

ASTRAZENECA PLC  
Form 6-K  
November 05, 2015

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 November 2015

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  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

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

5 November 2015

Year-To-Date and Q3 2015 Results

## Financial Summary

	\$m	YTD 2015		\$m	Q3 2015	
		% change			% change	
		CER1	Actual		CER1	Actual
Total Revenue <sup>2</sup>	18,309	-	(8)	5,945	(2)	(10)
Core <sup>3</sup> Op. Profit	5,346	-	(7)	1,728	7	(2)
Core EPS	\$3.32	2	(6)	\$1.03	8	(2)
Reported Op. Profit	3,026	31	22	1,170	137	116
Reported EPS	\$1.60	40	30	\$0.61	237	203

- Core EPS in the year to date up by 2% with Q3 Core EPS growth of 8%
  - Total Revenue stable in the year to date; Core Gross margin up by 1.0% points to 83.3%
- Resilient top-line performance underpinned continued investment in R&D. Core R&D costs up by 18% in Q3, reflecting the recent start of key Oncology trials
  - Core SG&A costs declined by 3% in the third quarter; increased by 2% in the year to date
  - Upgraded FY 2015 Total Revenue and Core EPS guidance at constant exchange rates

## YTD Commercial Highlights

Growth platforms grew by 10%, representing 57% of Total Revenue:

1. Respiratory: +8%, including 38% Q3 sales growth in Emerging Markets
  2. Brilinta/Brilique: +44%; Q3 US growth of 73%
3. Diabetes: +26%, including 73% sales growth in Emerging Markets
4. Emerging Markets: +12%. China sales growth of 17% (Q3 2015: +11%)
  5. Japan: +3%, with Q3 sales growth of 6%

Achieving Scientific Leadership: Progress since the prior results announcement

Regulatory Approvals	Brilinta - post-myocardial infarction (MI) (PEGASUS trial) (US)
Regulatory Submission	PT003 - COPD (US)
Acceptances	Brilinta - acute coronary syndrome, post-MI (JP)
	AZD9291 - lung cancer (JP)
	saxagliptin/dapagliflozin - type-2 diabetes (US): Complete Response Letter
	AZD9291: Granted Priority Review by FDA and Japanese
Other Key	MHLW
Developments	FDA Fast Track designation: anifrolumab - lupus, tremelimumab - mesothelioma, durvalumab - head & neck cancer

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

"I'm pleased with our continued progress as we focus on executing our plans across our growth platforms and pipeline. While we have more work to do on the submission of saxagliptin/dapagliflozin combination in Diabetes, the significant label update for Brilinta was accompanied by submission acceptances and accelerated reviews in cancer, respiratory diseases and lupus. In particular, our exciting Oncology portfolio maintained its momentum with four Priority Review and Fast Track designations as well as supportive data at key congresses.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

Our financial performance in the year to date, including an 8% increase in Core EPS in the third quarter, underpinned today's upgrade to full-year guidance. 2016 will be a pivotal year in our strategic journey as we face the impact of loss of exclusivity to Crestor in the US. Looking ahead however, the continued performance of our growth platforms and upcoming launches will combine with our increasing focus on costs and cash generation to help offset short-term headwinds and return AstraZeneca to sustainable growth."

### FY 2015 Guidance

All guidance is shown at CER1.

	New	Old
Total Revenue	In line with the prior year	A low single-digit percent decline versus the prior year
Core Earnings Per Share	A mid to high single-digit percent increase versus the prior year	A low single-digit percent increase versus the prior year

Non-guidance information is also provided:

Based on average daily spot rates in the nine months to the end of September 2015, Total Revenue in FY 2015 is expected to decline by high single-digit percent, with Core EPS expected to be broadly in line with FY 2014. In addition, the majority of FY 2015 Externalisation Revenue is anticipated to have been realised in the first half of the year. Core R&D costs are expected to grow at a lower rate in the final quarter versus the year to date and the Company is committed to reducing Core SG&A costs in FY 2015 versus the prior year, both in terms of absolute value and relative to Total Revenue.

### Pipeline: Forthcoming Major Newsflow

Q4 2015	lesinurad - gout: Regulatory decision (US)
	brodalumab - psoriasis: Regulatory submission (US, EU)
	durvalumab - lung cancer: Data read-out
	PT003 - COPD: Regulatory decision (US)
H1 2016	benralizumab - severe asthma: Data read-out
	Brilinta/Brilique - stroke: Data read-out
	AZD9291 - lung cancer: Regulatory decisions
	tremelimumab - mesothelioma: Data read-out
	Lynparza - breast cancer: Data read-out
H2 2016	Brilinta/Brilique - peripheral arterial disease: Data read-out
	saxagliptin/dapagliflozin - type-2 diabetes (EU): Regulatory decision
	durvalumab - head & neck cancer: Data read-out
	Lynparza - ovarian cancer: Data read-out
	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. For further details on the presentation of Total Revenue, see the announcement published by the Company in March 2015.
3. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
4. The performance shown in this announcement covers the nine and three month periods to 30 September 2015 (the year to date and the quarter respectively) compared to the nine and three month periods to 30 September 2014 (the prior year to date and the prior quarter respectively).

### Results Presentation

A conference call for investors and analysts, hosted by management, will begin at midday GMT today. Details can be accessed via [www.astrazeneca.com/investors](http://www.astrazeneca.com/investors).

## Reporting Calendar

The Company intends to publish its full-year financial results on 4 February 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 cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

## Contacts at AstraZeneca

### Media Enquiries

Esra Erkal-Paler	UK/Global	+44 20 7604 8030
Vanessa Rhodes	UK/Global	+44 20 7604 8037
Ayesha Bharmal	UK/Global	+44 20 7604 8034
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

### Investor Enquiries

#### UK

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

#### US

Lindsey Trickett	Oncology, ING	+1 240 543 7970
Mitchell Chan	Oncology	+1 240 477 3771
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 nine and three-month periods to 30 September 2015 (the year to date and the third quarter respectively) compared to the nine and three months to 30 September 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 was stable in the year to date at \$18,309m. The decline of 2% in the third quarter, compared to recent increases, reflected a lower level of Externalisation Revenue. Based on actual exchange rates, Total Revenue declined by 8% in the nine-month period reflecting the particular weakness of key trading currencies against the US dollar.

#### Product Sales

Product Sales declined by 2% in the year to date (Q3 2015: down by 2%) reflecting the US market entry of Nexium generic products from February 2015 as well as an adverse impact from the change in accounting for the US Branded Pharmaceutical Fee following issuance of final regulations in Q3 2014.

#### Externalisation Revenue

Externalisation Revenue of \$875m in the year to date (Q3 2015: \$95m) primarily reflected income from completion of the collaboration agreement in haematology with Celgene Corporation (Celgene) (\$450m), together with income from the co-commercialisation agreement with Daiichi Sankyo Co., Ltd. (Daiichi Sankyo) for Movantik in the US (\$200m) and the co-commercialisation of Nexium in Japan (\$55m), also 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 6 and 7.

	\$m	YTD 2015 % Change		\$m	Q3 2015 % Change	
		CER	Actual		CER	Actual
Respiratory, Inflammation & Autoimmunity						
Symbicort	2,535	(2)	(10)	848	(4)	(12)
Pulmicort	740	17	9	222	16	8
Tudorza/Eklira	143	n/m	n/m	58	n/m	n/m
Daliresp	72	n/m	n/m	33	n/m	n/m
Duaklir	15	n/m	n/m	8	n/m	n/m
Others	193	(5)	(15)	61	(6)	(15)
TOTAL	3,698	8	(1)	1,230	7	(1)
Cardiovascular & Metabolic Disease						
Brilinta/Brilique	445	44	30	170	48	34
Onglyza	594	2	(4)	203	-	(8)
Bydureon	425	38	34	162	34	30
Farxiga/Forxiga	340	180	158	135	107	88

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Byetta	244	(1)	(5)	72	(17)	(22)
Legacy:						
Crestor	3,695	(4)	(10)	1,218	(3)	(9)
Seloken/Toprol-XL	550	4	(6)	172	(2)	(13)
Atacand	272	(15)	(29)	78	(24)	(37)
Others	464	(10)	(18)	137	(23)	(30)
TOTAL	7,029	3	(4)	2,347	2	(6)
Oncology						
Iressa	414	(2)	(12)	141	1	(10)
Lynparza	58	n/m	n/m	28	n/m	n/m
Legacy:						
Zoladex	618	8	(11)	209	8	(13)
Faslodex	519	7	(4)	186	11	(1)
Casodex	204	(6)	(17)	65	(6)	(19)
Arimidex	190	(7)	(17)	64	(1)	(14)
Others	106	18	3	35	11	(5)
TOTAL	2,109	6	(8)	728	9	(6)
Infection, Neuroscience & Gastrointestinal						
Nexium	1,932	(26)	(32)	641	(24)	(30)
Seroquel XR	784	(9)	(14)	258	(14)	(18)
Synagis	387	(22)	(22)	117	(3)	(3)
Losec/Prilosec	263	(6)	(16)	82	(5)	(15)
FluMist/Fluenz	97	(39)	(40)	76	(48)	(49)
Movantik/Moventig	14	n/m	n/m	10	n/m	n/m
Others	1,121	(6)	(18)	361	(2)	(15)
TOTAL	4,598	(18)	(24)	1,545	(17)	(24)
TOTAL PRODUCT SALES	17,434	(2)	(10)	5,850	(2)	(11)

YTD Product Sales Summary

---

During 2014, final regulations relating to the US Branded Pharmaceutical Fee were issued, affecting how the fee is recognised; AstraZeneca consequently accrues for the obligation as each sale occurs. As 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 by an average of 2%.

Respiratory, Inflammation & Autoimmunity

Symbicort

Year-to-date Product Sales declined by 2% to \$2,535m and the medicine continues to be competitive.

## Edgar Filing: ASTRAZENECA PLC - Form 6-K

In the US, the year-to-date decline to \$1,110m was limited to 1% with continued lower net prices reflecting additional access and co-pay assistance. Robust volume growth was driven by higher market share within a growing market.

In Europe, Product Sales declined by 13% to \$825m 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 33% to \$296m with China sales growing by 50% to \$95m, primarily reflecting volume growth.

### Pulmicort

Pulmicort sales in the year to date were \$740m, an increase of 17%. Growth was driven primarily by the performance of Pulmicort Respules in Emerging Markets, which were up 40% at \$443m. China Product Sales increased by 47% to \$354m, reflecting sustained investment in supporting asthma and COPD patients, both in hospitals and more recently at home.

### Tudorza/Eklira

Product Sales in the year to date were \$143m, including \$77m in the US, where the brand name is Tudorza. In March 2015 the Company completed the acquisition of the Actavis plc product rights to the brand.

Rights were also acquired at that time for Daliresp, for which sales amounted to \$72m in the year to date.

### Duaklir

In the third quarter Duaklir continued its successful launch, principally in Europe. Year-to-date total sales of \$15m (Q3 2015: \$8m, Q2 2015: \$5m) reflected good progress of this leading LAMA/LABA medicine, with an encouraging formulary uptake in the UK and market-share increases in Germany.

### Cardiovascular & Metabolic Disease

#### Brilinta/Brilique

Sales in the year to date were \$445m, an increase of 44%, with the third quarter exhibiting growth driven by strong marketing execution (Q3 2015: up by 48%, Q2 2015: up by 38%). AstraZeneca announced on 3 September 2015 that the FDA had approved Brilinta tablets at a new 60mg dose to be used by patients with a history of heart attack beyond the first year of treatment.

Sales in the US were \$170m, increasing by 65% (Q3 2015: up by 73%, Q2 2015: up by 57%). This reflected higher total-prescription volumes driven by marketing and other initiatives, together with an element of stocking for the new 60mg dose.

In Europe, Brilique continued to perform well, with an increase in Product Sales of 19% to \$170m, reflecting indication leadership across a number of European markets. Emerging Markets sales grew by 93% to \$78m with China representing the largest single market for the medicine.

