which was 44% of Reported Profit Before Tax and 21% of Core Profit Before Tax.

Both the underlying Reported and underlying Core tax rates for the year ended 31 December 2014 were around 18%. Taking into account the one-off benefits totalling $309m in respect of a transfer pricing matter, non-Core revaluations of contingent consideration arising on business combinations, and the benefit of the UK Patent Box, the Reported and Core tax rates fell to 1% and 16% respectively.

Earnings Per Share (EPS)

Core EPS in the year increased by 7% to $4.26.

Reported EPS was up by 137% at $2.23. Core profit adjustments were lower in the year and represented 40% of Core Operating Profit compared to 69% in 2014, mainly as a result of the fair value movements described above.

Dividends

The Board has declared a second interim dividend of $1.90 per share (131.0 pence, 16.26 SEK) bringing the dividend per share for the full year to $2.80 (188.5 pence, 23.97 SEK). The Board reaffirms its commitment to the Company’s progressive dividend policy.

For holders of the Company’s American Depositary Shares (ADSs), the $1.90 per Ordinary Share equates to $0.95 per ADS. Following the ratio change to the Company’s NYSE-listed sponsored Level 2 American Depositary Receipt programme on 27 July 2015, two ADSs equal one Ordinary Share.

Productivity

Restructuring charges of $372m were recognised in the fourth quarter, bringing the full-year total to $1,034m, as the Company continued to make good progress in implementing its restructuring plans.

These charges included $683m related to the Phase 4 programme, initially announced in March 2013 and subsequently expanded. A $233m charge was associated with previously-announced site exits (including Avlon in the UK) and the integration of the Diabetes and Respiratory businesses acquired from BMS and Almirall respectively. A charge of $102m was associated with targeted restructuring of the Company's commercial business, implemented in late 2015, principally in Venezuela, in response to challenging economic conditions, and Europe.

Furthermore, as part of the ongoing commitment to improve productivity, the Company is initiating multi-year transformation programmes within back-office functions (principally finance and human resources) with anticipated costs by the end of 2018 of $270m. Once complete, these should deliver annualised benefits of approximately $100m by the end of 2018.

Final estimates for programme costs, benefits and headcount impacts in all functions will be subject to completion of the requisite consultation in the various areas. The Company's priority in undertaking these restructuring initiatives is to work with affected employees on the proposed changes, acting in accordance with relevant local consultation requirements and employment law.

Cash Flow and Balance Sheet

Cash Flow
The Company generated a cash inflow from operating activities of $3,324m in the year compared with $7,058m in the comparative period. Cash generated from operating activities reflects a modest increase in investment in working capital of $49m compared to a decline of $2,508m in 2014. Working capital improvements made in 2014 have been sustained, minimising the impact of increased acquired diabetes and launch product inventory balances.

Net cash outflows from investing activities were $4,239m compared with $7,032m in the prior year. This reflects cash payments relating to business acquisitions in FY 2014 of $4,461m, which primarily related to the BMS Diabetes alliance and Almirall acquisitions, being higher than those in FY 2015 of $3,025m, which primarily related to the ZS Pharma acquisition. In addition, there was a cash inflow from the disposal of intangible assets of $1,130m in FY 2015, principally related to the disposals of Entocort, Myalept and Caprelsa.

Debt and Capital Structure
At 31 December 2015, outstanding gross debt (interest-bearing loans and borrowings) was $15,053m (31 December 2014: $10,843m). In November 2015, the Company issued a total of $6bn of notes, with the proceeds of the issue to be used to fund corporate and business development activity, repay certain outstanding commercial paper obligations and for general corporate purposes. Of the gross debt outstanding at 31 December 2015, $916m was due within one year (31 December 2014: $2,446m). The Company's net debt position at 31 December 2015 was $7,762m (31 December 2014: $3,223m).

Shares in Issue
During the year, one million shares were issued in respect of share option exercises for a consideration of $43m. The total number of shares in issue as at 31 December 2015 was 1,264 million.

Capital Allocation
The Board's aim is to continue to strike a balance between the interests of the business, financial creditors and the Company's shareholders. After providing for investment in the business, supporting the progressive dividend policy and maintaining a strong, investment-grade credit rating, the Board will keep under review investment in earnings-accretive opportunities.

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

Currency	Primary Relevance	Average Exchange Rates Versus USD FY 2015	Average Exchange Rates Versus USD YTD 20161	Change %	Impact Of 5% Weakening In Exchange Rate Versus USD ($m)2 Total Revenue	Impact Of 5% Weakening In Exchange Rate Versus USD ($m)2 Core Operating Profit
EUR	Product Sales	0.90	0.92	(2)	(178)	(103)
JPY	Product Sales	121.04	118.27	2	(102)	(66)
CNY	Product Sales	6.28	6.57	(4)	(133)	(62)
SEK	Costs	8.43	8.54	(1)	(8)	71
GBP	Costs	0.65	0.69	(6)	(34)	96
Other3					(201)	(122)

1Based on average daily spot rates between 1 January 2016 and 29 January 2016
2Based on 2015 actual results at 2015 actual exchange rates
3Other important currencies include AUD, BRL, CAD, KRW and RUB

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 31 December 2015, AstraZeneca had hedged around 85% of forecast short-term currency exposure that arises between the booking and settlement dates on non-local currency purchases and Product Sales.

Corporate and Business Development Update

The highlights of the Company’s corporate and business development activities since the prior results announcement on 5 November 2015 are shown below.

a) Investment in Acerta Pharma
On 17 December 2015, AstraZeneca announced that it had entered into an agreement to invest in a majority equity stake in Acerta Pharma B.V. (Acerta), a privately-owned biopharmaceutical company based in the Netherlands and the US. The transaction will provide AstraZeneca with a potentially best-in-class irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase II/III development for B-cell blood cancers and in Phase I/II clinical trials in multiple solid tumours.

On 2 February 2016, on completion of the agreement, AstraZeneca acquired 55% of the entire issued share capital of Acerta for an upfront payment of $2.5bn. A further payment of $1.5bn will be paid either on receipt of the first regulatory approval for acalabrutinib in the US, or the end of 2018, whichever is sooner. The agreement also includes options, which if exercised, provide the opportunity for Acerta shareholders to sell, and AstraZeneca to buy, the remaining 45% of shares in Acerta (see Note 5).

b) Acquisition of ZS Pharma

On 6 November 2015, AstraZeneca announced that it had entered into an agreement to acquire ZS Pharma Inc. (ZS Pharma), a biopharmaceutical company based in San Mateo, California. The transaction, completed in Q4 2015, gives AstraZeneca access to the potassium-binding compound ZS-9. This is a potential best-in-class treatment for hyperkalaemia, a condition associated with increased mortality in chronic kidney disease (CKD) and chronic heart failure (CHF). Under the terms of the agreement, AstraZeneca acquired ZS Pharma for $90 per share (see Note 4).

c) Respiratory portfolio acquisition
On 16 December 2015, AstraZeneca announced that it had entered into a definitive agreement to acquire the core Respiratory business of Takeda Pharmaceutical Company Limited (Takeda). The transaction, once completed, will include the expansion of rights to roflumilast (marketed as Daliresp in the US and Daxas in other countries), the only approved oral PDE4 inhibitor for the treatment of COPD.

Under the terms of the agreement, AstraZeneca will make a payment of $575m. Upon completion approximately 200 staff will transfer to AstraZeneca.

d) Allergan - ATM-AVI
On 29 January 2016, it was announced that AstraZeneca had entered into a global agreement with Allergan plc (Allergan) to develop and commercialise ATM-AVI, an investigational, fixed-dose antibiotic, combining aztreonam and avibactam. Together, the two companies will evaluate the combination to treat serious infections caused by metallo lactamase MBL-producing Gram-negative pathogens, a difficult-to-treat sub-type of carbapenem-resistant Enterobacteriaceae, for which there are currently very limited treatments. ATM-AVI may present a new treatment option for patients with MBL-producing pathogens.

Under the terms of the agreement, Allergan will maintain commercialisation rights in the US and Canada and AstraZeneca will retain commercialisation rights in all other countries. AstraZeneca initiated a Phase I trial for ATM-AVI in 2012.

e) Agreement on rights to Entocort in the US
On 15 December 2015, AstraZeneca completed an agreement with Perrigo Company plc (Perrigo) for the divestment of US rights to Entocort (budesonide), a gastroenterology medicine for patients with mild to moderate Crohn’s disease. Under the terms of the agreement, Perrigo paid AstraZeneca $380m to acquire the rights to sell Entocort capsules and the authorised generic Entocort capsules marketed by Par Pharmaceuticals Companies, Inc.

The transaction did not include the transfer of any AstraZeneca employees or facilities. As a divestment, the income was recorded within Other Operating Income.

f) Strategic investments in China
On 16 December 2015, AstraZeneca announced a range of strategic initiatives to accelerate the delivery of innovative biologics and targeted medicines to patients in China. The initiatives and investments include a strategic alliance with WuXi AppTec, a leading Chinese biologics manufacturer and contract research organisation, to produce innovative biologics locally in China. Under the agreement, AstraZeneca has the option to acquire WuXi AppTec’s biologics manufacturing capacity in Wuxi City in the next few years through an overall investment approximating $100m. Prior to that, WuXi AppTec remains the Company’s exclusive partner for R&D manufacturing for innovative biologics in China.

Research and Development Update

A comprehensive table with AstraZeneca's pipeline of medicines in human trials can be found later in this document.

Since the prior results announcement on 5 November 2015:

Regulatory Approvals	3	- Zurampic (US) - Tagrisso (US, EU)
Regulatory Submission Acceptances	3	- brodalumab (US, EU) - ZS-9 (EU)
Other Key Developments	3	- CHMP positive recommendations (EU): Zurampic, Brilique, Tagrisso
New Molecular Entities (NMEs) in Pivotal Trials or under Regulatory Review*	15	RIA - PT003* - COPD - brodalumab* - benralizumab - tralokinumab - severe asthma - PT010 - COPD - anifrolumab - lupus (SLE) CVMD - roxadustat - ZS-9* Oncology - cediranib* - tremelimumab - durvalumab - multiple cancers - acalabrutinib - moxetumomab pasudotox - leukaemia - selumetinib ING - CAZ AVI*
Projects in clinical pipeline	125	

Key: RIA - Respiratory, Inflammation & Autoimmunity, CVMD - Cardiovascular & Metabolic Disease, ING - Infection, Neuroscience & Gastrointestinal

1. Respiratory, Inflammation & Autoimmunity (RIA)

Steady progress continues to be made in the RIA pipeline, which now includes six programmes in pivotal trials or under registration. AstraZeneca's Respiratory portfolio includes a range of differentiated potential medicines such as novel combinations, biologics and devices for the treatment of asthma and COPD. The pipeline also includes a number of assets in inflammatory and autoimmune diseases within areas such as psoriasis, systemic lupus and rheumatoid arthritis.

a) Symbicort (asthma)

Symbicort comprises budesonide (a corticosteroid, ICS) and formoterol (a long-acting beta agonist, LABA). The FDA required all manufacturers of medicines indicated for the treatment of asthma, containing LABA-based medicines, to conduct identical trials evaluating the safety when used in combination with an inhaled corticosteroid compared to the ICS alone.

The Symbicort LABA safety trial met its primary endpoint in the period, based on top-line results, demonstrating that the risk of serious asthma-related events for Symbicort is no different to that of budesonide alone. The trial was a randomised, double-blind, 26-week, active-controlled trial in 11,700 patients, aged at least 12 years of age and suffering from asthma.

b) Zurampic (gout)
On 22 December 2015, AstraZeneca announced that the FDA had approved Zurampic (lesinurad) 200mg tablets in combination with a xanthine oxidase inhibitor (XOI) for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric-acid levels with an XOI alone. The approval was based on data from three pivotal Phase III trials, CLEAR1, CLEAR2 and CRYSTAL. These represent the largest clinical trial data set of gout patients (n=1,537) treated with combination urate-lowering therapy.

On 18 December 2015, AstraZeneca announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the marketing authorisation of Zurampic 200mg tablets. Zurampic is recommended for the adjunctive treatment of hyperuricaemia in adult gout. Zurampic will now be reviewed by the European Commission (EC). AstraZeneca anticipates a final decision in the first half of 2016.

c) Brodalumab (psoriasis)
During the period, regulatory submissions for brodalumab for the treatment of moderate-to-severe psoriasis were accepted in the US and EU. The submissions were supported by data from the three AMAGINE Phase III pivotal trials. The results indicated that brodalumab has an effective mechanism of action that delivers clinical benefit and could help a significant number of moderate-to-severe plaque psoriasis patients achieve total clearance of skin disease.

Under a collaboration agreement, Valeant Pharmaceuticals International Inc. (Valeant) has an exclusive license to develop and commercialise brodalumab globally, except in Japan and certain other Asian countries. Valeant assumes decisions on future development and development costs associated with the regulatory approval of brodalumab, as well as decisions on future development.

d) Tralokinumab (IPF)
A Phase II trial for tralokinumab in idiopathic pulmonary fibrosis (IPF), a potential exploratory indication for the medicine, was terminated in the period due to lack of efficacy on endpoints of IPF progression. No safety issues were detected. The Phase III programme for severe asthma, the lead indication for tralokinumab, is ongoing, with top-line results expected in 2017. Tralokinumab is anticipated to become AstraZeneca's second biologic medicine in Respiratory diseases after benralizumab.

e) Anifrolumab (lupus)
Positive new data on anifrolumab in systemic lupus erythematosus (SLE) were presented at the American College of Rheumatology's annual scientific meeting in San Francisco. The trial met primary and secondary endpoints in Phase II, with anifrolumab significantly reducing lupus disease activity compared with placebo across multiple endpoints.

In line with the Company's dedication to personalised medicines, anifrolumab is being developed with an interferon-gene signature test designed to identify patients who may be more likely to benefit from treatment. The anifrolumab Phase III programme in SLE was initiated in July 2015 and is expected to read out with top-line results in 2018. Additional ongoing trials include a Phase II lupus nephritis trial and a Phase I trial with a subcutaneous route of administration.

2. Cardiovascular & Metabolic Disease (CVMD)

AstraZeneca's strategy in CVMD focuses on ways to reduce morbidity, mortality and organ damage by addressing multiple risk factors across CV disease, Diabetes and CKD indications. The patient-centric approach is reinforced by science-led life-cycle management programmes and technologies, including early research into regenerative methods.

a) Brilinta/Brilique (CV disease)
On 18 December 2015, AstraZeneca announced that the CHMP adopted a positive opinion, recommending approval of the 60mg dose of Brilique for the treatment of patients with a history of heart attack and at high risk of having a further coronary event. The opinion stated that treatment may be started as continuation therapy after an initial one-year treatment with dual anti-platelet therapy. The 90mg dose of Brilique is currently indicated in the EU to reduce the rate of cardiovascular death, myocardial infarction (MI, also known as heart attack) and stroke in patients with acute coronary syndrome.

b) Saxagliptin/dapagliflozin (type-2 diabetes)
AstraZeneca has continued to work closely with the FDA following the receipt of a Complete Response Letter in October 2015. The Company plans to submit additional clinical data for saxagliptin/dapagliflozin from a trial that is now completed and anticipates a new regulatory submission in the first half of 2016.

c) ZS-9 (hyperkalaemia)
The acquisition of ZS Pharma was completed on 17 December 2015 and ZS-9 (sodium zirconium cyclosilicate), a potential best-in-class treatment for hyperkaelemia, was accepted in the period by CHMP for regulatory review, in line with the Company’s expectations.

3. Oncology

AstraZeneca has a deep-rooted heritage in Oncology with a rejuvenating portfolio of medicines that has the potential to transform patients’ lives and the Company’s future. With at least six new medicines molecular entities to be launched between 2014 and 2020 and a broad pipeline of small molecules and biologics in development, the Company is committed to advance Oncology as one of AstraZeneca’s six Growth Platforms, focusing on lung, ovarian, breast and blood cancers. By exploiting the power of four scientific platforms -- immuno-oncology (IO), the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates -- and by championing the development of personalised medicines combinations, AstraZeneca has the vision to redefine cancer treatment and, one day, eliminate cancer as a cause of death.

a) Faslodex (breast cancer)
On 29 January 2016, the Company received notification that the FDA had accepted for regulatory submission a supplemental new drug application (sNDA) for Faslodex. The aim of the sNDA is to supplement the currently-approved indication for Faslodex to encompass the positive results of the Phase III PALOMA-3 trial. This trial tested adding Ibrance (palbociclib) to Faslodex versus Faslodex alone in women with HR-positive, HER2-negative metastatic breast cancer. The trial was conducted by Pfizer Inc., in collaboration with AstraZeneca.

b) Lynparza (ovarian and other cancers)
In January 2016 Breakthrough Therapy designation was granted by the FDA for Lynparza for prostate cancer patients with BRCA1/2 or ATM gene-mutated metastatic castrate-resistant prostate cancer (mCRPC) who have received previous taxane-based chemotherapy and one newer hormonal agent (abiraterone or enzalutamide). Accompanying this designation, Lynparza received a positive Phase III investment decision in the period from the Company for development in mCRPC.

These developments highlighted Lynparza's significant future potential, in addition to the approved use in treating patients with a particular form of ovarian cancer.

c) Tagrisso (lung cancer)
On 13 November 2015, Tagrisso was approved by the FDA for patients with epidermal growth factor receptor (EGFR) T790M mutation-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on an EGFR tyrosine kinase inhibitor (TKI). This followed one of the fastest medicine-development programmes in history, from the start of clinical trials to approval in two years and eight months. Tagrisso provides an important new option for patients, with an objective response rate of 59% and a median duration of response of over one year.

On 3 February 2016, Tagrisso received conditional approval in the EU for the treatment of adult patients with locally-advanced or metastatic EGFR T790M mutation-positive NSCLC. Tagrisso is the first T790M-directed inhibitor to receive marketing authorisation by the EU. Tagrisso's indication includes patients with T790M NSCLC regardless of previous treatment with an EGFR TKI, underlining the unmet medical need in the small number of EGFR-mutated NSCLC patients who are initially (de novo) diagnosed with the T790M mutation. The approval follows the positive opinion received on 18 December 2015.

Interactions with regulatory authorities in the rest of the world, including the accelerated review process in Japan, are ongoing.

The ADAURA Phase III trial in adjuvant EGFRm NSCLC began enrollment in the quarter and will measure disease-free survival.

d) Durvalumab (multiple cancers)
Monotherapy
As announced on 18 December 2015, the preliminary findings of the ATLANTIC trial supported the clinical activity of durvalumab. In the trial of 3rd-line or later-stage NSCLC patients, durvalumab demonstrated expected clinical activity and durable response in heavily pre-treated patients. The treatment and regulatory landscape in lung cancer is evolving however, and the Company does not anticipate any regulatory submission as a monotherapy for 3rd-line PD-L1-positive NSCLC patients. Durvalumab is a cornerstone of the IO portfolio, with a fast-advancing development programme focused primarily on novel combinations.

Combination therapy
New data from the Phase Ib durvalumab + tremelimumab (durva + treme) combination trial in NSCLC were presented at the Society for Immunotherapy of Cancer meeting in November 2015. The trial investigators presented updated safety and efficacy results for 102 patients. In 84 of the patients evaluable for efficacy, results showed an overall response rate of 25% (21/84, 95% CI of 16-36%), consistent with data presented at the American Society of Clinical Oncology's meeting in 2015. Response rates did not appear dependent on PD-L1 status: 35% (PD-L1-positive), 22% (PD-L1-negative, <25% tumour-cell staining) and 33% (PD-L1-negative, 0% tumour-cell staining). Higher response rates were observed in those patients who had only received one prior treatment: 47% (15/32, 95% CI of 29-65%).

The CAURAL trial, combining Tagrisso and durvalumab, remains on clinical hold, based on an increase in the incidence of interstitial lung disease, compared to what has been previously reported with each medicine used on its own. Investigation of the safety signal is ongoing.