#### Onglyza

Sales were up 2% in the nine-month period to \$594m despite an emphasis on the promotion of Farxiga in the US. Sales in the third quarter were stable year-on-year versus the 7% decline in Q2 2015.

US sales were down by 15% at \$322m in the year to date, due to competitive pressures in the DPP-4 class driving a lower market share, as well as a decline in the net price.

Sales in Europe grew by 17% to \$108m, while Emerging Markets sales grew by 47% to \$116m.

#### Farxiga/Forxiga

Sales of Farxiga/Forxiga were up 180% in the year to date to \$340m.

In the US, Product Sales of \$184m represented growth of 167%. Promotional activity underpinned increasing total-prescription market-share growth in the year to date; this was accompanied by overall growth in the market.

Sales in Europe reached \$89m, up by 159% in the year to date reflecting the launch phase of the medicine.

#### Bydureon/Byetta

Combined sales were \$669m in the nine-month period, growing by 16%, with Bydureon representing 64% of total Bydureon/Byetta sales.

In the US, sales were \$526m, up by 22%, with higher volumes driven by market growth and higher net prices. The majority of the remaining sales of Bydureon/Byetta resided in Europe, where year-to-date sales reached \$101m, reflecting the ongoing successful Pen launch.

#### Legacy: Crestor

Sales of Crestor declined in the year to date by 4% to \$3,695m, with volumes marginally falling. The performance reflected competition from generic statins and price pressures.

In the US, Crestor sales declined by 4% to \$2,067m, driven by lower market share and destocking, which was partially offset by favourable price movements.

In Europe sales declined by 9% to \$691m, reflecting prevailing competitive trends. Crestor consolidated its position as the leading statin in Japan, with sales growth of 6% to \$337m in the nine-month period. Sales in China grew by 17% to \$202m.

#### Oncology

##### Iressa

Sales of Iressa declined by 2% to \$414m in the year to date, driven by the competitive environment in Europe where sales were down by 6% to \$96m; Japan sales declined by 12% to \$91m. Since the US launch in July 2015, Iressa has seen an encouraging increase in new-patient starts.

Emerging Markets sales grew by 6% to \$214m, with China sales increasing by 8% to \$119m and Latin America sales increasing by 11% to \$8m.

##### Lynparza

Sales of Lynparza reached \$58m in the nine-month period. US sales of \$46m followed the launch of the medicine at the end of 2014. Growth was driven by the pool of eligible patients awaiting treatment as well as patients newly tested for BRCA mutation.

##### Legacy: Zoladex

Sales increased by 8% to \$618m, with a notable performance in China where sales reached \$91m, reflecting growth of 35%.

##### Legacy: Faslodex

Sales were up 7% to \$519m in the year to date. A 4% rise in US sales to \$261m was complemented by stable Europe sales of \$154m. The notable performance was in Emerging Markets, where sales of \$65m represented a growth rate of 46%. With the recent launch of 500mg Faslodex, China sales accelerated in the period to \$7m (Q3 2015: up by 50%, H1 2015: up by 33%). AstraZeneca Russia also achieved federal reimbursement for the medicine.

#### Infection, Neuroscience & Gastrointestinal



Nexium

Sales of Nexium declined by 26% to \$1,932m in the year to date.

US sales declined by 48% to \$727m following the loss of exclusivity in February 2015, directly impacting both pricing and volumes. The estimate for pipeline inventory returns was increased in the third quarter. Sales in Europe declined by 10% to \$209m.

Nexium sales in Emerging Markets were stable at \$585m, with growth in Latin America of 19% to \$98m, an exception to the overall performance. Japan sales increased by 16% in the period to \$298m.

Seroquel XR

Sales declined by 9% to \$784m in the nine-month period. In the US, sales were stable at \$540m; the performance was mainly driven by favourable market growth and higher underlying net prices.

Product Sales in Europe declined by 28% to \$160m, reflecting generic-product competition.

Synagis

Sales of Synagis declined by 22% to \$387m in the year to date, with a 41% decline to \$157m seen in the US reflecting lower demand related to the American Academy of Pediatrics Committee on Infectious Disease guidelines issued in mid-2014. These further restricted patients eligible for preventative therapy with Synagis. While these guidelines were inconsistent with the approved label, demand was significantly impacted; this is anticipated to continue in the remainder of the year. Product Sales in Europe to AbbVie were stable at \$230m.

FluMist/Fluenz

Product Sales in the year to date declined by 39% to \$97m, reflecting delays in supply. In the US, Product Sales fell by 38% to \$88m, while in Europe, the decline of 38% resulted in sales of \$9m.

Movantik/Moventig

Product Sales of Movantik were \$14m in the year to date (Q3 2015: \$10m); the medicine was launched in March 2015. The majority of Product Sales have been in the US. On 19 March 2015 the Company announced a co-commercialisation agreement with Daiichi Sankyo for Movantik in the US.

Regional Product Sales

	YTD 2015			Q3 2015		
	\$m	CER	Actual	\$m	CER	Actual
US	6,902	(8)	(8)	2,377	(6)	(6)
Europe	3,902	(6)	(20)	1,301	(8)	(21)
Established ROW1	2,236	(2)	(16)	745	-	(17)
Japan	1,479	3	(12)	502	6	(12)
Canada	399	5	(8)	126	1	(14)
Other Established ROW	358	(22)	(34)	117	(20)	(36)
Emerging Markets2	4,394	12	1	1,427	10	(3)
China	1,931	17	15	622	11	10

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Ex.China	2,463	10	(9)	805	9	(11)
Total	17,434	(2)	(10)	5,850	(2)	(11)

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 Product Sales declined by 8% to \$6,902m in the year to date. Excluding the impact of the change in accounting related to the Branded Pharmaceutical Fee, Product Sales in the year to date and third quarter declined by 6% and 4% versus the comparative period.

The declines reflected the loss of Nexium patent exclusivity, competition facing Crestor from therapeutic substitution by generic statins and the adverse impact of the Synagis guideline changes.

Favourable performances were delivered by Brilinta, Farxiga, Bydureon and Lynparza as well as the recently-acquired respiratory medicines Tudorza and Daliresp. Brilinta accelerated its strong quarterly growth, underpinned by total and new-to-brand prescription market share gains.

Continued growth in demand for Farxiga was supported by additional promotional activity. Bydureon continued to benefit 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 \$3,902m in the year to date. Strong growth from the diabetes medicines Onglyza and Forxiga was more than offset by continued generic competition facing Crestor and Seroquel XR. A 13% decline in Symbicort sales to \$825m reflected adverse pricing movements driven by competition from analogues in key markets. Duaklir more than doubled its first-half sales in Q3, bringing the year to date total to \$14m.

#### Established ROW

Sales in the Established ROW fell by 2% to \$2,236m in the year to date.

Japan sales increased by 6% in both the second and third quarters, reflecting the passing of the anniversary of the mandated April 2014 biennial price cut. Nexium and Crestor continued to grow in the nine-month period, increasing by 16% to \$298m and 6% to \$337m respectively. Crestor growth reflected a continued increase in the usage of the 5mg dosage. Symbicort sales in the year to date increased by 3% to \$132m; a 3% decline in the third quarter to \$47m however reflected the strong comparative period's performance. Market share of Symbicort was broadly stable in the third quarter and in the year to date.

Canada Product Sales grew by 5% to \$399m in the year to date, driven by the performances of Onglyza and Symbicort.

#### 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. Sales increased by 12% to \$4,394m in the nine-month period with growth delivered across the region. Emerging Markets sales in the third quarter increased by 10% to \$1,427m, ahead of the Company's long-term forecast of mid-to-high single-digit growth in the region's Product Sales.

China sales increased by 17% to \$1,931m and by 11% in the third quarter. In the year to date Brazil sales were up 20% to \$304m and Russia sales were up 22% to \$163m.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Financial Performance

YTD 2015	Reported	Restructuring	Intangible Amortisation & Impairments	Diabetes Alliance	Other <sup>1</sup>	Core		% Change	
						YTD 2015	YTD 2014 <sup>2</sup>	CER	Actual
Product Sales	17,434	-	-	-	-	17,434	19,412	(2)	(10)
Externalisation Revenue	875	-	-	-	-	875	419	112	109
Total Revenue	18,309	-	-	-	-	18,309	19,831	-	(8)
Cost of Sales	(3,377)	124	343	-	-	(2,910)	(3,529)	(8)	(18)
Gross Profit	14,932	124	343	-	-	15,399	16,302	2	(6)
Gross Margin <sup>3</sup>	80.6%					83.3%	81.8%	+1.0	+1.5
Distribution	(240)	-	-	-	-	(240)	(236)	15	2
% Total Revenue	1.3%					1.3%	1.2%	-0.2	-0.1
R&D	(4,251)	180	35	-	-	(4,036)	(3,581)	22	13
% Total Revenue	23.2%					22.0%	18.1%	-3.8	-3.9
SG&A	(8,444)	358	684	324	274	(6,804)	(7,263)	2	(6)
% Total Revenue	46.1%					37.2%	36.6%	-0.4	-0.6
Other Operating Income	1,029	-	156	-	(158)	1,027	531	105	94
% Total Revenue	5.6%					5.6%	2.7%	+2.8	+2.9
Operating Profit	3,026	662	1,218	324	116	5,346	5,753	-	(7)
% Total Revenue	16.5%					29.2%	29.0%	-0.2	+0.2
Net Finance Expense	(750)	-	-	305	90	(355)	(381)		
Joint Ventures	(9)	-	-	-	-	(9)	(2)		
Profit Before Tax	2,267	662	1,218	629	206	4,982	5,370	-	(7)
Taxation	(249)	(139)	(247)	(141)	(14)	(790)	(921)		
Tax Rate	11%					16%	17%		
Profit After Tax	2,018	523	971	488	192	4,192	4,449	2	(6)
	(1)	-	-	-	-	(1)	(2)		

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Non-controlling Interests									
Net Profit	2,017	523	971	488	192	4,191	4,447	2	(6)
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,262		
Earnings Per Share	1.60	0.41	0.77	0.39	0.15	3.32	3.52	2	(6)

1 Other adjustments include provision charges and settlement income related to certain legal matters (see Note 5) and fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 4).

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.

Q3 2015	Reported	Restructuring	Intangible Amortisation & Impairments	Diabetes Alliance	Other <sup>1</sup>	Core		% Change	
						Q3 2015	Q3 2014 <sup>2</sup>	CER	Actual
Product Sales	5,850	-	-	-	-	5,850	6,542	(2)	(11)
Externalisation Revenue	95	-	-	-	-	95	67	50	41
Total Revenue	5,945	-	-	-	-	5,945	6,609	(2)	(10)
Cost of Sales	(1,041)	23	26	-	-	(992)	(1,180)	(8)	(16)
Gross Profit	4,904	23	26	-	-	4,953	5,429	-	(9)
Gross Margin <sup>3</sup>	82.2%					83.0%	82.0%	+1.1	+1.0
Distribution	(79)	-	-	-	-	(79)	(87)	2	(9)
% Total Revenue	1.3%					1.3%	1.3%	-0.1	-
R&D	(1,429)	56	(27)	-	-	(1,400)	(1,275)	18	10
% Total Revenue	24.0%					23.5%	19.3%	-3.8	-4.2
SG&A	(2,679)	135	240	108	(24)	(2,220)	(2,486)	(3)	(11)
% Total Revenue	45.1%					37.3%	37.6%	+0.5	+0.3
Other Operating Income	453	-	21	-	-	474	189	156	152
% Total Revenue	7.6%					8.0%	2.9%	+4.6	+5.1
	1,170	214	260	108	(24)	1,728	1,770	7	(2)

Operating Profit % Total Revenue	19.7%					29.1%	26.8%	+2.4	+2.3
Net Finance Expense	(237)	-	-	101	31	(105)	(114)		
Joint Ventures	(2)	-	-	-	-	(2)	(2)		
Profit Before Tax	931	214	260	209	7	1,621	1,654	8	(2)
Taxation	(161)	(45)	(54)	(46)	(12)	(318)	(321)		
Tax Rate	17%					20%	19%		
Profit After Tax	770	169	206	163	(5)	1,303	1,333	8	(2)
Non-controlling Interests	-	-	-	-	-	-	1		
Net Profit	770	169	206	163	(5)	1,303	1,334	8	(2)
Weighted Average Shares	1,264	1,264	1,264	1,264	1,264	1,264	1,263		
Earnings Per Share	0.61	0.13	0.17	0.13	(0.01)	1.03	1.05	8	(2)

1 Other adjustments include fair value adjustments to contingent consideration liabilities arising on business combinations (see Note 4).