During the period, first patients were dosed in a number of durva + treme combination trials, including NEPTUNE, EAGLE, KESTREL, DANUBE and ALPS as well as in the safety lead-in of the triple combination trial in NSCLC with chemotherapy. AstraZeneca is planning a Phase III trial with durvalumab in small cell lung cancer that will include the first IO-IO-chemotherapy triple-combination arm. A second, earlier-stage trial will also pair durvalumab with other portfolio medicines such as Lynparza and AZD1775 (WEE-1).

The MYSTIC trial saw its primary endpoint updated to a co-primary endpoint of progression-free survival (PFS) and overall survival. The trial is recruiting ahead of expectations and is expected to be the first IO-IO combination 1st-line NSCLC trial to provide PFS data, in the first half of 2017.

An update on ongoing trials with durvalumab is provided over the page:

LUNG CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Early disease						
Monotherapy						
ADJUVANT1	III	N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	FPD Q1 2015 Data expected 2020	Recruiting
PACIFIC	III	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPD Q2 2014 Data expected 2017	Recruiting; >50% of patients now randomised
Advanced/metastatic disease						
Combination therapy						
ARCTIC	III	3rd line	PD-L1 neg. NSCLC	durvalumab vs tremelimumab vs durva + treme vs SoC	FPD Q2 2015 Data expected H1 2017	Recruiting
MYSTIC	III	1st line	NSCLC	durvalumab vs durva + treme vs SoC	FPD Q3 2015 Data expected H1 2017	Recruiting
NEPTUNE	III	1st line	NSCLC	durva + treme vs SoC	FPD Q4 2015 Data expected 2018	First patient now dosed
-	III	1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab	-	First patient now dosed in safety lead-in
-	III	1st line	SCLC	durva + treme + chemotherapy vs SoC	-	Awaiting first patient dosed

1Conducted by the National Cancer Institute of Canada

METASTATIC OR RECURRENT HEAD AND NECK CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Monotherapy						
HAWK	II	2nd line	PD-L1 pos. SCCHN	durvalumab (single arm)	FPD Q1 2015 Data expected H2 2016	Recruiting Indication granted FDA Fast Track

						designation
Combination therapy						
CONDOR	II	2nd line	PD-L1 neg. SCCHN	durvalumab vs tremelimumab vs durva + treme	FPD Q2 2015 Data expected 2017	Recruiting
EAGLE	III	2nd line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	First patient now dosed
KESTREL	III	1st line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015 Data expected 2018	First patient now dosed

OTHER METASTATIC CANCERS

Name	Phase	Line of treatment	Population	Design	Timelines	Status
DANUBE	III	1st line	Cisplatin chemo-therapy eligible/ ineligible bladder cancer	durvalumab vs durva + treme -vs SoC	FPD Q4 2015 Data expected 2018	First patient now dosed
ALPS	II	2nd line	Metastatic pancreatic cancer	durva + treme (single arm)	FPD Q4 2015 Data expected 2017	First patient now dosed
-	II	2nd/3rd line	Metastatic gastric cancer	durvalumab vs tremelimumab vs durva + treme	-	In preparation
-	II	2nd line	Unresectable liver cancer	durvalumab vs tremelimumab vs durva + treme	-	In preparation

FPD=First Patient Dosed, LPD=Last Patient Dosed, SoC=Standard of Care, SCCHN = Squamous Cell Carcinoma of the Head and Neck

e) Early-stage Oncology

New Oncology programmes that progressed into human trials during the period included MEDI9197, a TLR 7/8 agonist, in solid tumours and a GITR fusion protein, MEDI1873. Furthermore, two small-molecule programmes developed in collaboration with BIND Therapeutics moved into clinical trials: AZD0156, a first-in-class ATM kinase inhibitor which further strengthens the Company's leading position in DNA damage response and AZD2811, a nanoparticle formulation of a novel, selective inhibitor of Aurora B kinase that has been shown to be active in both solid and haematological tumours.

Additionally the Company now has a HER2-targeted, bi-specific antibody drug conjugate, MEDI4276, in a Phase I trial in solid tumours. HER2 (receptor tyrosine-protein kinase) is over-expressed in several cancers, including breast and gastric cancers. AZD3759, an EGFR inhibitor designed to cross the blood brain barrier, progressed into Phase II

expansion cohorts in leptomeningeal disease, a form of brain cancer, and in patients with brain metastases.

ASTRAZENECA DEVELOPMENT PIPELINE 31 DECEMBER 2015
Includes AstraZeneca-sponsored or directed studies only
Phase III / Pivotal Phase II / Registration

NMEs and significant additional indications

Regulatory submission dates shown for assets in Phase III and beyond. As disclosure of compound information is balanced by the business need to maintain confidentiality, information in relation to some compounds listed here has not been disclosed at this time.

† US and EU dates correspond to anticipated acceptance of the regulatory submission.
# Partnered and/or in collaboration.

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission / Submission Acceptance†			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
anifrolumab# TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019	
benralizumab# CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe asthma	Q4 2013	H2 2016	H2 2016	N/A	N/A
benralizumab# TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	2018	2018	N/A	N/A
brodalumab# AMAGINE-1,2,3	IL-17R mAb	psoriasis	Q3 2012	Accepted1	Accepted	N/A	N/A
Zurampic (lesinurad) CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	Q4 2011	Approved	Accepted2		
PT003 GFF PINNACLE	LABA/LAMA	COPD	Q2 2013	Accepted	H2 2016	2017	2017
PT010	LABA/LAMA/ ICS	COPD	Q3 2015	2018	2018	2017	2019
tralokinumab STRATOS 1,2 TROPOS MESOS	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018	
Cardiovascular and Metabolic Diseases							
Brilinta/Brilique3	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Accepted	Launched
Epanova#	omega-3 carboxylic acids	severe hypertrigly-ceridemia		Approved		2018	2019

Farxiga/Forxiga4	SGLT2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Accepted
roxadustat#	hypoxia-inducible	anaemia in	Q3 2014	2018	N/A	N/A	H2 20165
OLYMPUS	factor prolyl	CKD/ESRD					
ROCKIES	hydroxylase						
	inhibitor						
ZS-9 (sodium	potassium binder	hyperkalaemia		Accepted	Accepted		
zirconium							
cyclosilicate)							
Oncology							
acalabrutinib#6	Bruton's tyrosine	B-cell blood cancers		H2 2016			
	kinase (BTK)						
	inhibitor						
cediranib	VEGFR tyrosine	PSR ovarian cancer	Q2 2007		Accepted		
ICON 6	kinase inhibitor				(Orphan		
					Drug)		
durvalumab# +	PD-L1 mAb +	metastatic pancreatic	Q4 2015	2017	2017	2017	
tremelimumab	CTLA-4 mAb	ductal carcinoma					
ALPS¶							
durvalumab#	PD-L1 mAb	stage III NSCLC	Q2 2014	2017	2020	2020	
PACIFIC							
durvalumab#	PD-L1 mAb	2nd-line SCCHN	Q1 2015	2017	2019	2019	
HAWK¶		(PD-L1 positive)		(Fast Track)			
durvalumab# +	PD-L1 mAb +	3rd-line NSCLC	Q2 2015	2017	2017	2017	
tremelimumab	CTLA-4 mAb						
ARCTIC							
durvalumab# +	PD-L1 mAb +	2nd-line SCCHN	Q2 2015	2017	2019	2019	
tremelimumab	CTLA-4 mAb	(PD-L1 negative)					
CONDOR¶							
durvalumab# +	PD-L1 mAb +	1st-line bladder	Q4 2015	2018	2018	2018	
tremelimumab	CTLA-4 mAb						
DANUBE							
durvalumab# +	PD-L1 mAb +	2nd-line SCCHN	Q4 2015	2019	2019	2019	
tremelimumab	CTLA-4 mAb						
EAGLE							
durvalumab# +	PD-L1 mAb +	1st-line SCCHN	Q4 2015	2018	2018	2018	
tremelimumab	CTLA-4 mAb						
KESTREL							
durvalumab# +	PD-L1 mAb +	1st-line NSCLC	Q3 2015	2017	2017	2017	
tremelimumab	CTLA-4 mAb						
MYSTIC							
durvalumab# +	PD-L1 mAb +	1st-line NSCLC	Q4 2015	2019	2019	2019	
tremelimumab	CTLA-4 mAb						
NEPTUNE							
moxetumomab	anti-CD22	hairy cell leukaemia	Q2 2013	2017	2018		
pasudotox#	recombinant			(Orphan			
PLAIT	immunotoxin			Drug)			
selumetinib#	MEK inhibitor	differentiated thyroid	Q3 2013	2018	2018		
ASTRA		cancer					
selumetinib#	MEK inhibitor	2nd-line KRASm	Q4 2013	2017	2017		
SELECT-1		NSCLC					

Tagrisso (AZD9291) AURA, AURA 2	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q2 2014	Launched (Breakthrough designation, Priority Review, Orphan Drug)	Approved (Accelerated assessment)	Accepted (Priority Review)	2017
Tagrisso (AZD9291) AURA 3	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q3 2014	2017	2017	2017	
tremelimumab¶ DETERMINE	CTLA-4 mAb	mesothelioma	Q2 2014	H2 2016 (Orphan Drug, Fast Track)	H2 2016	H2 2016	
Infection, Neuroscience and Gastrointestinal							
CAZ AVI#	cephalosporin/ beta lactamase inhibitor	serious infections, complicated intra-abdominal infection, complicated urinary tract infection	Q1 2012	N/A	Accepted		2017
CAZ AVI#	cephalosporin/ beta lactamase inhibitor	hospital-acquired pneumonia/ ventilator-associated pneumonia	Q2 2013	N/A	Accepted		2017
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis		N/A	H1 20168	N/A	N/A
Zinforo#	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections		N/A	Launched	N/A	Submitted

¶ Registrational Phase II/III trial.
1 US regulatory submission accepted Q1 2016.
2 CHMP Positive Opinion received December 2015.
3 Brilinta in the US; Brilique in rest of world.
4 Farxiga in the US; Forxiga in rest of world.
5 Rolling NDA submission to be initiated in H2 2016.
6 Completion of the agreement with Acerta Pharma Q1 2016
7 CHMP Positive Opinion received December 2015. Approval received Q1 2016.
8 MAA submitted December 2015. Regulatory acceptance anticipated H1 2016.

Phases I and II

NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase

Respiratory, Inflammation and Autoimmunity				
abediterol (AZD0548)	LABA	asthma/COPD	II	Q4 2007
anifrolumab#	IFN-alphaR mAb	lupus nephritis	II	Q4 2015
AZD7594	inhaled SGRM	asthma/COPD	II	Q3 2015
AZD7624	inhaled P38 inhibitor	COPD	II	Q4 2014
AZD9412#	inhaled interferon beta	asthma/COPD	II	Q3 2015
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
MEDI-551#	CD19 mAb	neuromyelitis optica1	II	Q1 2015
MEDI2070#	IL-23 mAb	Crohn's disease	II	Q1 2013
abrilumab#	alpha(4)beta(7) mAb	Crohn's disease / ulcerative colitis	II	Q4 2012
MEDI9929#	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
RDEA3170	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	II	Q3 2013
tralokinumab	IL-13 mAb	atopic dermatitis	II	Q1 2015
anifrolumab#	IFN-alphaR mAb	systemic lupus erythematosus (subcutaneous)	I	Q4 2015
lesinurad+allopurinol	selective uric acid reabsorption inhibitor (URAT-1)+xanthine oxidase inhibitor	chronic treatment of hyperuricemia in patients with gout	I	Q4 2015
AZD1419#	TLR9 agonist	Asthma	I	Q3 2013
AZD7986	DPP1	COPD	I	Q4 2014
AZD8871	MABA	COPD	I	Q4 2015
AZD8999	MABA	COPD	I	Q4 2013
AZD9567	oral SGRM	rheumatoid arthritis	I	Q4 2015
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI5872#	B7RP1 mAb	systemic lupus erythematosus	I	Q4 2008
MEDI7836	IL-13 mAb-YTE	Asthma	I	Q1 2015
Cardiovascular and Metabolic Diseases				
AZD4076	anti-miR103/107 oligonucleotide	non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	I	Q4 2015
MEDI6012	LCAT	ACS	II	Q4 2015
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	I	Q1 2015
MEDI4166	PCSK9/GLP-1 mAb + peptide fusion	diabetes / cardiovascular	I	Q4 2015
MEDI8111	Rh-factor II	trauma / bleeding	I	Q1 2014
Oncology				

AZD1775#	WEE-1 inhibitor	ovarian cancer	II	Q4 2012
AZD2014	mTOR serine/ threonine kinase inhibitor	solid tumours	II	Q1 2013
AZD3759 BLOOM	EGFR tyrosine kinase inhibitor	brain metastases in advanced EGFRm NSCLC	II	Q4 2015
Tagrisso (AZD9291) BLOOM	EGFR tyrosine kinase inhibitor			
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011
AZD5069+durvalumab#	CXCR2 + PD-L1 mAb	SCCHN	II	Q3 2015
AZD9150#+durvalumab#	STAT3 inhibitor + PD-L1 mAb			
AZD5363#	AKT kinase inhibitor	breast cancer	II	Q1 2014
durvalumab#	PD-L1 mAb	solid tumours	II	Q3 2014
durvalumab# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
MEDI-551#	CD19 mAb	diffuse B-cell lymphoma	II	Q1 2012
MEDI-573#	IGF mAb	metastatic breast cancer	II	Q2 2012
savolitinib/ volitinib#	MET tyrosine kinase inhibitor	papillary renal cell carcinoma	II	Q2 2014
selumetinib#	MEK inhibitor	2nd-line KRAS wt NSCLC	II	Q1 2013
AZD0156	ATM serine/threonine kinase inhibitor	solid tumours	I	Q4 2015
AZD2811	Aurora B kinase inhibitor	solid tumours	I	Q4 2015
AZD5312#	androgen receptor inhibitor	solid tumours	I	Q2 2014
AZD6738	ATR serine/threonine kinase inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3 kinase beta inhibitor	solid tumours	I	Q2 2013
AZD8835	PI3 kinase alpha inhibitor	solid tumours	I	Q4 2014
AZD9150#	STAT3 inhibitor	haematological malignancies	I	Q1 2012
Tagrisso (AZD9291) + (durvalumab# or selumetinib# or savolitinib#) TATTON	EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or MET tyrosine kinase inhibitor)	advanced EGFRm NSCLC	I	Q3 2014
AZD9496	selective oestrogen receptor downregulator	ER+ breast cancer	I	Q4 2014

	(SERD)			
durvalumab#	PD-L1 mAb	solid tumours	I	Q3 2014
durvalumab# + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	I	Q2 2014
durvalumab# + MEDI6383#	OX40 agonist + PD-L1 mAb	solid tumours	I	Q2 2015
durvalumab# + dabrafenib + trametinib2	PD-L1 mAb+ BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
durvalumab# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	I	Q4 2013
Iressa + durvalumab#	PD-L1 mAb+ EGFR tyrosine kinase inhibitor	NSCLC	I	Q2 2014
MEDI0562#	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI-551# + rituximab	CD19 mAb + CD20 mAb	haematological malignancies	I	Q2 2014
MEDI-565#	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0639#	DLL-4 mAb	solid tumours	I	Q2 2012
MEDI0680	PD-1 mAb	solid tumours	I	Q4 2013
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3617#	ANG-2 mAb	solid tumours	I	Q4 2010
MEDI4276	HER2 bispecific ADC mAb	solid tumours	I	Q4 2015
MEDI6383#	OX40 agonist	solid tumours	I	Q3 2014
MEDI9197#	TLR 7/8 agonist	solid tumours	I	Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
Infection, Neuroscience and Gastrointestinal				
AZD3241	myeloperoxidase inhibitor	multiple system atrophy	II	Q2 2015 (Orphan Drug)
AZD3293#	beta-secretase inhibitor	Alzheimer’s disease	II	Q4 2014
CXL#	beta lactamase inhibitor / cephalosporin	methicillin-resistant S. aureus	II	Q4 2010
MEDI7510	RSV sF+GLA-SE	prevention of RSV disease in older adults	II	Q3 2015
MEDI8852	influenza A mAb	influenza A treatment	II	Q4 2015
MEDI8897#	RSV mAb-YTE	passive RSV prophylaxis	II	Q1 2015 (FDA Fast Track)
MEDI4893	mAb binding to S. aureus toxin	hospital-acquired pneumonia / serious S. aureus infection	II	Q4 2014 (FDA Fast Track)
ATM AVI#	monobactam/ beta lactamase inhibitor	targeted serious bacterial infections	I	Q4 2012
AZD8108	NMDA antagonist	suicidal ideation	I	Q4 2014
MEDI1814	amyloid beta mAb	Alzheimer’s disease	I	Q2 2014
MEDI3902	anti-Psl/PcrV	prevention of nosocomial	I	Q3 2014 (FDA Fast Track)

		pseudomonas pneumonia					

1 Neuromyelitis optica: Now lead indication. Multiple sclerosis trial completed in 2015.
2 MedImmune-sponsored trial in collaboration with Novartis AG.

Significant Life-Cycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced Phase	Estimated Regulatory Submission Acceptance†			
				US	EU	Japan	China
Respiratory, Inflammation and Autoimmunity							
Duaklir Genuair#	LAMA/LABA	COPD		2018	Launched	2018	2018
Symbicort SYGMA	ICS/LABA	as-needed use in mild asthma	Q4 2014	N/A	2018		2019
Symbicort	ICS/LABA	breath actuated Inhaler asthma/COPD		2018			
Cardiovascular and Metabolic Diseases							
Brilinta/Brilique1 EUCLID	P2Y12 receptor antagonist	outcomes trial in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
Brilinta/Brilique1 HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q4 2014	2020	2020		
Brilinta/Brilique1 PEGASUS-TIMI 54	P2Y12 receptor antagonist	outcomes trial in patients with prior myocardial infarction	Q4 2010	Launched (Priority Review)	Accepted2	Accepted	H2 2016
Brilinta/Brilique1 SOCRATES	P2Y12 receptor antagonist	outcomes trial in patients with stroke or TIA	Q1 2014	H1 2016	H1 2016	H2 2016	2017
Brilinta/Brilique1 THEMIS	P2Y12 receptor antagonist	outcomes trial in patients with type-2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2018	2018	2018	2019
Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	2018	2018	2018	
Bydureon weekly suspension	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	2017	2017		
Epanova STRENGTH	omega-3 carboxylic acids	outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low	Q4 2014	2020	2020	2020	2020

Epanova/ Farxiga/Forxiga3	omega-3 carboxylic acids/ SGLT2 inhibitor	HDL-cholesterol non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	Q1 2015				
Farxiga/Forxiga3 DECLARE-TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes trial	Q2 2013	2020	2020		
Farxiga/Forxiga3	SGLT2 inhibitor	type-1 diabetes	Q4 2014	2018	2017	2018	
Kombiglyze XR/Komboglyze4	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Submitted
Onglyza SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes trial	Q2 2010	Accepted	Launched		H2 20165
saxagliptin/ dapagliflozin FDC	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes	Q2 2012	Accepted6	Accepted		
Xigduo XR/ Xigduo7	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
Oncology							
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer	Q4 2012	H2 2016	H2 2016	H2 2016	2020
Lynparza (olaparib) SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2017	2017	2017	
Lynparza (olaparib) SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	H2 2016	2017	2017	
Lynparza (olaparib) SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
Lynparza (olaparib) GOLD	PARP inhibitor	2nd-line gastric cancer	Q3 2013			2017	
Lynparza (olaparib) OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
Lynparza (olaparib) OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	H2 2016	2017	2017	
Lynparza (olaparib) POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2018	2018	2018	
Lynparza (olaparib)	PARP inhibitor	prostate cancer	Q3 2014	(Breakthrough Therapy Designation)8			
Tagrisso (AZD9291)			Q4 2015	2022	2022		

ADAURA	EGFR tyrosine kinase inhibitor	adjuvant EGFRm NSCLC					
Tagrisso (AZD9291) FLAURA	EGFR tyrosine kinase inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	2017	2017	2017	2020
Tagrisso (AZD9291) +dur-valumab# CAURAL9	EGFR tyrosine kinase inhibitor + PD-L1 mAb	≥2nd-line advanced EGFRm T790M NSCLC	Q3 2015				
Infection, Neuroscience and Gastrointestinal							
Diprivan#	sedative and anaesthetic	conscious sedation		N/A	Launched	Accepted	Launched
linaclotide#	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)		N/A	N/A	N/A	Accepted10
Nexium	proton pump inhibitor	stress ulcer prophylaxis					H2 2016
Nexium	proton pump inhibitor	paediatrics		Launched	Launched	H2 2016	Accepted

1 Brilinta in the US; Brilique in rest of world.
2 CHMP Positive Opinion received December 2015.
3 Farxiga in the US; Forxiga in rest of world.
4 Kombiglyze XR in the US; Komboglyze in the EU.
5 Timing of China submission dependent on US regulatory approval.
6 Complete Response Letter received October 2015.
7 Xigduo XR in the US; Xigduo in the EU.
8 Breakthrough Therapy designation granted for prostate cancer patients with BRCA1/2 or ATM gene mutated mCRPC who have received previous taxane-based chemotherapy and one newer hormonal agent (abiraterone or enzalutamide).
9 Temporarily closed to enrolment.
10 Submission accepted January 2016.