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 nine-month period to \$15,399m. Excluding the impact of externalisation, the Core Gross-Profit margin increased by 1% point. Drivers of the margin increase included the mix of Product Sales and manufacturing efficiencies.

### Operating Expenses

Core R&D costs were up 22% in the year to date to \$4,036m as the Company continued its focused investment in the pipeline. Oncology is anticipated to attract over 40% of total Core R&D costs over the full year, reflecting a number of key new and active trials.

After a 1% reduction of Core SG&A costs in Q2 2015, third-quarter costs declined by 3% to \$2,220m. Core SG&A costs were up 2% to \$6,804m in the nine-month period as the Company continued to invest in the product-launch programme and the growth platforms.

The Company is committed to reducing Core SG&A costs in FY 2015 versus the prior year, both in terms of absolute value and relative to Total Revenue. A number of programmes designed to meet this target are progressing. These initiatives are centred 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 are being deployed more selectively to meet changing customer needs and the evolving portfolio, while driving top-line growth more efficiently.

#### Other Operating Income

Core Other Operating Income of \$1,027m in the year to date included royalty income of \$261m, together with gains on the disposals of Entocort (\$215m), Myalept (\$193m), Caprelsa (\$165m) and other disposals, including the US rights to Tenormin.

#### Operating Profit

Core Operating Profit was stable at \$5,346m in the year to date. The Core Operating Margin declined by 0.2% points to 29.2% of Total Revenue as the Company continued to invest in the pipeline and the growth platforms. The increase of 2.4% points in the Core Operating Margin in the third quarter to 29.1% reflected the 3% decline in Core SG&A costs and increases in Core Other Operating Income.

Reported Operating Profit of \$3,026m was 31% higher than the first nine months of 2014.

#### Finance Expense

The Core Net Finance Expense was \$355m versus \$381m in the comparative period. Reported net finance expense of \$750m included a charge of \$395m relating to the discount unwind on contingent consideration liabilities recognised on business combinations, principally relating to the acquisition of BMS's share of the global diabetes alliance last year.

#### 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 provision releases and the benefit of the UK patent box, the Core tax rate and Reported tax rates for the nine months were 22% and 24% respectively. Including the impact of these benefits, the Core and Reported tax rates for the nine months ended 30 September 2015 were 16% and 11% respectively. The cash tax paid for the nine-month period was \$954m, which is 42% of Reported Profit Before Tax and 19% of Core Profit Before Tax.

The Core and Reported tax rates for the same period in 2014 were 19% and 21% respectively when excluding the impact of the one-off tax benefit of \$117m in respect of prior periods following the inter-governmental agreement of a transfer pricing matter. Including the impact of this benefit, the Core and Reported tax rates for the nine months ended 30 September 2014 were 17% and 15% respectively.

#### Earnings Per Share (EPS)

Core EPS in the year to date increased by 2% to \$3.32. Reported EPS was up by 40% at \$1.60.

#### Productivity

The Company continued to make good progress in implementing the fourth wave of restructuring announced in the first quarter of 2013 that was subsequently expanded during 2014 and in the first half of 2015. Restructuring charges of \$214m were taken in the third quarter, bringing the year to date total to \$662m.

#### Cash Flow and Balance Sheet

### Cash Flow

The Company generated a cash inflow from operating activities of \$2,753m in the year to date, compared with an inflow of \$5,216m in the comparative period, reflecting the operational performance of the business and an adverse movement in working capital.

Net cash outflows from investing activities were \$1,654m compared with \$5,516m in the first nine months of 2014, the difference primarily reflecting the acquisition of the BMS share of the global diabetes alliance in 2014 and the proceeds from disposals of intangible assets in 2015.

Net cash distributions to shareholders were \$3,456m through dividends of \$3,486m, offset by proceeds from the issue of shares of \$30m due to the exercise of stock options.

The Company has embarked upon an initiative to further improve cash generation from the business including standardisation of global processes and payment terms.

### Debt and Capital Structure

At 30 September 2015, outstanding gross debt (interest-bearing loans and borrowings) was \$10,947m (30 September 2014: \$9,926m). Of the gross debt outstanding at 30 September 2015, \$2,671m is due within one year (30 September 2014: \$2,399m).

The Company's net debt position at 30 September 2015 was \$5,886m (30 September 2014: \$3,596m).

### Shares in Issue

During the year to date, 0.7 million shares were issued in respect of share option exercises for a consideration of \$30m. The total number of shares in issue at 30 September 2015 was 1,264 million.

### Capital Allocation

In setting the dividend distribution policy and the overall financial strategy, 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 business investment, funding the progressive dividend policy and meeting debt-service obligations, the Board will keep under review the opportunity to return cash in excess of these requirements to shareholders through periodic share repurchases. The Board has decided however that no share repurchases will take place in FY 2015 in order to maintain the strategic flexibility to invest in the business.

### Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

Currency	Primary Relevance	Average Exchange Rates Versus USD		Change %	Impact Of 5% Weakening In Exchange Rate Versus USD (\$m) <sup>2</sup>	
		FY 2014	YTD 2015		Total Revenue	Core Operating Profit
EUR	Product Sales	0.75	0.90	(16)	(225)	(138)
JPY	Product Sales	105.87	120.91	(12)	(119)	(84)
CNY	Product Sales	6.16	6.25	(1)	(115)	(49)
SEK	Costs	6.86	8.41	(18)	(6)	114

GBP	Costs	0.61	0.65	(7)	(37)	112
Other <sup>3</sup>					(242)	(139)

<sup>1</sup>Based on average daily spot rates YTD to the end of September 2015

<sup>2</sup>Based on 2014 actual average exchange rates and group currency exposures

<sup>3</sup>Other 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 30 September 2015 AstraZeneca had hedged over 90% 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

---

##### a) Purchase of US Biologics Manufacturing Facility

On 11 September 2015 AstraZeneca announced that it had added to its biologics manufacturing capability in the US with the purchase of a high-tech biologics bulk manufacturing facility from Amgen Inc., (Amgen). Over time, the LakeCentre facility, located in Boulder, Colorado will increase manufacturing and production capacity to support the Company's extensive portfolio of biologics medicines.

##### b) Entocort Divestment

In the third quarter AstraZeneca completed an agreement with Tillotts, part of Zeria Pharmaceutical Co., Ltd, for the divestment of global rights, outside the US, to Entocort (budesonide), a gastroenterology medicine for patients with mild-moderate Crohn's disease and ulcerative colitis.

Entocort is currently available in over 40 countries, with total Product Sales of \$53m outside the US in 2014. Under the terms of the agreement, Tillotts made an upfront payment to AstraZeneca of \$215m upon completion of the transaction to acquire the rights to sell and develop Entocort capsules and enema formulations outside the US. The payment has been shown within Other Operating Income in the Company's financial statements in the third quarter.

##### c) Caprelsa Divestment

In the third quarter AstraZeneca completed an agreement with Genzyme Corporation (Genzyme), part of Sanofi S.A., for the divestment of Caprelsa (vandetanib), a rare-disease medicine. Caprelsa was granted Orphan Drug Designation by the US FDA in 2005 and is currently available in 28 countries for the treatment of aggressive and symptomatic medullary thyroid carcinoma.

Under the terms of the agreement, Genzyme will pay AstraZeneca up to \$300m, including an upfront payment of \$165m to acquire the global rights to sell and develop Caprelsa. The upfront payment has been shown within Other Operating Income in the Company's financial statements in the third quarter; further development and sales milestone payments may reach up to \$135m and will be reported in Other Operating Income. The transaction did not include the transfer of any AstraZeneca employees or facilities.

##### d) Agreement to Develop Novel Immuno-Oncology Treatments

On 6 August 2015 it was announced that AstraZeneca and Heptares Therapeutics, the wholly-owned subsidiary of Sosei Group Corporation, had entered into a licensing agreement under which AstraZeneca will acquire exclusive global rights to develop, manufacture and commercialise the adenosine A2A receptor antagonist, HTL-1071, a small molecule immuno-oncology candidate, and potential additional A2A receptor-blocking compounds. AstraZeneca will



explore the assets across a range of cancers, including in combination with its existing portfolio of immunotherapies.

e) Adding New Combination Clinical Trials to Existing Immuno-Oncology Research Collaboration

On 22 October 2015 AstraZeneca and Eli Lilly and Company (Lilly) announced an extension to their existing Immuno-Oncology collaboration exploring novel combination therapies for the treatment of patients with solid tumours. Under the terms of the expanded agreement, AstraZeneca and Lilly will evaluate the safety and efficacy of a range of additional combinations across the companies' complementary portfolios.

Durvalumab, AstraZeneca's investigational anti-PD-L1 immune-checkpoint inhibitor, will be combined with Lilly molecules including a TGF-beta kinase inhibitor, galunisertib; a CXCR4 peptide antagonist; and an anti-CSF-1R monoclonal antibody, which will be assessed additionally with AstraZeneca's anti-CTLA-4 monoclonal antibody, tremelimumab.

Management Update

---

On 24 August 2015 AstraZeneca announced the appointment of Sean Bohem MD, PhD, as Executive Vice President of Global Medicines Development and Chief Medical Officer. He joined the Company on 15 September 2015.

Dr. Bohem is responsible for driving the progress of AstraZeneca's portfolio of small molecules and biologics investigational medicines through late-stage development to regulatory approval. As Chief Medical Officer, he is responsible for patient safety across the entire AstraZeneca and MedImmune portfolio.

Dr. Bohem joined AstraZeneca from Genentech where he was most recently Senior Vice President of Early Development. He oversaw preclinical and clinical development programmes across all therapy areas, including oncology, respiratory and autoimmune diseases, to deliver trial-ready drug candidates to late-stage development. Before this, he held a number of positions in early and late-stage development, playing a key role in the growth and progress of the Genentech/Roche portfolio. Dr. Bohem was instrumental in bringing a large number of new medicines to patients, in particular for cancer and led activities to incorporate diagnostics into clinical programmes.

Prior to joining Genentech, Dr. Bohem was a Clinical Instructor in Oncology at Stanford University School of Medicine, a research associate at the Howard Hughes Medical Institute and a postdoctoral fellow at the National Cancer Institute in the US.

Research and Development Update

---

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

Progress since the prior results announcement on 30 July 2015:

Regulatory Approvals	1	-	Brilinta - post-MI (PEGASUS trial) (US)
Regulatory Submission	3	-	PT003 - COPD (US)
Acceptances		-	Brilinta - ACS, post-MI (JP)
		-	AZD9291 - lung cancer (JP)
Other Key Developments	6	-	saxagliptin/dapagliflozin - type-2 diabetes (US): Complete Response Letter
		-	AZD9291: Granted Priority Review by FDA and Japanese MHLW

- FDA Fast Track designation:  
anifrolumab - lupus (SLE), tremelimumab -  
mesothelioma, durvalumab - head & neck cancer

New Molecular Entities (NMEs) in Pivotal Trials or under Regulatory Review	15	RIA
		<ul style="list-style-type: none"><li>- lesinurad</li><li>- PT003</li><li>- brodalumab</li><li>- benralizumab</li><li>- tralokinumab - severe asthma</li><li>- PT010 - COPD</li><li>- anifrolumab</li></ul>

CVMD

- roxadustat

Oncology

- AZD9291
- cediranib - ovarian cancer
- tremelimumab
- durvalumab
- moxetumomab pasudotox - leukaemia
- selumetinib - lung cancer

ING

- CAZ AVI

Projects in clinical pipeline	113
----------------------------------	-----

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

In the period 2015-2016 AstraZeneca anticipates 12-16 Phase II starts, 14-16 NME and major line-extension regulatory submissions and 8-10 NME and major line-extension approvals.