Terminations (discontinued projects between 1 October and 31 December 2015)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD5847	Safety / efficacy	tuberculosis
NME	AZD9977	Safety / efficacy	diabetic kidney disease
NME	durvalumab#	Strategic	

	ATLANTIC		3rd-line NSCLC (PD-L1 positive)
LCM	durvalumab# after Tagrisso (AZD9291) or Iressa or selumetinib# +docetaxel or tremelimumab	Strategic	NSCLC
LCM	tralokinumab	Safety / efficacy	idiopathic pulmonary fibrosis

Completed Projects / Divestitures

Compound	Mechanism	Area Under Investigation	Completed/ Divested	Estimated Regulatory Submission Acceptance†			
				US	EU	Japan	China
AZD49011	NK3 receptor antagonist	polycystic ovarian syndrome	Divested in Phase II				

1 Divested to Millendo Therapeutics, Inc. Agreement announced January 2016.

Condensed Consolidated Statement of Comprehensive Income

	2015	Restated 2014*
For the year ended 31 December	$m	$m
Product sales	23,641	26,095
Externalisation revenue	1,067	452
Total revenue	24,708	26,547
Cost of sales	(4,646)	(5,842)
Gross profit	20,062	20,705
Distribution costs	(339)	(324)
Research and development expense	(5,997)	(5,579)
Selling, general and administrative costs	(11,112)	(13,000)
Other operating income and expense	1,500	335
Operating profit	4,114	2,137
Finance income	46	78
Finance expense	(1,075)	(963)
Share of after tax losses in joint ventures	(16)	(6)
Profit before tax	3,069	1,246
Taxation	(243)	(11)
Profit for the period	2,826	1,235
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	652	(766)
Tax on items that will not be reclassified to profit or loss	(199)	216
	453	(550)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(528)	(823)
	(333)	(529)

Foreign exchange arising on designating borrowings in net investment hedges		
Fair value movements on derivatives designated in net investment hedges	14	100
Amortisation of loss on cash flow hedge	1	1
Net available for sale (losses)/gains taken to equity	(32)	245
Tax on items that may be reclassified subsequently to profit or loss	87	50
	(791)	(956)
Other comprehensive income for the period, net of tax	(338)	(1,506)
Total comprehensive income for the period	2,488	(271)
Profit attributable to:		
Owners of the Parent	2,825	1,233
Non-controlling interests	1	2
	2,826	1,235
Total comprehensive income attributable to:		
Owners of the Parent	2,488	(266)
Non-controlling interests	-	(5)
	2,488	(271)
Basic earnings per $0.25 Ordinary Share	$2.23	$0.98
Diluted earnings per $0.25 Ordinary Share	$2.23	$0.98
Weighted average number of Ordinary Shares in issue (millions)	1,264	1,262
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,264

* 2014 comparatives restated for reclassification of Externalisation revenue (see Note 1)

Condensed Consolidated Statement of Comprehensive Income

	2015	Restated 2014*
For the quarter ended 31 December	$m	$m
Product sales	6,207	6,683
Externalisation revenue	192	33
Total revenue	6,399	6,716
Cost of sales	(1,269)	(1,667)
Gross profit	5,130	5,049
Distribution costs	(99)	(88)
Research and development expense	(1,746)	(1,499)
Selling, general and administrative costs	(2,668)	(4,084)
Other operating income and expense	471	273
Operating profit	1,088	(349)
Finance income	13	33
Finance expense	(292)	(260)
Share of after tax losses of joint ventures	(7)	(4)
Profit before tax	802	(580)
Taxation	6	259
Profit for the period	808	(321)

Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	618	(268)
Tax on items that will not be reclassified to profit or loss	(187)	89
	431	(179)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(169)	(411)
Foreign exchange arising on designating borrowings in net investment hedges	(11)	(237)
Fair value movements on derivatives designated in net investment hedges	(10)	64
Net available for sale gains taken to equity	31	172
Tax on items that may be reclassified subsequently to profit or loss	3	20
	(156)	(392)
Other comprehensive income for the period, net of tax	275	(571)
Total comprehensive income for the period	1,083	(892)
Profit attributable to:		
Owners of the Parent	808	(321)
Non-controlling interests	-	-
	808	(321)
Total comprehensive income attributable to:		
Owners of the Parent	1,083	(892)
Non-controlling interests	-	-
	1,083	(892)
Basic earnings/(loss) per $0.25 Ordinary Share	$0.63	($0.25)
Diluted earnings/(loss) per $0.25 Ordinary Share	$0.63	($0.25)
Weighted average number of Ordinary Shares in issue (millions)	1,264	1,263
Diluted weighted average number of Ordinary Shares in issue (millions)	1,265	1,265

* 2014 comparatives restated for reclassification of Externalisation revenue (see Note 1)

Condensed Consolidated Statement of Financial Position

	At 31 Dec 2015 $m	At 31 Dec 2014 $m
ASSETS		
Non-current assets		
Property, plant and equipment	6,413	6,010
Goodwill	11,868	11,550
Intangible assets	22,646	20,981
Derivative financial instruments	446	465
Investments in joint ventures	85	59
Other investments	458	502

Other receivables	907	1,112
Deferred tax assets	1,294	1,219
	44,117	41,898
Current assets		
Inventories	2,143	1,960
Trade and other receivables	6,622	7,232
Other investments	613	795
Derivative financial instruments	2	21
Income tax receivable	387	329
Cash and cash equivalents	6,240	6,360
	16,007	16,697
Total assets	60,124	58,595
LIABILITIES		
Current liabilities		
Interest-bearing loans and borrowings	(916)	(2,446)
Trade and other payables	(11,663)	(11,886)
Derivative financial instruments	(9)	(21)
Provisions	(798)	(623)
Income tax payable	(1,483)	(2,354)
	(14,869)	(17,330)
Non-current liabilities		
Interest-bearing loans and borrowings	(14,137)	(8,397)
Derivative financial instruments	(1)	-
Deferred tax liabilities	(2,733)	(1,796)
Retirement benefit obligations	(1,974)	(2,951)
Provisions	(444)	(484)
Other payables	(7,457)	(7,991)
	(26,746)	(21,619)
Total liabilities	(41,615)	(38,949)
Net assets	18,509	19,646
EQUITY		
Capital and reserves attributable to equity holders of the Company		
Share capital	316	316
Share premium account	4,304	4,261
Other reserves	2,036	2,021
Retained earnings	11,834	13,029
	18,490	19,627
Non-controlling interests	19	19
Total equity	18,509	19,646

Condensed Consolidated Statement of Cash Flows

	2015	2014
For the year ended 31 December	$m	$m
Cash flows from operating activities		
Profit before tax	3,069	1,246
Finance income and expense	1,029	885
Share of after tax losses in joint ventures	16	6
Depreciation, amortisation and impairment	2,852	3,282
(Increase)/decrease in working capital and short-term provisions	(49)	2,508

Gains on disposal of intangible assets	(961)	-
Non-cash and other movements	(782)	865
Cash generated from operations	5,174	8,792
Interest paid	(496)	(533)
Tax paid	(1,354)	(1,201)
Net cash inflow from operating activities	3,324	7,058
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	283	34
Purchase of property, plant and equipment	(1,328)	(1,012)
Disposal of property, plant and equipment	47	158
Purchase of intangible assets	(1,460)	(1,740)
Disposal of intangible assets	1,130	-
Purchase of non-current asset investments	(57)	(130)
Disposal of non-current asset investments	93	59
Payments to joint ventures	(45)	(70)
Upfront payments on business acquisitions	(2,446)	(3,804)
Payment of contingent consideration on business acquisitions	(579)	(657)
Interest received	123	140
Payments made by subsidiaries to non-controlling interests	-	(10)
Net cash outflow from investing activities	(4,239)	(7,032)
Net cash (outflow)/inflow before financing activities	(915)	26
Cash flows from financing activities		
Proceeds from issue of share capital	43	279
Issue of loans	5,928	919
Repayment of loans	(884)	(750)
Dividends paid	(3,486)	(3,521)
Hedge contracts relating to dividend payments	(51)	(14)
Repayment of obligations under finance leases	(42)	(36)
Payments to acquire non-controlling interest	-	(102)
Movement in short-term borrowings	(630)	520
Net cash inflow/(outflow) from financing activities	878	(2,705)
Net decrease in cash and cash equivalents in the period	(37)	(2,679)
Cash and cash equivalents at the beginning of the period	6,164	8,995
Exchange rate effects	(76)	(152)
Cash and cash equivalents at the end of the period	6,051	6,164
Cash and cash equivalents consists of:		
Cash and cash equivalents	6,240	6,360
Overdrafts	(189)	(196)
	6,051	6,164

Condensed Consolidated Statement of Changes in Equity

	Share capital $m	Share premium account $m	Other reserves* $m	Retained earnings $m	Total $m	Non-controlling interests $m	Total equity $m
At 1 Jan 2014	315	3,983	1,966	16,960	23,224	29	23,253
Profit for the period	-	-	-	1,233	1,233	2	1,235
	-	-	-	(1,499)	(1,499)	(7)	(1,506)

Other comprehensive income							
Transfer to other reserves	-	-	40	(40)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,532)	(3,532)	-	(3,532)
Issue of Ordinary Shares	1	278	-	-	279	-	279
Share-based payments	-	-	-	(93)	(93)	-	(93)
Transfer from non-controlling interests to payables	-	-	-	-	-	(5)	(5)
True-up to Astra AB non-controlling interest buy out	-	-	15	-	15	-	15
Net movement	1	278	55	(3,931)	(3,597)	(10)	(3,607)
At 31 Dec 2014	316	4,261	2,021	13,029	19,627	19	19,646

	Share capital $m	Share premium account $m	Other reserves* $m	Retained earnings $m	Total $m	Non-controlling interests $m	Total equity $m
At 1 Jan 2015	316	4,261	2,021	13,029	19,627	19	19,646
Profit for the period	-	-	-	2,825	2,825	1	2,826
Other comprehensive income	-	-	-	(337)	(337)	(1)	(338)
Transfer to other reserves	-	-	15	(15)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,537)	(3,537)	-	(3,537)
Issue of Ordinary Shares	-	43	-	-	43	-	43
Share-based payments	-	-	-	(131)	(131)	-	(131)
Net movement	-	43	15	(1,195)	(1,137)	-	(1,137)
At 31 Dec 2015	316	4,304	2,036	11,834	18,490	19	18,509

* Other reserves include the capital redemption reserve and the merger reserve.