1. Respiratory, Inflammation & Autoimmunity (RIA)

Steady progress continues to be made in the RIA pipeline, which now includes seven 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 chronic obstructive pulmonary disease (COPD). The pipeline also includes a number of assets in inflammatory and autoimmune diseases within areas such as gout, psoriasis, systemic lupus and rheumatoid arthritis.

At the European Respiratory Society (ERS) meeting in Amsterdam, Netherlands in September 2015, positive Phase III results were presented for PT003 for COPD. PT003 could be the first LAMA/LABA combination to be delivered in a pressurised metered-dose inhaler using a unique co-suspension technology. Overall 33 abstracts were presented from across the Respiratory disease portfolio, including findings from the Company's biologics pipeline and early-science programmes.

a) Lesinurad (gout)

On 23 October 2015 the FDA's Arthritis Advisory Committee (AAC) voted 10 to 4 to recommend the approval of lesinurad 200mg tablets for the treatment of hyperuricemia associated with gout, in combination with a xanthine-oxidase inhibitor. The AAC reviewed safety and efficacy data from the pivotal Phase III combination-therapy programme trials, representing the largest clinical-trial data set of gout patients treated with combination urate-lowering therapy.

The FDA is not bound by the AAC's recommendation but takes its advice into consideration when reviewing the application for a potential medicine. The Prescription Drug User Fee Act (PDUFA) target goal date for lesinurad is 29 December 2015. If approved, lesinurad will be the first selective uric acid reabsorption inhibitor, or SURI, in the US.

b) PT003 (COPD)

Among key abstracts presented at the ERS meeting were the positive Phase III efficacy and safety data from the PINNACLE programme of the novel LAMA (glycopyrronium) and LABA (formoterol fumarate) combination.

The two pivotal 24-week trials, PINNACLE-1 and PINNACLE-2, tested the potential to improve lung function in patients with COPD and showed that PT003 had positive effects on both co-primary and secondary endpoints. There were no unexpected safety findings, with adverse events being consistent with previous results from the development programme.

During the period the FDA accepted the PT003 New Drug Application for standard full review with an expected PDUFA action date in Q2 2016, as anticipated.

c) Brodalumab (psoriasis)

Brodalumab is an IL-17 receptor monoclonal antibody in development for patients with moderate-to-severe plaque psoriasis.

On 1 September 2015 AstraZeneca announced that it had entered into a collaboration agreement with Valeant Pharmaceuticals International, Inc. (Valeant) under which it will grant an exclusive license for Valeant to develop and commercialise brodalumab globally, except in Japan and certain other Asian countries where rights are held by Kyowa Hakko Kirin Co., Ltd under a prior arrangement with Amgen, the originator of brodalumab. Completion of the transaction occurred on 1 October 2015.

Brodalumab is supported by data from the three AMAGINE Phase III pivotal trials. The results highlighted 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 their skin disease. At the 210mg dose, brodalumab was shown to be efficacious in total skin clearance of psoriasis compared to placebo and superior to ustekinumab at week 12 in two replicate comparator trials, involving over 3,500 patients.

On 1 October 2015 The New England Journal of Medicine published positive results from the AMAGINE-2 and AMAGINE-3 Phase III trials.

d) Anifrolumab (lupus)

Anifrolumab is an investigational, monoclonal antibody that binds to the type I interferon (IFN)- receptor and blocks the biological effects of all type I IFNs. It is currently in Phase III development for systemic lupus erythematosus; the first patient was dosed in July 2015. The Company anticipates the publication of Phase IIb data next week in an oral presentation at the American College of Rheumatology annual meeting in San Francisco, California.

In August 2015 the FDA granted Fast Track designation to anifrolumab, designed to expedite the development and review of drugs that treat serious conditions and meet an unmet medical need.

## 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 chronic kidney-disease indications. The patient-centric approach is reinforced by science-led life-cycle management programmes and technologies, including early research into regenerative methods.

In the third quarter, AstraZeneca presented 54 abstracts from the Company's research and development in diabetes at the 51st Annual Meeting of the European Association for the Study of Diabetes in Stockholm, Sweden.

The presentations included data on a number of approved products for the treatment of type-2 diabetes, including Onglyza, Farxiga/Forxiga, Bydureon and Byetta. Additionally several abstracts representing AstraZeneca's early-stage and pre-clinical research explored novel pathways and modalities to address the underlying pathophysiology of diabetes.

### a) Brilinta/Brilique (CV disease)

Brilinta/Brilique is an oral anti-platelet treatment that works by inhibiting platelet activation and was first approved by the FDA in July 2011 on the basis of data from the PLATO study. For at least the first 12 months following a myocardial infarction, it is superior to clopidogrel and is the first and only oral anti-platelet medicine to demonstrate superior reductions in cardiovascular death.

On 29 August 2015, the European Society of Cardiology updated NSTEMI-acute coronary syndrome (ACS) guidelines, continuing to recommend ticagrelor over clopidogrel in ACS for all patients at moderate to high risk of ischaemic events, regardless of initial treatment strategy and including those pre-treated with clopidogrel. The society also guided that dual anti-platelet therapy (P2Y12-inhibitor plus aspirin) beyond one year may be considered after careful assessment of the ischaemic and bleeding risks of patients.

AstraZeneca announced on 3 September 2015 that the 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.

The SOCRATES trial evaluating the efficacy of Brilinta/Brilique compared to aspirin in reducing thrombotic events in patients with acute ischaemic stroke and high-risk transient ischaemic attack saw its last patient randomised in November 2015. This trial is scheduled to report data in the first half of 2016. SOCRATES is an event-driven global clinical trial involving 13,200 patients in 33 countries and is part of the broader PARTHENON lifecycle programme for Brilinta/Brilique.

### b) Saxagliptin/dapagliflozin (type-2 diabetes)

On 15 October 2015 AstraZeneca announced that the FDA had issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for the investigational fixed-dose combination of saxagliptin and dapagliflozin for the treatment of adult patients with type-2 diabetes. The CRL stated that more clinical data are required to support the application. This includes clinical-trial data from ongoing or completed trials and may require information from new trials.

AstraZeneca will work closely with the FDA to determine the appropriate next steps for the NDA and remains committed to the development of the saxagliptin/dapagliflozin fixed-dose combination. This announcement did not affect ongoing interactions with other health authorities as part of individual-application procedures. Based on the information available, the CRL is not expected to affect the individual components of saxagliptin or dapagliflozin, which are approved for the treatment of adult patients with type-2 diabetes.

### c) Onglyza (type-2 diabetes)

AstraZeneca is working closely with regulators as part of the ongoing review of the full Phase III SAVOR cardiovascular outcomes trial data-set. The Company is currently awaiting a forthcoming decision from the FDA on a possible label update for Onglyza and Kombiglyze XR respectively.

### 3. Oncology

AstraZeneca continues to make progress in both early and late-stage programmes toward the goal of eliminating cancer as a major cause of death. In the third quarter, partnerships and collaborations were established with Inovio Pharmaceuticals, Peregrine Pharmaceuticals, Heptares Therapeutics and Mirati Therapeutics, all operating in the Immuno-Oncology sector. In parallel, the early portfolio is advancing molecules into human trials. In the quarter, the first patient was dosed with MEDI9447, a CD73 monoclonal antibody. Other targets, including GITR and TLR7/8 are planned to start shortly and will bolster the Company's ongoing Oncology efforts.

During the third quarter, the Company presented new data for its Oncology portfolio at the World Conference on Lung Cancer (WCLC) and the European Cancer Congress (ECC) to share ongoing progress.

#### a) AZD9291 (lung cancer)

At the WCLC data on AZD9291 was a major focus. In the 1st-line EGFR-mutation positive non-small cell lung cancer (NSCLC) setting, AZD9291 showed an overall response rate of 75%; 72% of patients were progression-free at 12 months and the longest duration of response was ongoing at 18 months.

At ECC, data were presented from a pooled analysis of the AURA Phase II trials (AURA extension and AURA2) in patients with EGFR-mutated NSCLC who had progressed on an EGFR-targeted treatment and whose tumours had the T790M resistance mutation. The data confirmed findings already reported at previous meetings for AZD9291; data from over 400 pre-treated patients with EGFRm T790M showed an objective response rate of 66% (95% confidence interval (CI); 61% to 71%). Preliminary median progression-free survival (PFS) was 9.7 months (95% CI; 8.3 months to non-calculable) and median duration of response was non-calculable (95% CI; 8.3 months to NC).

Furthermore, clinical anecdotes and pre-clinical data recently presented at the WCLC and the ECC suggest that AZD9291 penetrates the blood-brain barrier and may have activity on brain metastases. New data from the BLOOM (NCT02228369) study on the activity of AZD9291 in the brain is anticipated to be presented at the forthcoming American Association for Cancer Research NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts.

#### b) Durvalumab (solid and haematological tumours)

Durvalumab, AstraZeneca's cornerstone Immuno-Oncology medicine, is currently being tested in a number of clinical trials in monotherapy and in combination with other potential AstraZeneca medicines such as tremelimumab, with the potential to be part of the first chemotherapy-free treatment option for first-line patients across several tumour types.

Anti-PD1/PD-L1 monotherapy is transforming cancer medicine, but the benefit is largely limited to patients with PD-L1 positive tumours. Data from the combination of durvalumab and tremelimumab have demonstrated anti-tumour activity in patients with heavily pre-treated NSCLC regardless of PD-L1 status, including in patients with no tumour-cell-membrane PD-L1 staining. A comprehensive registration programme with durvalumab monotherapy and in combination with tremelimumab is underway across multiple tumour types, stages of disease, and lines of therapy. Additional combination trials of durvalumab with other immunotherapies, targeted therapies and chemotherapies are also underway.

A development programme for durvalumab in haematological malignancies in combination with effective therapies through the alliance with Celgene has also been accelerated.

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Finally a new potential biomarker for use with durvalumab was presented at the ECC, showing that gamma interferon, along with PD-L1, was shown to be associated with responses to durvalumab monotherapy in lung-cancer patients.

The table overleaf illustrates ongoing trials with durvalumab:

LUNG CANCER						
Name	Phase	Line of treatment	Population	Design	Timelines	Status
Early disease						
Monotherapy ADJUVANT III		N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	FPD Q1 2015	Recruiting
					Data expected 2020	
PACIFIC	III	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPD Q2 2014	Recruiting
					Data expected 2017	
Advanced/metastatic disease						
Monotherapy ATLANTIC II		3rd line	PD-L1+ NSCLC	durvalumab (single arm)	FPD Q1 2014	First data by year-end 2015
					LPD Q2 2015 (certain cohorts)	
Combination therapy ARCTIC	III	3rd line	NSCLC	durvalumab vs SoC (PD-L1+) or durvalumab vs tremelimumab vs durva + treme vs SoC (PD-L1-)	FPD Q2 2015	Recruiting
					Data expected 2017	
CAURAL	III	2nd line	T790M+ NSCLC	AZD9291 vs AZD9291 + durvalumab	FPD Q3 2015	Initiated enrolment; currently on partial hold to characterise incidence of interstitial lung disease
					Data expected 2017	
MYSTIC	III	1st line	NSCLC (PFS endpoint)	durvalumab vs durva + treme vs SoC	FPD Q3 2015	First patient dosed

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Name	Phase	Line of treatment	Population	Design	Timelines	Status
NEPTUNE	III	1st line	NSCLC (OS endpoint)	durva + treme vs SoC	Data expected 2017	Awaiting first patient dosed
-	III	1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab	Data expected 2018	In preparation

METASTATIC HEAD AND NECK CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Monotherapy						
HAWK	II	2nd line	PD-L1+ SCCHN	durvalumab (single arm)	FPD Q1 2015	Recruiting
					Data expected H2 2016	Indication granted FDA Fast Track designation
Combination therapy						
CONDOR	II	2nd line	PD-L1-SCCHN	durvalumab vs tremelimumab vs durva + treme	FPD Q2 2015	Recruiting
					Data expected 2017	
EAGLE	III	2nd line	SCCHN	durvalumab vs durva + treme vs SoC	Data expected 2018	In preparation
KESTREL	III	1st line	SCCHN	durvalumab vs durva + treme vs SoC	FPD Q4 2015	In preparation
					Data expected 2018	

METASTATIC BLADDER CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
DANUBE	III	1st line	Cisplatin chemo-therapy-eligible/ineligible	durvalumab vs durva + treme vs SoC	FPD Q4 2015	First patient dosed
					Data expected 2018	

Name	Phase	Line of treatment	Indication	OTHER TUMOUR TYPES		Status
				Design	Timelines	
-	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
ALPS	II	2nd line	Metastatic pancreatic cancer	durva + treme (single arm)		In preparation

FPD=First Patient Dosed, LPD=Last Patient Dosed, SoC=Standard of Care

#### c) Lynparza (ovarian cancer)

Exploratory biomarker data presented at the ECC from a Phase II study of Lynparza are contributing to an enhanced scientific understanding of why some women with ovarian cancer without a BRCA1/2 mutation demonstrate anti-tumour activity with poly ADP-ribose polymerase (PARP) inhibitor treatment.