Notes to the Interim Financial Statements

1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2015 has been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB).

The annual financial statements of the Group are prepared in accordance with IFRSs as adopted by the EU and as issued by the IASB. Except as detailed below, the preliminary announcement has been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2014.

Externalisation revenue

As announced on 6 March 2015, the Group updated its revenue accounting policy with effect from 1 January 2015. The Group's business model includes externalisation as a component of our portfolio management strategy. Externalisation stems from our increased R&D productivity and our focus on three main therapy areas. Historically, reported revenue reflected only product sales, with externalisation revenue forming part of other operating income presented below gross profit. From 1 January 2015 externalisation revenue, alongside product sales, is included in total revenue. Externalisation revenue includes development, commercialisation and collaboration revenue, such as royalties and milestone receipts, together with income from services or repeatable licences. Income is recorded as externalisation revenue when the Group has a significant ongoing interest in the product and/or it is repeatable business and there is no derecognition of an intangible asset. Disposals of assets and businesses, where the Group does not retain an interest, will continue to be recorded in other operating income. The updated financial presentation reflects the Group's entrepreneurial approach and provides a clearer picture of this additional revenue stream. The updated revenue accounting policy results in a presentational change to the Statement of Comprehensive Income only, and has no impact on the Group's net results or net assets. The prior period Condensed Consolidated Statement of Comprehensive Income has been restated accordingly, resulting in $452m of income being reclassified from other operating income to externalisation revenue for the year ended 31 December 2014, and $33m for the quarter ended 31 December 2014.

New accounting standards

The Group has adopted the amendments to IAS 19 Employee Benefits, issued by IASB in November 2013 and effective for periods beginning on or after 1 July 2014. The adoption has not had a significant impact on the Group's profit for the period, net assets or cash flows. There have been no other significant new or revised accounting standards applied in the year ended 31 December 2015.

Legal proceedings

The information contained in Note 7 updates the disclosures concerning legal proceedings and contingent liabilities included in the Group's Annual Report and Form 20-F Information 2014 and Interim Financial Statements for the year ended 31 December 2015.

Going concern

The Group has considerable financial resources available. As at 31 December 2015 the Group has $8.3bn in financial resources (cash balances of $6.2bn and undrawn committed bank facilities of $3.0bn which are available until April 2020, with only $0.9bn of debt due within one year). Although no liability was recognised at 31 December 2015, the Group had entered into an agreement to invest in a majority equity stake in Acerta with an upfront payment of $2.5bn which was paid on 2 February 2016. The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although our revenue is expected to continue to be significantly impacted by the expiry of patents over the medium term. In addition, government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of our mature markets. However, we anticipate new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers

across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

On the basis of the above paragraph and after making enquiries, the Directors have a reasonable expectation that the Company and the Group have adequate resources to continue in operational existence for the foreseeable future. Accordingly, the preliminary announcement has been prepared on a going concern basis.

Financial information

The financial information contained in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2015 and 2014 but is derived from those accounts. Statutory accounts for 2014 have been delivered to the registrar of companies and those for 2015 will be delivered in due course. Those accounts have been reported on by the Group auditor; their report was (i) unqualified, (ii) did not include a reference to any matters to which the auditor drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006. The quarterly information for the three month period to 31 December 2015 and to 31 December 2014 has not been subject to audit.

2 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2015 is stated after charging restructuring costs of $1,034m ($372m for the fourth quarter of 2015). These have been charged to profit as follows:

	FY 2015 $m	FY 2014 $m	Q4 2015 $m	Q4 2014 $m
Cost of sales	158	107	34	35
Research and development expense	258	497	78	97
Selling, general and administrative costs	618	662	260	259
Other operating income and expense	-	292	-	-
Total	1,034	1,558	372	391

3 NET DEBT

The table below provides an analysis of net debt and a reconciliation of net cash flow to the movement in net debt.

	At 1 Jan 2015 $m	Cash Flow $m	Non-cash & Other $m	Exchange Movements $m	At 31 Dec 2015 $m
Loans due after one year	(8,337)	(5,928)	40	116	(14,109)
Finance leases due after one year	(60)	-	31	1	(28)
Total long-term debt	(8,397)	(5,928)	71	117	(14,137)
Current instalments of loans	(912)	884	-	28	-
Current instalments of finance leases	(48)	42	(63)	2	(67)
Total current debt	(960)	926	(63)	30	(67)

Other investments – current	795	(244)	103	(41)	613
Net derivative financial instruments	465	12	(39)	-	438
Cash and cash equivalents	6,360	(39)	-	(81)	6,240
Overdrafts	(196)	2	-	5	(189)
Short-term borrowings	(1,290)	630	-	-	(660)
	6,134	361	64	(117)	6,442
Net debt	(3,223)	(4,641)	72	30	(7,762)

Non-cash movements in the period include fair value adjustments under IAS 39.

4 ACQUISITION OF ZS PHARMA

On 17 December 2015, AstraZeneca completed the acquisition of ZS Pharma, a biopharmaceutical company based in San Mateo, California. ZS Pharma uses its proprietary ion-trap technology to develop novel treatments for hyperkalaemia, a serious condition of elevated potassium in the bloodstream, typically associated with CKD and CHF.

The acquisition gives AstraZeneca access to the potassium-binding compound ZS-9, a potential best-in-class treatment for hyperkalaemia, which is under regulatory review by the US Food and Drug Administration with a Prescription Drug User Fee Act goal date of 26 May 2016. A submission for European Marketing Application Authorisation was made late in 2015.

ZS Pharma represents a strong fit with AstraZeneca's pipeline and portfolio in Cardiovascular and Metabolic Disease, one of the Company's three main therapy areas. AstraZeneca's strategy focuses on reducing morbidity, mortality and organ damage by addressing multiple risk factors across cardiovascular disease, diabetes and chronic kidney disease. ZS-9 complements the Company's increasing focus on CKD and CHF, including the investigational medicine roxadustat, which is currently in Phase III development for patients with anaemia associated with CKD, as well as its leading diabetes portfolio.

Under the terms of the agreement, AstraZeneca has acquired 100% of the share capital of ZS Pharma for $90 per share in an all-cash transaction, or approximately $2.7bn in aggregate transaction value.

ZS Pharma has around 200 employees across three sites in California, Texas and Colorado. The combination of intangible product rights with an established workforce and their associated operating processes, principally those related to research and development and manufacturing, requires that the transaction is accounted for as a business combination in accordance with IFRS 3.

Goodwill is principally attributable to the commercial synergies AstraZeneca expects to be able to realise upon launch of ZS-9, the value of the specialist know-how inherent in the acquired workforce and the accounting for deferred taxes. Goodwill of nil is expected to be deductible for tax purposes.

ZS Pharma's results have been consolidated into the Company's results from 17 December 2015. From the period from acquisition to 31 December 2015, ZS Pharma's revenue and loss were immaterial.

Given the proximity of the completion of the transaction to the date the Financial Statements were approved, the finalisation of the accounting entries for this transaction has yet to be completed. Our provisional assessment of the fair values of the assets and liabilities acquired is detailed below. Our assessment will be completed in 2016.

	Fair value

	$m
Non-current assets	
Intangible assets	3,162
Property, plant and equipment	21
	3,183
Current assets	169
Current liabilities	(50)
Non-current liabilities	
Deferred tax liabilities	(1,045)
Other liabilities	(13)
	(1,058)
Total net assets acquired	2,244
Goodwill	456
Total upfront consideration	2,700
Less: cash and cash equivalents acquired	(73)
Less: deferred upfront consideration	(181)
Net cash outflow	2,446

5 AGREEMENT WITH ACERTA PHARMA

On 2 February 2016, AstraZeneca completed an agreement to invest in a majority equity stake in Acerta Pharma, a privately-owned biopharmaceutical company based in the Netherlands and US. The transaction provides AstraZeneca with a potential best-in-class irreversible oral Bruton's tyrosine kinase (BTK) inhibitor, acalabrutinib (ACP-196), currently in Phase II/III development for B-cell blood cancers and in Phase I/II clinical trials in multiple solid tumours.

Under the terms of the agreement, AstraZeneca has acquired 55% of the issued share capital of Acerta for an upfront payment of $2.5bn. A further payment of $1.5bn will be paid either on receipt of the first regulatory approval for acalabrutinib in the US, or the end of 2018, depending on whichever is sooner. The agreement also includes options which, if exercised, provide the opportunity for Acerta shareholders to sell, and AstraZeneca to buy, the remaining 45% of shares in Acerta. The options can be exercised at various points in time, conditional on the first approval of acalabrutinib in both the US and Europe and when the extent of the commercial opportunity has been fully established, at a price of approximately $3bn net of certain costs and payments incurred by AstraZeneca and net of agreed future adjusting items, using a pre-agreed pricing mechanism. Acerta has approximately 150 employees.