The data suggest that these women have tumours with mutations in other homologous recombination repair (HRR) genes that behave in a similar way to BRCA mutations. The potential of Lynparza to target tumours with HRR mutations beyond those in BRCA genes is under investigation in ongoing clinical trials.

#### 4. Infection, Neuroscience & Gastrointestinal

##### a) CAZ AVI (serious infections)

On 2 September 2015 the Company announced that the CAZ AVI pivotal trials RECAPTURE 1 and RECAPTURE 2 had met the objective of statistical non-inferiority compared to doripenem for both the EMA primary and FDA co-primary endpoints. In addition and for the EMA primary endpoint, CAZ AVI was statistically superior (at the 5% level) to doripenem. CAZ AVI is being developed to treat a broad range of Gram-negative bacterial infections which are becoming increasingly resistant to antibiotics and pose a threat to public health. CAZ AVI is currently under regulatory review by the EU.

##### b) FluMist/Fluenz (influenza vaccine)

The Company completed a strategic agreement in the third quarter with Daiichi Sankyo for the development and commercialisation of FluMist in the Japanese market.

##### c) Strategic Alliance to Accelerate New Antibiotic Development

On 16 September 2015 it was announced that multiple drugs to combat bioterrorism threats and other life-threatening bacterial infections will be developed under a public-private partnership agreement between the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) and AstraZeneca.

ASPR's Biomedical Advanced Research and Development Authority (BARDA) and AstraZeneca will manage and fund the portfolio over the next five years. In the arrangement, BARDA initially will provide \$50m toward product development and could provide up to a total of \$170m for development of additional products in the portfolio during the five-year period. The first candidate medicine in the portfolio combines two antibiotics, Aztreonam and



Edgar Filing: ASTRAZENECA PLC - Form 6-K

Avibactam, known together as ATM AVI. The Phase I trial for ATM AVI was commenced by the Company in 2012.

ASTRAZENECA DEVELOPMENT PIPELINE 30 SEPTEMBER 2015

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 product.

Compound	Mechanism	Area Under Investigation	Date Commenced	Estimated Regulatory Submission / Submission			
				US	Acceptance† 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	Q4 2015	Q4 2015	N/A	N/A
lesinurad CLEAR 1,2 CRYSTAL	selective uric acid reabsorption inhibitor (URAT-1)	chronic treatment of hyperuricemia in patients with gout	Q4 2011	Accepted	Accepted		
PT003 GFF PINNACLE	LABA / LAMA	COPD	Q2 2013	Accepted	H2 2016	2017	2017
PT010	LABA / LAMA / ICS	COPD	Q3 2015	2018	2018	2018	2018
tralokinumab STRATOS 1,2 TROPOS	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018	
Cardiovascular and Metabolic Disease							
Brilinta/Brilique1	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Submitted	Launched
Epanova#	omega-3 carboxylic acids	severe hypertrigly-ceridemia		Approved		2018	2018
Farxiga/Forxiga2 roxadustat# OLYMPUS ROCKIES	SGLT2 inhibitor hypoxia-inducible factor prolyl hydroxylase inhibitor	type-2 diabetes anaemia in CKD/ESRD	Q3 2014	Launched 2018	Launched N/A	Launched N/A	Submitted H2 2015
Oncology							

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AZD9291 AURA, AURA 2	EGFR tyrosine kinase inhibitor	≥2nd-line advanced EGFRm T790M NSCLC	Q2 2014	Accepted (Breakthrough designation, Priority Review) 2017	Accepted (Accelerated assessment) 2017	Accepted (Priority Review) 2017	2017
AZD9291 FLAURA	EGFR tyrosine kinase inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	2017	2017	2017	2020
AZD9291+dur-valumab# CAURAL3	EGFR tyrosine kinase inhibitor + PD-L1 mAb	≥2nd-line advanced EGFRm T790M NSCLC	Q3 2015				
cediranib ICON 6	VEGFR tyrosine kinase inhibitor	PSR ovarian cancer	Q2 2007		Accepted (Orphan Drug) 2017		
durvalumab# ATLANTIC¶	PD-L1 mAb	3rd-line NSCLC (PD-L1 positive)	Q1 2014	H1 2016 (Fast Track) 2017	2017	2017	
durvalumab# PACIFIC	PD-L1 mAb	stage III NSCLC	Q2 2014	2017	2020	2020	
durvalumab# HAWK¶	PD-L1 mAb	2nd-line SCCHN (PD-L1 positive)	Q1 2015	2017 (Fast Track)	2017	2017	
durvalumab# + tremelimumab ARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	2017	2017	2017	
durvalumab# + tremelimumab CONDOR¶	PD-L1 mAb + CTLA-4 mAb	2nd-line SCCHN (PD-L1 negative)	Q2 2015	2017	2017	2017	
durvalumab# + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	2017	2017	2017	
moxetumomab pasudotox#	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018	2018		
selumetinib# ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018	2018		
selumetinib# SELECT-1	MEK inhibitor	2nd-line KRASm NSCLC	Q4 2013	2017	2017		
tremelimumab¶ DETERMINE	CTLA-4 mAb	mesothelioma	Q2 2014	H1 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#	cephalos-porin/ beta lactamase inhibitor	hospital-acquired pneumonia/ ventilator-associated pneumonia	Q2 2013	N/A	Accepted		2017
Zinforo#	extended spectrum cephalosporin	pneumonia/skin infections		N/A	Launched	N/A	Submitted

with affinity to  
penicillin-binding  
proteins

¶ Registrational Phase II/III study.

- 1 Brilinta in the US; Brilique in rest of world.
- 2 Farxiga in the US; Forxiga in rest of world.
- 3 Temporarily closed to enrolment.

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
AZD7594	inhaled SGRM	asthma/COPD	II	Q3 2015
AZD7624	inhaled P38 inhibitor	COPD	II	Q4 2014
AZD9412#	inhaled interferon beta	asthma/COPD	II	Q1 2010
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
MEDI-551#	CD19 mAb	neuromyelitis optica2	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	idiopathic pulmonary fibrosis	II	Q4 2012
tralokinumab	IL-13 mAb	atopic dermatitis	II	Q1 2015
AZD1419#	TLR9 agonist	asthma	I	Q3 2013
AZD7986	DPP1	COPD	I	Q4 2014
AZD8999	MABA	COPD	I	Q4 2013
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 Disease				
AZD4901	NK3 receptor antagonist	polycystic ovarian syndrome	II	Q2 2013
AZD9977			I	Q3 2015

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	selective mineralocorticoid receptor modulator	diabetic kidney disease		
MEDI0382	GLP-1/ glucagon dual agonist	diabetes / obesity	I	Q1 2015
MEDI6012	LCAT	ACS	I	Q1 2012
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
AZD4547	FGFR tyrosine kinase inhibitor	solid tumours	II	Q4 2011
AZD5069+durvalumab#	CXCR2 + PD-L1 mAb			
AZD9150#+durvalumab#	STAT3 inhibitor + PD-L1 mAb	SCCHN	II	Q3 2015
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
AZD3759 BLOOM	EGFR tyrosine kinase inhibitor	brain metastases in advanced EGFRm NSCLC	I	Q4 2014
AZD9291 BLOOM	EGFR tyrosine kinase inhibitor			
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
AZD9291 + (durvalumab# or selumetinib# or savolitinib#) TATTON	EGFR tyrosine kinase inhibitor + (PD-L1 mAb or MEK inhibitor or	advanced EGFRm NSCLC	I	Q3 2014

Edgar Filing: ASTRAZENECA PLC - Form 6-K

AZD9496	MET tyrosine kinase inhibitor) selective oestrogen receptor downregulator (SERD)	ER+ breast cancer	I	Q4 2014
durvalumab# after (AZD9291 or Iressa or (selumetinib# +docetaxel) or tremelimumab)	PD-L1 mAb + (EGFR tyrosine kinase inhibitor or MEK inhibitor or CTLA-4 mAb)	NSCLC	I	Q3 2014
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 + trametinib1	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
MEDI3617#	ANG-2 mAb	solid tumours	I	Q4 2010
MEDI6383#	OX40 agonist	solid tumours	I	Q3 2014
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
Infection, Neuroscience and Gastrointestinal				
AZD3241	myeloperoxidase inhibitor	multiple system atrophy	II	Q2 2012
AZD3293#	beta-secretase inhibitor	Alzheimer's disease	II	Q4 2014
AZD5847	oxazolidinone anti-bacterial inhibitor	tuberculosis	II	Q4 2012
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
MEDI8897#	RSV mAb-YTE	passive RSV prophylaxis	II	Q1 2015 (FDA Fast Track)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

susatoxumab (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
MEDI-550	pandemic influenza virus vaccine	pandemic influenza prophylaxis	I	Q2 2006
MEDI1814	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI3902	anti-Psl/PcrV	prevention of nosocomial pseudomonas pneumonia	I	Q3 2014 (FDA Fast Track)
MEDI8852	influenza A mAb	influenza A treatment	I	Q1 2015

1 MedImmune-sponsored study in collaboration with Novartis AG.

2 Neuromyelitis optica: Now lead indication. Multiple sclerosis Phase I study continuing.

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	ICS/LABA	as-needed use in mild asthma	Q4 2014	N/A	2018		2019
Symbicort1	ICS/LABA	breath actuated Inhaler asthma/COPD		2018			
Cardiovascular and Metabolism							
Brilinta/Brilique2 EUCLID	P2Y12 receptor antagonist	outcomes study in patients with peripheral artery disease	Q4 2012	2017	2017	2017	2018
Brilinta/Brilique2 HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises in paediatric patients with sickle cell disease	Q4 2014	2020	2020		
Brilinta/Brilique2 PEGASUS-TIMI 54	P2Y12 receptor antagonist	outcomes study in patients with prior myocardial infarction	Q4 2010	Launched (Priority Review)	Accepted	Accepted	H2 2016
Brilinta/Brilique2 SOCRATES	P2Y12 receptor antagonist	outcomes study in patients with stroke or TIA	Q1 2014	H1 2016	H1 2016	H2 2016	2017
Brilinta/Brilique2 THEMIS	P2Y12 receptor antagonist	outcomes study in patients with type-2 diabetes and CAD, but without a previous history of MI or stroke	Q1 2014	2018	2018	2018	2019

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes study	Q2 2010	2018	2018	2018	
Bydureon weekly suspension	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	Q4 2015	Q4 2015		
Epanova STRENGTH	omega-3 carboxylic acids	outcomes study in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low HDL-cholesterol	Q4 2014	2020	2020	2020	2020
Epanova/ Farxiga/Forxiga3	omega-3 carboxylic acids/ SGLT2 inhibitor	Non-alcoholic fatty liver disease/non-alcoholic steatohepatitis (NASH)	Q1 2015				
Farxiga/Forxiga3 DECLARE- TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes study	Q2 2013	2020	2020		
Farxiga/Forxiga3 Kombiglyze XR/Komboglyze4	SGLT2 inhibitor/ DPP-4 inhibitor/ metformin FDC	type-1 diabetes type-2 diabetes	Q4 2014	2018 Launched	2017 Launched	2018	Submitted
Onglyza SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes study	Q2 2010	Accepted	Launched		Q4 2015
saxagliptin/ dapagliflozin FDC	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes	Q2 2012	Accepted 5	Accepted		
Xigduo XR/ Xigduo6	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	H1 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	H2 2016	H2 2016	
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 triple negative breast cancer	Q2 2014	2020	2020	2020	
Lynparza (olaparib) OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer pancreatic cancer	Q2 2014	H2 2016	H2 2016	H2 2016	
			Q1 2015	2018	2018	2018	

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Lynparza (olaparib) POLO	PARP inhibitor						
Lynparza (olaparib)	PARP inhibitor	prostate cancer	Q3 2014				
Infection, Neuroscience Diprivan#	and Gastrointestinal 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	Q4 2015
Nexium	proton pump inhibitor	stress ulcer prophylaxis					H2 2016
Nexium	proton pump inhibitor	paediatrics		Launched	Launched	H2 2016	Accepted

- 1 Development of a new breath-actuated pressurised metered dose inhaler is ongoing.
- 2 Brilinta in the US; Brilique in rest of world.
- 3 Farxiga in the US; Forxiga in rest of world.
- 4 Kombiglyze XR in the US; Komboglyze in the EU.
- 5 Complete Response Letter received October 2015.
- 6 Xigduo XR in the US; Xigduo in the EU.

Terminations (discontinued projects between 1 July and 30 September 2015)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	AZD5213	Safety / efficacy	Tourette's syndrome / neuropathic pain
NME	MEDI-551# + MEDI0680	Safety / efficacy	diffuse large B-cell lymphoma
NME	MEDI6469#	Strategic	solid tumours
NME	durvalumab# + MEDI6469#	Strategic	solid tumours
NME	MEDI6469# + rituximab	Strategic	solid tumours
NME	MEDI6469# + tremelimumab	Strategic	solid tumours
NME	sifalimumab#	Strategic	systemic lupus erythematosus chronic
LCM	MEDI-551#	Safety / efficacy	lymphocytic leukaemia
LCM	moxetumomab pasudotox#	Safety / efficacy	paediatric acute lymphoblastic



## leukemia

1 SLE project stopped but molecule under evaluation for alternative indications.

## Completed Projects / Divestitures

Compound	Mechanism	Area Under Investigation	Completed/ Divested	Estimated Regulatory Submission			Acceptance† China
				US	EU	Japan	
Bydureon Dual Chamber Pen	GLP-1 receptor agonist	type-2 diabetes	Completed	Launched	Launched	Launched	
brodalumab AMVISION-1,21	IL-17R mAb	psoriatic arthritis	Partnered				
Caprelsa2	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	medullary thyroid cancer	Divested	Launched	Launched	Approved <sup>3</sup>	Accepted
Caprelsa2	VEGFR / EGFR tyrosine kinase inhibitor with RET kinase activity	differentiated thyroid cancer	Divested				
Entocort <sup>4</sup>	glucocorticoid steroid	Crohn's disease / ulcerative colitis	Completed/Divested	Launched	Launched	Q4 2015	N/A
Iressa	EGFR tyrosine kinase inhibitor	EGFRm NSCLC	Completed	Launched <sup>5</sup>	Launched	Launched	Launched

1 AstraZeneca has granted Valeant Pharmaceuticals an exclusive license to develop and commercialise brodalumab.

2 Divested to Genzyme (deal completed October 2015).

3 Approved in Japan in September 2015.

4 Global rights, outside the US, divested to Tillotts Pharma AG in July 2015. AstraZeneca continues to support the Japanese regulatory submission.

5 Launched in US Q3 2015.

## Condensed Consolidated Statement of Comprehensive Income

	2015	Restated 2014*
For the nine months ended 30 September	\$m	\$m
Product sales	17,434	19,412
Externalisation revenue	875	419

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Total revenue	18,309	19,831
Cost of sales	(3,377)	(4,175)
Gross profit	14,932	15,656
Distribution costs	(240)	(236)
Research and development expense	(4,251)	(4,080)
Selling, general and administrative costs	(8,444)	(8,916)
Other operating income and expense	1,029	62
Operating profit	3,026	2,486
Finance income	33	45
Finance expense	(783)	(703)
Share of after tax losses in joint ventures	(9)	(2)
Profit before tax	2,267	1,826
Taxation	(249)	(270)
Profit for the period	2,018	1,556
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	34	(498)
Tax on items that will not be reclassified to profit or loss	(12)	127
	22	(371)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(359)	(412)
Foreign exchange arising on designating borrowings in net investment hedges	(322)	(292)
Fair value movements on derivatives designated in net investment hedges	24	36
Amortisation of loss on cash flow hedge	1	1
Net available for sale (losses)/gains taken to equity	(63)	73
Tax on items that may be reclassified subsequently to profit or loss	84	30
	(635)	(564)
Other comprehensive income for the period, net of tax	(613)	(935)
Total comprehensive income for the period	1,405	621
Profit attributable to:		
Owners of the Parent	2,017	1,554
Non-controlling interests	1	2
	2,018	1,556
Total comprehensive income attributable to:		
Owners of the Parent	1,405	626
Non-controlling interests	-	(5)
	1,405	621
Basic earnings per \$0.25 Ordinary Share	\$1.60	\$1.23
Diluted earnings per \$0.25 Ordinary Share	\$1.59	\$1.23
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

Edgar Filing: ASTRAZENECA PLC - Form 6-K

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

Condensed Consolidated Statement of Comprehensive Income

	2015	Restated 2014*
	\$m	\$m
For the quarter ended 30 September		
Product sales	5,850	6,542
Externalisation revenue	95	67
Total revenue	5,945	6,609
Cost of sales	(1,041)	(1,415)
Gross profit	4,904	5,194
Distribution costs	(79)	(87)
Research and development expense	(1,429)	(1,552)
Selling, general and administrative costs	(2,679)	(3,132)
Other operating income and expense	453	118
Operating profit	1,170	541
Finance income	9	19
Finance expense	(246)	(236)
Share of after tax losses of joint ventures	(2)	(2)
Profit before tax	931	322
Taxation	(161)	(69)
Profit for the period	770	253
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(208)	(210)
Tax on items that will not be reclassified to profit or loss	45	42
	(163)	(168)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(348)	(476)
Foreign exchange arising on designating borrowings in net investment hedges	(105)	(170)
Fair value movements on derivatives designated in net investment hedges	4	47
Net available for sale (losses)/gains taken to equity	(34)	24
Tax on items that may be reclassified subsequently to profit or loss	41	25
	(442)	(550)
Other comprehensive income for the period, net of tax	(605)	(718)
Total comprehensive income for the period	165	(465)
Profit attributable to:		
Owners of the Parent	770	254
Non-controlling interests	-	(1)
	770	253
Total comprehensive income attributable to:		
Owners of the Parent	166	(463)
Non-controlling interests	(1)	(2)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

	165	(465)
Basic earnings per \$0.25 Ordinary Share	\$0.61	\$0.20
Diluted earnings per \$0.25 Ordinary Share	\$0.60	\$0.20
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	1,264

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

Condensed Consolidated Statement of Financial Position

	At 30 Sep 2015 \$m	At 31 Dec 2014 \$m	At 30 Sep 2014 \$m
<b>ASSETS</b>			
Non-current assets			
Property, plant and equipment	6,205	6,010	5,989
Goodwill	11,430	11,550	11,368
Intangible assets	19,997	20,981	20,351
Derivative financial instruments	479	465	390
Investments in joint ventures	48	59	66
Other investments	444	502	281
Other receivables	925	1,112	1,239
Deferred tax assets	1,391	1,219	1,408
	40,919	41,898	41,092
Current assets			
Inventories	2,193	1,960	1,957
Trade and other receivables	5,876	7,232	6,809
Other investments	496	795	804
Derivative financial instruments	30	21	7
Income tax receivable	523	329	349
Cash and cash equivalents	4,081	6,360	5,146
	13,199	16,697	15,072
Total assets	54,118	58,595	56,164
<b>LIABILITIES</b>			
Current liabilities			
Interest-bearing loans and borrowings	(2,671)	(2,446)	(2,399)
Trade and other payables	(10,593)	(11,886)	(10,149)
Derivative financial instruments	(25)	(21)	(17)
Provisions	(682)	(623)	(564)
Income tax payable	(2,065)	(2,354)	(2,695)
	(16,036)	(17,330)	(15,824)
Non-current liabilities			
Interest-bearing loans and borrowings	(8,276)	(8,397)	(7,527)
Deferred tax liabilities	(1,559)	(1,796)	(2,151)
Retirement benefit obligations	(2,542)	(2,951)	(2,733)
Provisions	(381)	(484)	(557)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Other payables	(7,956)	(7,991)	(6,906)
	(20,714)	(21,619)	(19,874)
Total liabilities	(36,750)	(38,949)	(35,698)
Net assets	17,368	19,646	20,466
EQUITY			
Capital and reserves attributable to equity holders of the Company			
Share capital	316	316	316
Share premium account	4,291	4,261	4,245
Other reserves	2,035	2,021	1,991
Retained earnings	10,707	13,029	13,893
	17,349	19,627	20,445
Non-controlling interests	19	19	21
Total equity	17,368	19,646	20,466

Condensed Consolidated Statement of Cash Flows

	2015	2014
For the nine months ended 30 September	\$m	\$m
Cash flows from operating activities		
Profit before tax	2,267	1,826
Finance income and expense	750	658
Share of after tax losses in joint ventures	9	2
Depreciation, amortisation and impairment	2,136	2,261
(Increase)/decrease in working capital and short-term provisions	(35)	1,752
Non-cash and other movements	(987)	208
Cash generated from operations	4,140	6,707
Interest paid	(433)	(446)
Tax paid	(954)	(1,045)
Net cash inflow from operating activities	2,753	5,216
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	285	(25)
Purchase of property, plant and equipment	(874)	(621)
Disposal of property, plant and equipment	16	143
Purchase of intangible assets	(1,379)	(1,662)
Disposal of intangible assets	737	-
Purchase of non-current asset investments	(47)	(9)
Disposal of non-current asset investments	59	-
Payments to joint ventures	-	(70)
Upfront payments on business acquisitions	-	(2,778)
Payment of contingent consideration on business acquisitions	(553)	(572)
Interest received	102	88
Payments made by subsidiaries to non-controlling interests	-	(10)
Net cash outflow from investing activities	(1,654)	(5,516)
Net cash inflow/(outflow) before financing activities	1,099	(300)
Cash flows from financing activities		
Proceeds from issue of share capital	30	263
Repayment of loans	(884)	(750)

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Dividends paid	(3,486)	(3,521)
Hedge contracts relating to dividend payments	(51)	(14)
Repayment of obligations under finance leases	(40)	(27)
Payments to acquire non-controlling interest	-	(102)
Movement in short-term borrowings	1,025	295
Net cash outflow from financing activities	(3,406)	(3,856)
Net decrease in cash and cash equivalents in the period	(2,307)	(4,156)
Cash and cash equivalents at the beginning of the period	6,164	8,995
Exchange rate effects	(70)	(30)
Cash and cash equivalents at the end of the period	3,787	4,809
Cash and cash equivalents consists of:		
Cash and cash equivalents	4,081	5,146
Overdrafts	(294)	(337)
	3,787	4,809