AstraZeneca’s 55% holding is a controlling interest and Acerta’s combination of intangible product rights with an established workforce and their operating processes requires that the transaction is accounted for as a business combination in accordance with IFRS 3. Acerta’s results and net assets will be consolidated into the Company’s results from 2 February 2016.

Given the close proximity of the completion of the transaction to the date the Financial Statements were approved, the accounting entries for this transaction have not yet been determined. Our provisional assessment of the fair values of the assets and liabilities acquired will be completed in 2016.

6 FINANCIAL INSTRUMENTS

As detailed in the Group’s most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the

accounting policies for financial instruments, including fair value measurement, from those disclosed on pages 140 and 141 of the Company's Annual Report and Form 20-F Information 2014. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include $1,071m of other investments, $1,753m of loans, and $438m of derivatives as at 31 December 2015. The total fair value of interest-bearing loans and borrowings at 31 December 2015, which have a carrying value of $15,053m in the Condensed Consolidated Statement of Financial Position, was $16,277m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair value hierarchy and movements in fair value are shown below:

	Diabetes Alliance 2015 $m	Other 2015 $m	Total 2015 $m	Total 2014 $m
At 1 January	5,386	1,513	6,899	514
Additions through business combinations	-	-	-	6,138
Settlements	(325)	(254)	(579)	(657)
Revaluations	(378)	(54)	(432)	512
Discount unwind	409	115	524	391
Foreign exchange	-	(1)	(1)	1
At 31 December	5,092	1,319	6,411	6,899

7 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2014, the Company's Half-Yearly Financial Report for the six-month period to 30 June 2015, and the Third Quarter and Nine-Month Results 2015 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the Disclosures, for the majority of claims in which AstraZeneca is involved it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases but no provision is made.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, we record the loss absorbed or make a provision for our best estimate of the expected loss.

The position could change over time and the estimates that we have made and upon which we have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Disclosures and herein.

AstraZeneca has full confidence in, and will vigorously defend and enforce, its intellectual property.

Matters disclosed in respect of the fourth quarter of 2015 to 4 February 2016.

Patent litigation

Byetta (exenatide)
Patent proceedings in the US
In November 2015, Sanofi-Aventis U.S. LLC and Sanofi-Aventis Deutschland GmbH (together, Sanofi) served AstraZeneca with a complaint for declaratory judgment that Sanofi's proposed lixisenatide product would not infringe three AstraZeneca patents. Sanofi also alleges invalidity of the patents. In December 2015, AstraZeneca filed an answer including counterclaims that Sanofi's proposed lixisenatide product would infringe several AstraZeneca patents. Certain patents-at-issue are listed in the FDA Orange Book with reference to Byetta. Proceedings are in early stages in the US District Court for the District of Delaware. No trial date has been set.

Separately, in December 2015, Sanofi filed petitions in the US Patent Trial and Appeals Board for inter partes review of certain patents that are also at issue in the above-referenced District Court litigation. Proceedings are in early stages.

In December 2015, AstraZeneca commenced patent litigation in response to a Paragraph IV notice from Amneal Pharmaceuticals LLC (Amneal) in the US District Court for the District of Delaware. The Amneal proceedings are at an early stage and no trial date has been set.

Crestor (rosuvastatin)
Patent proceedings in the US
As previously disclosed, AstraZeneca has been defending three patent infringement lawsuits in the US District Court for the District of South Carolina which, among other things, claim that AstraZeneca's Crestor sales induce infringement of the plaintiffs' patents. In December 2015, the court issued an order dismissing the first of these cases, which was filed by Palmetto Pharmaceuticals, LLC (Palmetto), and entered judgment in AstraZeneca's favour. In January 2015, Palmetto filed a notice of appeal.

Patent proceedings outside the US
As previously disclosed, in the UK, in October 2015, Resolution Chemicals Ltd. commenced an action alleging partial invalidity and non-infringement of the supplementary protection certificate related to the Crestor substance patent. AstraZeneca has responded.

As previously disclosed, in Australia, AstraZeneca was unsuccessful in defending the validity of Crestor-related patents, at trial and on appeal. This patent litigation concluded in September 2015 when the High Court of Australia dismissed an appeal filed by AstraZeneca. Relevant parties could pursue damages claims against AstraZeneca. A provision has been taken in respect of generic entities which were prevented by court order from launching their products in Australia before AstraZeneca's patents were subsequently found invalid.

Faslodex (fulvestrant)
Patent proceedings in the US
As previously disclosed, AstraZeneca is engaged in patent litigation against several companies that are seeking to market generic versions of Faslodex prior to the expiry of AstraZeneca's relevant FDA Orange Book listed patents. In November 2015 and February 2016, AstraZeneca filed patent infringement lawsuits against two additional companies that sent Paragraph IV notices relating to Faslodex to AstraZeneca.

Patent proceedings outside the US
As previously disclosed, in Brazil, in February 2013, Eurofarma Laboratorios S.A. (Eurofarma) filed a nullity action against a formulation patent for Faslodex in the 31st Specialized Intellectual Property Federal Court of Rio de Janeiro (the Court). In October 2015, the Court ruled in Eurofarma's favour and invalidated AstraZeneca's patent. In November 2015, AstraZeneca appealed the decision.

As previously disclosed, in Germany, in July 2015, AstraZeneca was served with a nullity complaint by Hexal AG (Hexal), commencing invalidity proceedings before the Federal Patent Court, and requesting revocation of the German part of a Faslodex formulation use patent, European Patent No. 1,250,138. In September 2015, AstraZeneca filed a request for a provisional injunction against Hexal in the Regional Court of Düsseldorf after Hexal threatened to launch a generic Faslodex product in the fourth quarter of 2015. The provisional injunction request was denied and AstraZeneca filed an appeal against this decision in November 2015. In December 2015, AstraZeneca filed an infringement suit against Hexal in the Regional Court of Mannheim referring to their threatened launch of a generic Faslodex product.

In October 2015, Hexal filed a notice of opposition against European Patent No. 2,266,573, a patent granted in June 2015. European Patent No. 2,266,573 is related to European Patent No. 1,250,138 referred to above.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)
Patent proceedings in the US
As previously disclosed, in June 2015, Mylan Pharmaceuticals, Inc. (Mylan) filed a petition for an inter partes review (IPR) with the US Patent and Trademark Office (USPTO) challenging the validity of US Patent No. RE44,186. In December 2015 the USPTO declined to institute the IPR (the December Decision). In January 2016, Mylan filed a Request for Rehearing with the USPTO seeking reconsideration of the December Decision.

Seroquel XR (quetiapine fumarate)
Patent proceedings outside the US
As previously disclosed, in France, in the third quarter of 2015, Mylan SAS (Mylan) launched its generic Seroquel XR product at-risk. In November 2015, AstraZeneca obtained a preliminary injunction against Mylan, which was overturned on appeal in December 2015.

As previously disclosed, Accord Healthcare France SAS and Accord Healthcare Limited (together, Accord) and AstraZeneca were involved in patent litigation in France regarding the French designation of the Seroquel XR formulation patent, European Patent No. 0,907,364. In January 2016, AstraZeneca settled the litigation with Accord.

In Germany, generic entities have claimed, or could claim, damages relating to the preliminary injunction issued in April 2012 that prevented generic Seroquel XR sales by those entities until the injunction was lifted following a November 2012 Federal Patent Court decision that held that the Seroquel XR patent was invalid. A provision has been taken.

Product liability litigation

Byetta/Bydureon (exenatide)
As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the US involving approximately 2,500 claims of physical injury from treatment with Byetta and/or Bydureon. The lawsuits allege multiple types of injuries including pancreatitis, pancreatic cancer, thyroid cancer, and kidney cancer. A multi-district litigation has been established in the US District Court for the Southern District of California (the District Court) in regard to the alleged pancreatic cancer cases in federal courts. Further, a co-ordinated proceeding has been established in Los Angeles, California in regard to the various lawsuits in California state courts.

In November 2015, the District Court granted the defendants' motion for summary judgment and dismissed all claims alleging pancreatic cancer that accrued prior to 11 September 2015. The plaintiffs have appealed that ruling. A similar motion was granted in favour of the defendants in the California state co-ordinated proceeding, and judgment has not yet been entered.

A single case pending in Alabama state court has been set for trial on 21 June 2016. A motion for summary judgment is pending.

Farxiga (dapagliflozin)
AstraZeneca has been named as one of multiple defendants in a lawsuit filed in the US District Court for the Western District of Kentucky involving one plaintiff claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with Farxiga.

Onglyza (saxagliptin)
As previously disclosed, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts in the US involving multiple plaintiffs claiming physical injury from treatment with Onglyza. The lawsuits allege injuries including pancreatic cancer. The lawsuit that was pending, and was previously disclosed, claiming congestive heart failure from treatment with Onglyza has been dismissed.

Commercial litigation

Nexium/Prilosec trademark litigation
As previously disclosed, AstraZeneca filed separate complaints in the US District Court for the District of Delaware against Camber Pharmaceuticals, Inc. (Camber) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's) to enforce certain AstraZeneca trademark rights related to Nexium and Prilosec. Dr. Reddy's has filed its own separate claims against AstraZeneca in both the US District Court for the District of Delaware (the Delaware District Court) as well as the US District Court for the District of New Jersey. The Delaware District Court has issued preliminary injunctions against Camber's and Dr. Reddy's sales of generic esomeprazole magnesium in purple capsules. Dr. Reddy's has appealed the decision of the Delaware District Court to the US Court of Appeals for the Third Circuit, and the appeal is pending. All cases related to this matter have been stayed pending this appeal.

Synagis (palivizumab)
As previously disclosed, in September 2011, MedImmune filed an action against AbbVie, Inc. (AbbVie) (formerly Abbott International, LLC) in the Circuit Court of Montgomery County, Maryland, seeking a declaratory judgment in a contract dispute. AbbVie's motion to dismiss was granted. In September 2011, AbbVie filed a parallel action against MedImmune in Illinois State Court and, as previously disclosed, trial began in August 2015. In September 2015, a jury returned a verdict in favour of AbbVie and awarded AbbVie damages in the amount of approximately $94m. In December 2015, MedImmune and AbbVie reached a settlement of this matter bringing this litigation to a conclusion.