Condensed Consolidated Statement of Changes in Equity

	Share capital	Share premium account	Other reserves*	Retained earnings	Total	Non-controlling interests	Total equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 Jan 2014	315	3,983	1,966	16,960	23,224	29	23,253
Profit for the period	-	-	-	1,554	1,554	2	1,556
Other comprehensive income	-	-	-	(928)	(928)	(7)	(935)
Transfer to other reserves	-	-	25	(25)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,532)	(3,532)	-	(3,532)
Issue of Ordinary Shares	1	262	-	-	263	-	263
Share-based payments	-	-	-	(136)	(136)	-	(136)
Transfer from non-controlling interests to payables	-	-	-	-	-	(3)	(3)
Net movement	1	262	25	(3,067)	(2,779)	(8)	(2,787)
At 30 Sep 2014	316	4,245	1,991	13,893	20,445	21	20,466

	Share capital	Share premium account	Other reserves*	Retained earnings	Total	Non-controlling interests	Total equity
	\$m	\$m	\$m	\$m	\$m	\$m	\$m
At 1 Jan 2015	316	4,261	2,021	13,029	19,627	19	19,646
Profit for the period	-	-	-	2,017	2,017	1	2,018

Other comprehensive income	-	-	-	(612)	(612)	(1)	(613)
Transfer to other reserves	-	-	14	(14)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,537)	(3,537)	-	(3,537)
Issue of Ordinary Shares	-	30	-	-	30	-	30
Share-based payments	-	-	-	(176)	(176)	-	(176)
Net movement	-	30	14	(2,322)	(2,278)	-	(2,278)
At 30 Sep 2015	316	4,291	2,035	10,707	17,349	19	17,368

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

## Notes to the Interim Financial Statements

### 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These unaudited condensed consolidated interim financial statements ("interim financial statements") for the nine months ended 30 September 2015 have been prepared in accordance with IAS 34 Interim Financial Reporting 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 International Financial Reporting Standards (IFRSs) as adopted by the EU and as issued by the IASB. Except as detailed below, the interim financial statements have 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 now includes an increasing level of externalisation activity to create value from the strong science that exists in the pipeline. 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, are included in total revenue. Externalisation revenue includes development, commercialisation, partnership and out-licence 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 \$419m of income being reclassified from other operating income to externalisation revenue for the nine months ended 30 September 2014, and \$67m for the quarter ended 30 September 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 nine months ended 30 September 2015.

### Legal proceedings

The information contained in Note 5 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 six months ended 30 June 2015.

### Going concern

The Group has considerable financial resources available. As at 30 September 2015 the Group has \$4.4bn in financial resources (cash balances of \$4.1bn and undrawn committed bank facilities of \$3.0bn which are available until April 2020, with only \$2.7bn of debt due within one year). 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 a period of at least 12 months. Accordingly, the interim financial statements have been prepared on a going concern basis.

### Comparative figures

The comparative figures for the financial year ended 31 December 2014 are not the Company's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and delivered to the registrar of companies. The report of the auditors was (i) unqualified, (ii) did not include a reference to any matters to which the auditors 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.

## 2 RESTRUCTURING COSTS

Profit before tax for the nine months ended 30 September 2015 is stated after charging restructuring costs of \$662m (\$214m for the third quarter of 2015). These have been charged to profit as follows:

	YTD 2015	YTD 2014	Q3 2015	Q3 2014
	\$m	\$m	\$m	\$m
Cost of sales	124	72	23	48
Research and development expense	180	400	56	210
Selling, general and administrative costs	358	403	135	137
Other operating income and expense	-	292	-	-
Total	662	1,167	214	395



## 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 Movements \$m	Exchange Movements \$m	At 30 Sep 2015 \$m
Loans due after one year	(8,337)	-	19	82	(8,236)
Finance leases due after one year	(60)	-	19	1	(40)
Total long-term debt	(8,397)	-	38	83	(8,276)
Current instalments of loans	(912)	884	-	28	-
Current instalments of finance leases	(48)	40	(57)	2	(63)
Total current debt	(960)	924	(57)	30	(63)
Other investments - current	795	(275)	9	(33)	496
Net derivative financial instruments	465	41	(22)	-	484
Cash and cash equivalents	6,360	(2,205)	-	(74)	4,081
Overdrafts	(196)	(102)	-	4	(294)
Short-term borrowings	(1,290)	(1,025)	1	-	(2,314)
	6,134	(3,566)	(12)	(103)	2,453
Net debt	(3,223)	(2,642)	(31)	10	(5,886)

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

## 4 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 \$940m of other investments, \$1,175m of loans, and \$484m of derivatives as at 30 September 2015. The total fair value of interest-bearing loans and borrowings at 30 September 2015, which have a carrying value of \$10,947m in the Condensed Consolidated Statement of Financial Position, was \$12,038m. 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	-	-	-	5,169

Settlements	(298)	(255)	(553)	(572)
Revaluations	-	58	58	6
Discount unwind	305	90	395	277
Foreign exchange	-	2	2	(3)
At 30 September	5,393	1,408	6,801	5,391

## 5 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 and Interim Management Statement 2015 as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 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 third quarter of 2015 to 5 November 2015.

### Patent litigation

#### Brilinta (ticagrelor)

##### Patent proceedings in the US

In September and October 2015, AstraZeneca received Paragraph IV notices challenging patents listed in the FDA Orange Book with reference to Brilinta. AstraZeneca has received notice from 15 companies that each submitted an Abbreviated New Drug Application (ANDA) seeking to market ticagrelor. In October and November 2015, in the US District Court for the District of Delaware, AstraZeneca filed patent infringement lawsuits in response to these Paragraph IV notices from ANDA filers. Litigation is at an early stage and no trial dates have been set.

#### Crestor (rosuvastatin)

##### Patent proceedings outside the US

As previously disclosed, in April 2014, AstraZeneca received a writ of summons from Resolution Pharmaceuticals Inc. (Resolution) alleging partial invalidity and non-infringement of the supplementary protection certificate (SPC) related to the Crestor substance patent. In July 2015, the District Court of The Hague determined that the SPC does not extend to zinc salts of rosuvastatin and that Resolution's product does not infringe the SPC. AstraZeneca has

appealed and the appeal is scheduled to be heard on 12 November 2015.

In October 2015, in the UK, AstraZeneca received a notice letter from Resolution Chemicals Ltd. indicating that it has commenced an action in the UK Patent Courts alleging partial invalidity and non-infringement of the SPC related to the Crestor substance patent.

As previously disclosed, in 2014, in Japan, Shionogi & Co., Ltd. the licensor of the Crestor patent, received confirmation of a request for trial for patent invalidation in the Japanese Patent Office (JPO). The request was initiated by Teva Pharma Japan Inc. (Teva) and relates to the Crestor substance patent. In June 2015, the JPO dismissed Teva's claim. Teva appealed the decision but subsequently withdrew the appeal.

As previously disclosed, in Australia, in 2011 and 2012, AstraZeneca instituted proceedings against Actavis Australia Pty Ltd, Apotex Pty Ltd and Watson Pharma Pty Ltd asserting infringement of three formulation and method patents for Crestor. In March 2013, the Federal Court of Australia held all three patents at issue invalid. AstraZeneca appealed in relation to two patents. In August 2014, the Full Court of the Federal Court of Australia held the two patents invalid. In March 2015, the High Court granted AstraZeneca leave to appeal in relation to one method patent. On 2 September 2015, the High Court dismissed AstraZeneca's appeal.

#### Faslodex (fulvestrant)

##### Patent proceedings in the US

As previously disclosed, in June and September 2014 and in January 2015, AstraZeneca filed patent infringement lawsuits against Sandoz Inc., Sandoz International GmbH, Sagent Pharmaceuticals, Inc. and Glenmark Generics, Inc. USA in the US District Court in New Jersey relating to four patents listed in the FDA Orange Book with reference to Faslodex, after those companies sent Paragraph IV notices seeking FDA approval to market generic versions of Faslodex prior to the expiration of AstraZeneca's patents. Also as previously disclosed, in July 2015, AstraZeneca received a Paragraph IV notice from Agila Specialties Inc. (Agila), on behalf of Onco Therapies Limited (Onco), which was also seeking FDA approval to market a generic version of Faslodex prior to the expiration of the same four patents. In September 2015, AstraZeneca received a Paragraph IV notice from Mylan Pharmaceuticals, Inc., on behalf of Mylan Laboratories Limited (collectively, Mylan), after Agila and Onco assigned their ANDA to Mylan. In September 2015, AstraZeneca filed patent infringement lawsuits against Agila, Onco, and Mylan in the US District Court in New Jersey and also against Mylan in the US District Court in West Virginia relating to all four Orange Book listed patents. In October 2015, AstraZeneca received a Paragraph IV notice from Teva Pharmaceuticals USA Inc., which is also seeking FDA approval to market a generic version of Faslodex prior to the expiration of the same four patents.

##### 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. In October 2015, the Court ruled in Eurofarma's favour and invalidated AstraZeneca's patent. AstraZeneca is considering all available options, including appeal.

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 the revocation of the German part of the Faslodex formulation use patent, EP 1,250,138. In September 2015, AstraZeneca filed a request for a provisional injunction against Hexal in Regional Court Düsseldorf after Hexal threatened to launch a generic Faslodex product in the fourth quarter of 2015 which, following a hearing in October, remains pending.

#### Movantik (naloxegol)

##### Patent proceedings in the US

In October 2015, Neptune Generics LLC, an affiliate of Gerchen Keller Capital LLC, filed for Inter Partes Review (IPR) with the US Patent Office challenging the validity of one of the six patents listed in the FDA Orange Book with

reference to Movantik. The IPR relates to US Patent No. 7,786,133, which is licensed to AstraZeneca from Nektar Therapeutics. AstraZeneca is considering its response.

Nexium (esomeprazole)

Patent proceedings in the US

In September 2015, AstraZeneca received a Paragraph IV notice from Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (together Zydus) challenging certain patents listed in the FDA Orange Book with reference to Nexium oral suspension. Zydus submitted an ANDA seeking to market esomeprazole magnesium oral suspension. In October 2015, in response to Zydus' notice, AstraZeneca filed a patent infringement lawsuit against Zydus in the US District Court for the District of New Jersey. The litigation is at an early stage and no trial date has been set.

In October 2015, AstraZeneca received a Paragraph IV notice from Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (together DRL) challenging certain patents listed in the FDA Orange Book with reference to Nexium 24HR (OTC). DRL has submitted an ANDA seeking to market OTC esomeprazole magnesium capsules. AstraZeneca is reviewing DRL's notice.

Patent proceedings outside the US

As previously disclosed, in July 2014, in Canada, the Federal Court found Canadian Patent No. 2,139,653 invalid and not infringed by Apotex Inc. On 6 July 2015, AstraZeneca's appeal was dismissed. AstraZeneca has sought leave to appeal to the Supreme Court of Canada.

Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

Patent proceedings in the US

As previously disclosed, AstraZeneca filed lawsuits against a number of generics companies who sent notices that they had submitted ANDAs alleging that patents listed in the FDA Orange Book with reference to Onglyza and Kombiglyze, are invalid, unenforceable and/or will not be infringed by the products as described in the ANDAs. In August 2015, Teva Pharmaceuticals USA, Inc. sent a Paragraph IV certification with respect to the formulation patent, US Patent No. 8,628,799, on Kombiglyze and in October 2015 AstraZeneca filed a lawsuit in the US District Court for the District of Delaware.

Pulmicort Respules (budesonide inhalation suspension)

Patent proceedings in the US

As previously disclosed, in February 2015, the US District Court for the District of New Jersey (the District Court) determined that the asserted claims of US Patent No. 7,524,834 (the '834 Patent) was invalid. AstraZeneca appealed that decision and, on 7 May 2015, the US Court of Appeals for the Federal Circuit affirmed the District Court's decision and lifted the injunction that was issued pending the appeal. Since 2009, various injunctions were issued in this matter. Damages claims to recover under those injunctions have been filed and a provision has been taken.

Seroquel XR (quetiapine fumarate)

Patent proceedings outside the US

As previously disclosed, in Germany, Ratiopharm GmbH, CT Arzneimittel GmbH and AbZ Pharma GmbH brought a claim for 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. That claim has now been settled. AstraZeneca had taken a reserve in relation to this matter.

In April 2015, Mylan SAS (Mylan) brought a patent invalidation action against AstraZeneca's French designation of the Seroquel XR formulation patent, European Patent No. 0 907 364 (the '364 Patent). AstraZeneca is defending that action and has brought a claim against Mylan for infringement of the '364 Patent. In the third quarter of 2015, Mylan launched its generic Seroquel XR product at-risk. As previously disclosed, in July 2014, AstraZeneca has a similar action pending with Accord Healthcare France SAS and Accord Healthcare Limited (together, Accord), wherein

Accord asserts that the '364 Patent is invalid. AstraZeneca is defending against that claim and claims patent infringement.

#### Product liability litigation

##### Onglyza (saxagliptin)

As previously disclosed, in 2014, 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 plaintiffs claiming injuries, including pancreatic cancer. AstraZeneca was recently served with a case, claiming congestive heart failure, from treatment with Onglyza.

#### Commercial litigation

##### Nexium settlement anti-trust litigation

As previously disclosed, a jury returned a verdict in favour of AstraZeneca in a Multi-District Litigation class action and individual lawsuits alleging that AstraZeneca's settlements of certain patent litigation in the US relating to Nexium violated US anti-trust law and various state laws. In July 2015, the Court denied the plaintiffs' motions for a new trial and preliminary injunction. In September 2015, the Court entered judgment in favour of AstraZeneca. Plaintiffs have appealed the judgment.

##### Nexium/Prilosec trademark litigation

In October 2015, AstraZeneca filed separate complaints in the US Federal District Court in 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. The Court has issued a temporary restraining order against Camber's sales of generic esomeprazole magnesium in purple capsules and is yet to consider the case against Dr. Reddy's.

##### Synagis (palivizumab)

As previously disclosed, in September 2011, MedImmune filed an action against AbbVie, Inc. (AbbVie) (formerly Abbott International, LLC) in the Circuit Court for 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 \$93.8m. MedImmune intends to appeal the jury's verdict.

#### Government investigations/proceedings

##### Crestor (rosuvastatin calcium)

As previously disclosed, the DOJ and all US states have declined to intervene in the civil component of an investigation regarding Crestor. Prior to September 2015, one additional component of the investigation remained. In September 2015, AstraZeneca was informed that the additional component of the investigation has been closed.

##### Seroquel IR and Seroquel XR (quetiapine fumarate) Qui Tam litigation

AstraZeneca has been named as a defendant in a lawsuit filed in US Federal Court in New York under the qui tam (whistleblower) provisions of the federal and certain state False Claims Acts. The lawsuit alleges that the Company misrepresented the safety profile of and improperly promoted Seroquel IR and Seroquel XR. The US government and the named states have declined to intervene in this case.

#### Other government investigations/proceedings

#### Foreign Corrupt Practices Act

Edgar Filing: ASTRAZENECA PLC - Form 6-K

As previously disclosed, in connection with investigations into anti-bribery and corruption issues in the pharmaceutical industry, AstraZeneca has received inquiries from enforcement agencies, including the DOJ and the Securities and Exchange Committee, regarding, among other things, sales practices, internal controls, certain distributors and interactions with healthcare providers and other government officials in several countries. AstraZeneca is cooperating with these inquiries. AstraZeneca's investigation has involved indications of inappropriate conduct in certain countries, including China. Resolution of these matters could involve the payment of fines and/or other remedies.

6 PRODUCT ANALYSIS - YTD 2015

	World		US		Europe		Established ROW		Emerging Markets	
	YTD	CER	YTD	CER	YTD	CER	YTD	CER	YTD	CER
	2015	%	2015	%	2015	%	2015	%	2015	%
	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Respiratory, Inflammation & Autoimmunity:										
Symbicort	2,535	(2)	1,110	(1)	825	(13)	304	5	296	33
Pulmicort	740	17	148	(5)	88	(10)	61	3	443	40
Tudorza/Eklira	143	n/m	77	n/m	57	n/m	7	n/m	2	n/m
Daliresp	72	n/m	72	n/m	-	n/m	-	n/m	-	n/m
Duaklir	15	n/m	-	-	14	n/m	1	n/m	-	-
Others	193	(5)	12	(45)	66	(6)	18	(5)	97	4
Total Respiratory, Inflammation & Autoimmunity	3,698	8	1,419	10	1,050	(5)	391	6	838	32
Cardiovascular & Metabolic disease:										
Brilinta/Brilique	445	44	170	65	170	19	27	33	78	93
Onglyza	594	2	322	(15)	108	17	48	29	116	47
Bydureon	425	38	360	33	56	69	6	75	3	33
Farxiga/Forxiga	340	180	184	167	89	159	22	160	45	350
Byetta	244	(1)	166	4	45	(15)	15	(15)	18	24
Legacy:										
Crestor	3,695	(4)	2,067	(4)	691	(9)	417	(3)	520	2
Seloken/Toprol-XL	550	4	70	(8)	73	(4)	9	(27)	398	10
Atacand	272	(15)	27	(18)	80	(28)	21	(29)	144	(3)
Others	464	(10)	41	(33)	108	(15)	44	(19)	271	(1)
Total Cardiovascular & Metabolic Disease	7,029	3	3,407	3	1,420	(1)	609	(1)	1,593	11
Oncology:										
Iressa	414	(2)	2	n/m	96	(6)	102	(11)	214	6
Lynparza	58	n/m	46	n/m	12	n/m	-	-	-	-
Legacy:										
Zoladex	618	8	22	22	128	(13)	202	(1)	266	29
Faslodex	519	7	261	4	154	-	39	5	65	46
Casodex	204	(6)	1	(80)	23	(13)	98	(11)	82	10
Arimidex	190	(7)	15	25	37	(27)	59	(15)	79	13
Others	106	18	19	(5)	22	4	44	59	21	-
Total Oncology	2,109	6	366	20	472	(6)	544	(3)	727	19

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Infection, Neuroscience  
& Gastrointestinal:

Nexium	1,932	(26)	727	(48)	209	(10)	411	(4)	585	-
Seroquel XR	784	(9)	540	-	160	(28)	20	(32)	64	3
Synagis	387	(22)	157	(41)	230	-	-	-	-	-
Losec/Prilosec	263	(6)	18	(5)	71	(13)	55	(19)	119	10
FluMist/Fluenz	97	(39)	88	(38)	9	(38)	-	n/m	-	-
Movantik/Moventig	14	n/m	13	n/m	1	n/m	-	-	-	-
Others	1,121	(6)	167	(13)	280	(15)	206	2	468	(1)
Total Infection, Neuroscience & Gastrointestinal	4,598	(18)	1,710	(33)	960	(14)	692	(5)	1,236	-
TOTAL PRODUCT SALES	17,434	(2)	6,902	(8)	3,902	(6)	2,236	(2)	4,394	12

7 PRODUCT SALES ANALYSIS - Q3 2015

	World		US		Europe		Established ROW		Emerging Markets	
	Q3 2015 \$m	CER %	Q3 2015 \$m	CER %	Q3 2015 \$m	CER %	Q3 2015 \$m	CER %	Q3 2015 \$m	CER %
Respiratory, Inflammation & Autoimmunity:										
Symbicort	848	(4)	393	(1)	243	(21)	103	(2)	109	42
Pulmicort	222	16	40	(22)	22	(19)	20	14	140	46
Tudorza/Eklira	58	n/m	32	n/m	21	n/m	3	n/m	2	n/m
Daliresp	33	n/m	33	n/m	-	n/m	-	n/m	-	n/m
Duaklir	8	n/m	-	n/m	8	n/m	-	n/m	-	n/m
Others	61	(6)	2	(60)	20	(4)	8	(10)	31	3
Total Respiratory, Inflammation & Autoimmunity	1,230	7	500	11	314	(11)	134	3	282	38
Cardiovascular & Metabolic disease:										
Brilinta/Brilique	170	48	69	73	60	16	10	30	31	119
Onglyza	203	-	111	(15)	37	7	16	27	39	32
Bydureon	162	34	138	29	21	67	3	200	-	(50)
Farxiga/Forxiga	135	107	69	60	36	110	11	n/m	19	213
Byetta	72	(17)	45	(18)	15	(19)	5	(38)	7	13
Legacy:										
Crestor	1,218	(3)	693	2	222	(13)	135	(2)	168	(4)
Seloken/Toprol-XL	172	(2)	22	(4)	24	(6)	2	(40)	124	1
Atacand	78	(24)	9	(31)	27	(14)	6	(42)	36	(26)
Others	137	(23)	6	(75)	33	(19)	14	(15)	84	(14)
Total Cardiovascular & Metabolic Disease	2,347	2	1,162	4	475	(2)	202	2	508	2
Oncology:										
Iressa	141	1	2	n/m	30	(10)	34	(11)	75	13
Lynparza	28	n/m	20	n/m	8	n/m	-	-	-	-
Legacy:										

Edgar Filing: ASTRAZENECA PLC - Form 6-K

Zoladex	209	8	8	14	43	(9)	69	-	89	24
Faslodex	186	11	96	8	53	(2)	14	6	23	78
Casodex	65	(6)	-	(100)	8	-	32	(5)	25	(4)
Arimidex	64	(1)	8	167	12	(26)	19	(15)	25	12
Others	35	11	6	(14)	7	(11)	15	31	7	25
Total Oncology	728	9	140	30	161	(4)	183	(3)	244	20
Infection, Neuroscience & Gastrointestinal:										
Nexium	641	(24)	248	(47)	66	(8)	139	1	188	1
Seroquel XR	258	(14)	187	(4)	47	(34)	6	(36)	18	(12)
Synagis	117	(3)	(3)	(150)	120	5	-	-	-	n/m
Losec/Prilosec	82	(5)	6	-	23	(16)	16	(23)	37	18
FluMist/Fluenz	76	(48)	67	(50)	9	(38)	-	-	-	-
Movantik/Moventig	10	n/m	9	n/m	1	n/m	-	n/m	-	n/m
Others	361	(2)	61	36	85	(20)	65	7	150	(2)
Total Infection, Neuroscience & Gastrointestinal	1,545	(17)	575	(33)	351	(14)	226	(1)	393	-
TOTAL PRODUCT SALES	5,850	(2)	2,377	(6)	1,301	(8)	745	-	1,427	10

Shareholder Information

Announcements and Meetings

A Announcement of full year and fourth quarter 4 February 2016  
results

Announcement of first quarter 2016 results 29 April 2016

A Annual General Meeting 29 April 2016

Announcement of half year and second  
quarter 2016 results 28 July 2016

Announcement of nine months and third  
quarter 2016 results 10 November 2016

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 Depository 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.

#### 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 Daliresp, a trademark of Takeda GmbH; Duaklir Genuair, Duaklir, Eklira, and Tudorza, trademarks of Almirall, S.A.; Epanova, a trademark of Chrysalis Pharma AG; Myalept, a trademark of Aegerion Pharmaceuticals, Inc.; and Zinforo, a trademark of Forest Laboratories.

#### Addresses for Correspondence

Registrar and Transfer Office Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK	US Depository Citibank Shareholder Services PO Box 43077 Providence RI 02940-3077 USA	Registered Office 2 Kingdom Street London W2 6BD UK	Swedish Central Securities Depository Euroclear Sweden AB PO Box 191 SE-101 23 Stockholm Sweden
--	---	---	---

Tel (freephone in UK): 0800 389 1580	Tel: +44 (0)207 500 2030	Tel: +44 (0)20 7604 8000	Tel: +46 (0)8 402 9000
Tel (outside UK): +44 (0)121 415 7033	or +1 877 248 4237 (1 877-CITI-ADR)/ E-mail: citiadr@citi.com		

#### 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 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: 05 November 2015

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