Ocimum Lawsuit
In December 2015, AstraZeneca was served with a complaint filed by Ocimum Biosciences, Ltd. (Ocimum) in the Superior Court for the State of Delaware that alleges, among other things, breaches of contractual obligations and misappropriation of trade secrets, relating to a now terminated 2001 licensing agreement between AstraZeneca and Gene Logic, Inc. (Gene Logic), the rights to which Ocimum purports to have acquired from Gene Logic.

Government investigations/proceedings

Good Manufacturing Practices subpoena
As previously disclosed, in March 2013, AstraZeneca received a subpoena duces tecum from the US Attorney's Office in Boston seeking documents and information relating to products manufactured or packaged at AstraZeneca's Macclesfield facility in the UK. AstraZeneca co-operated with this inquiry which is now closed.

8 PRODUCT ANALYSIS – FY 2015

	World	US	Europe

							Established ROW		Emerging Markets	
	FY 2015 $m	CER %	FY 2015 $m	CER %	FY 2015 $m	CER %	FY 2015 $m	CER %	FY 2015 $m	CER %
Respiratory, Inflammation & Autoimmunity:										
Symbicort	3,394	(3)	1,520	1	1,076	(14)	404	2	394	22
Pulmicort	1,014	15	200	(5)	117	(13)	88	4	609	35
Tudorza/Eklira	190	n/m	103	n/m	76	n/m	9	n/m	2	n/m
Daliresp	104	n/m	104	n/m	-	-	-	-	-	-
Duaklir	27	n/m	-	-	26	n/m	1	n/m	-	-
Others	258	(5)	18	(31)	88	(6)	25	4	127	(1)
Total Respiratory, Inflammation & Autoimmunity	4,987	7	1,945	11	1,383	(7)	527	5	1,132	25
Cardiovascular & Metabolic disease:										
Brilinta/Brilique	619	44	240	64	230	18	37	33	112	91
Onglyza	786	2	420	(13)	141	8	66	27	159	41
Bydureon	580	35	482	29	81	65	8	80	9	150
Farxiga/Forxiga	492	137	261	114	126	126	32	124	73	n/m
Byetta	316	2	209	5	62	(11)	22	(7)	23	30
Legacy:										
Crestor	5,017	(3)	2,844	(3)	916	(9)	571	(1)	686	2
Seloken/Toprol-XL	710	4	89	(2)	97	(6)	12	(26)	512	9
Atacand	358	(15)	34	(23)	105	(26)	26	(30)	193	(4)
Others	611	(10)	55	(28)	143	(15)	60	(15)	353	(3)
Total Cardiovascular & Metabolic Disease	9,489	4	4,634	4	1,901	(1)	834	1	2,120	11
Oncology:										
Iressa	543	(2)	6	n/m	128	(8)	137	(10)	272	4
Lynparza	94	n/m	70	n/m	23	n/m	-	-	1	n/m
Tagrisso	19	n/m	15	n/m	4	n/m	-	-	-	-
Legacy:										
Zoladex	816	7	28	8	171	(12)	272	(2)	345	27
Faslodex	704	9	356	5	207	2	54	5	87	49
Casodex	267	(6)	1	(80)	30	(14)	131	(11)	105	9
Arimidex	250	(5)	19	27	49	(24)	79	(17)	103	16
Others	132	6	19	(24)	23	(18)	60	44	30	-
Total Oncology	2,825	7	514	25	635	(4)	733	(4)	943	18
Infection, Neuroscience & Gastrointestinal:										
Nexium	2,496	(26)	902	(52)	284	(7)	549	5	761	3
Seroquel XR	1,025	(12)	716	(3)	202	(30)	25	(34)	82	(1)
Synagis	662	(26)	285	(43)	377	(6)	-	-	-	-
Losec/Prilosec	340	(10)	18	(32)	97	(10)	74	(19)	151	(1)
FluMist/Fluenz	288	-	206	(6)	76	16	7	14	(1)	(100)
Movantik/Moventig	29	n/m	28	n/m	1	n/m	-	-	-	-
Others	1,500	-	226	50	367	(15)	273	(3)	634	1
	6,340	(16)	2,381	(32)	1,404	(13)	928	(1)	1,627	2

Total Infection, Neuroscience & Gastrointestinal										
TOTAL PRODUCT SALES	23,641	(1)	9,474	(6)	5,323	(6)	3,022	-	5,822	12

9 PRODUCT SALES ANALYSIS – Q4 2015zz

	World		US		Europe		Established ROW		Emerging Markets	
	Q4 2015 $m	CER %	Q4 2015 $m	CER %	Q4 2015 $m	CER %	Q4 2015 $m	CER %	Q4 2015 $m	CER %
Respiratory, Inflammation & Autoimmunity:										
Symbicort	859	(6)	410	4	251	(18)	100	(5)	98	(3)
Pulmicort	274	9	52	(7)	29	(20)	27	7	166	24
Tudorza/Eklira	47	n/m	26	n/m	19	n/m	2	n/m	-	n/m
Daliresp	32	n/m	32	n/m	-	-	-	-	-	-
Duaklir	12	n/m	-	-	12	n/m	-	-	-	-
Others	65	(4)	6	50	22	(8)	7	33	30	(13)
Total Respiratory, Inflammation & Autoimmunity	1,289	4	526	15	333	(12)	136	-	294	9
Cardiovascular & Metabolic disease:										
Brilinta/Brilique	174	43	70	63	60	15	10	33	34	86
Onglyza	192	3	98	(3)	33	(14)	18	24	43	29
Bydureon	155	28	122	18	25	56	2	100	6	n/m
Farxiga/Forxiga	152	76	77	45	37	72	10	71	28	n/m
Byetta	72	10	43	10	17	-	7	14	5	67
Legacy:										
Crestor	1,322	-	777	2	225	(9)	154	5	166	2
Seloken/Toprol-XL	160	5	19	27	24	(10)	3	(25)	114	6
Atacand	86	(15)	7	(36)	25	(19)	5	(33)	49	(7)
Others	147	(9)	14	(7)	35	(13)	16	-	82	(9)
Total Cardiovascular & Metabolic Disease	2,460	6	1,227	8	481	(2)	225	8	527	11
Oncology:										
Iressa	129	(5)	4	n/m	32	(12)	35	(7)	58	(5)
Lynparza	36	n/m	24	n/m	11	n/m	-	-	1	n/m
Tagrisso	18	n/m	15	n/m	3	n/m	-	-	-	-
Legacy:										
Zoladex	198	4	6	(25)	43	(8)	70	(4)	79	21
Faslodex	185	12	95	6	53	7	15	7	22	60
Casodex	63	(7)	-	-	7	(20)	33	(10)	23	4
Arimidex	60	(1)	4	33	12	(13)	20	(22)	24	27
Others	27	(26)	-	(100)	2	(75)	16	13	9	(10)
Total Oncology	716	9	148	40	163	1	189	(6)	216	15
Infection, Neuroscience & Gastrointestinal:										
Nexium	564	(26)	175	(63)	75	1	138	47	176	14

Seroquel XR	241	(18)	176	(10)	42	(38)	5	(40)	18	(12)
Synagis	275	(32)	128	(45)	147	(14)	-	-	-	-
Losec/Prilosec	77	(23)	-	100	26	-	19	(19)	32	(26)
FluMist/Fluenz	191	46	118	57	67	31	7	60	(1)	(100)
Movantik/Moventig	15	n/m	15	n/m	-	-	-	-	-	-
Others	379	25	59	(238)	87	(15)	67	(19)	166	11
Total Infection, Neuroscience & Gastrointestinal	1,742	(13)	671	(29)	444	(10)	236	11	391	7
TOTAL PRODUCT SALES	6,207	-	2,572	(3)	1,421	(7)	786	4	1,428	10

Shareholder Information

Announcements and Meetings

Announcement of first quarter 2016 results	29 April 2016
A A nnual General Meeting	29 April 2016
Announcement of half year and second quarter 2016 results	28 July 2016
A Announcement of nine months and third quarter 2016 results	10 November 2016

D Dividends

Future dividends will normally be paid as follows:

First interim	Announced with half year and second quarter results and paid in September
Second interim	Announced with full year and fourth quarter results and paid in March

The record date for the second interim dividend for 2015, payable on 21 March 2016, will be 19 February 2016. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 18 February 2016. American Depositary Shares listed in New York will trade ex-dividend from 17 February 2016.

The record date for the first interim dividend for 2016, payable on 12 September 2016, will be 12 August 2016. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 11 August 2016. American Depositary Shares listed in New York will trade ex-dividend from 10 August 2016.

T Trademarks

Trademarks of the AstraZeneca group of companies and of companies other than AstraZeneca appear throughout this document in italics. AstraZeneca, the AstraZeneca logotype and the AstraZeneca symbol are all trademarks of the AstraZeneca group of companies. Trademarks of companies other than AstraZeneca that appear in this document include Caprelsa, a trademark of Genzyme Corporation; Daliresp and Daxas, trademarks of Takeda GmbH; Duaklir Genuair, Duaklir, Eklira, and Tudorza, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG; Ibrance, a trademark of Pfizer Inc.; Myalept, a trademark of Aegerion Pharmaceuticals, Inc.; and Zinforo, a trademark of Forest Laboratories.

A Addresses for Correspondence

Registrar and Transfer Office	US Depositary	Registered Office	Swedish Central Securities Depository
Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK	Citibank Shareholder Services PO Box 43077 Providence RI 02940-3077 USA	2 Kingdom Street London W2 6BD UK	Euroclear Sweden AB PO Box 191 SE-101 23 Stockholm Sweden
Tel (freephone in UK): 0800 389 1580 Tel (outside UK): +44 (0)121 415 7033	Tel: +44 (0)207 500 2030 or +1 877 248 4237 (1 877-CITI-ADR)/ E-mail: citiadr@citi.com	Tel: +44 (0)20 7604 8000	Tel: +46 (0)8 402 9000

C Cautionary Statements Regarding 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 medial 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 document/presentation/webcast should be construed as a

profit forecast.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AstraZeneca PLC

Date: 04 February 2016

By: /s/ Adrian Kemp
Name: Adrian Kemp
Title: Company Secretary