

AstraZeneca PLC

2 February 2017 07:00

Full-Year and Q4 2016 Results Performance in line with expectations; 2017 has the potential to be a defining year

Financial Summary

	FY 2016				Q4 2016			
	¢m	% ch	ange		\$m	% change		
	\$m	CER ¹	Actual		φIII	CER	Actual	
Total Revenue	23,002	(5)	(7)		5,585	(12)	(13)	
Product Sales	21,319	(8)	(10)		5,260	(15)	(15)	
Externalisation Revenue	1,683	59	58		325	77	69	
Reported Operating Profit	4,902	9	19		2,533	n/m	n/m	
Core Operating Profit ²	6,721	(7)	(3)		2,026	15	30	
Reported Earnings Per Share (EPS)	\$2.77	9	24		\$1.46	93	n/m	
Core EPS	\$4.31	(5)	1		\$1.21	9	29	

The fall in Product Sales primarily reflected the entry of *Crestor* generic medicines in the US; *Crestor* represents the last anticipated blockbuster³ patent expiry, ahead of significant late-stage pipeline news flow
 Good progress on cost control in the year, reflecting the evolving shape of the business:

Reported and Core R&D cost growth of 2% to \$5,890m and 5% to \$5,631m, respectively, including the absorption of the R&D costs of Acerta Pharma and ZS Pharma

- Reported and Core SG&A costs declined by 12% to \$9,413m and by 9% to \$8,169m, respectively

- Reported EPS increased by 9% in the year to \$2.77, reflecting a revaluation of acquisition-related liabilities. A 5% fall in Core EPS was driven by a corresponding rate of decline in Total Revenue
- A second interim dividend of \$1.90 per share has been declared, bringing the dividend for the full year to \$2.80 per share. The Board reaffirms its commitment to the Company's progressive dividend policy

Commercial Highlights

The Growth Platforms grew by 5% in the year (Q4 2016: Up by 3%). Highlights included:

- Emerging Markets: 6% growth (Q4 2016: Up by 7%) to \$5,794m, supported by China, up by 10% to \$2,636m
- Diabetes: Growth of 11%, as Farxiga became the Company's largest-selling Diabetes medicine
- Japan: A sales decline of 3% to \$2,184m, reflecting the biennial price reduction in the year
- Brilinta: Sales grew by 39% to \$839m; on track to be a blockbuster medicine
- Respiratory: A decline of 3% to \$4,753m (Q4 2016: Down by 5%), reflecting US pricing pressure for Symbicort
- New Oncology: Strong sales of \$664m (Q4 2016: \$216m); Tagrisso delivered sales of \$423m in its first year

Achieving Scientific Leadership

The pipeline-driven progress of AstraZeneca continued in the year. Twelve potential new medicines are in Phase III/under regulatory review, primarily within the three therapy areas of Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Oncology pipeline, which attracted over 40% of R&D investment in the year, is progressing ahead of the Company's expectations, in particular *Tagrisso* and the Immuno-Oncology programmes. The table below highlights successes in the late-stage pipeline since the last results announcement:

Regulatory Submission Acceptances	 durvalumab - bladder cancer (US) <i>Tagrisso</i> - lung cancer (AURA3 trial) (US, EU) <i>Faslodex</i> - breast cancer (1st line) (US, EU) roxadustat - anaemia (CN) (rolling submission) benralizumab - severe, uncontrolled asthma (US, EU)
Other Key Developments	 Priority Review Designation: durvalumab (US) Priority Review Designation: <i>Tagrisso</i> (US)



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

"Our financial results in the year were in line with expectations and reflected the ongoing transition of our company. We brought a sharper strategic focus to our three main therapy areas, boosting pipeline productivity further as we saw with Priority Review Designations for durvalumab and *Tagrisso*, as well as regulatory submission acceptances for durvalumab in bladder cancer and for benralizumab in severe, uncontrolled asthma. Our underlying business is growing as a new AstraZeneca emerges, driven by competitive franchises and Emerging Markets.

2017 has the potential to be a turning point for our company as we near the end of our patent-expiry period and bring new medicines to patients across the globe. We anticipate defining data, in particular from our outstanding pipeline of Immuno-Oncology and targeted treatments. This year we have the opportunity to launch several life-changing medicines for cancer, respiratory and metabolic diseases. It is an exciting time as we rapidly approach the inflection point for our anticipated return to long-term growth, built on the solid foundations of a science-led pipeline."

FY 2017 Guidance

The Company provides guidance on Total Revenue and Core EPS only. All measures in this section are at constant exchange rates¹:

Total Revenue	A low to mid single-digit percentage decline
Core EPS	A low to mid teens percentage decline*

*The Core EPS guidance anticipates a normalised effective Core tax rate of 16-20% (FY 2016: 11%).

Guidance is subject to base-case assumptions of the progression of the pipeline and the extensive level of news flow listed on the following page. Variations in performance between quarters can be expected to continue, with year-on-year comparisons expected to ease in the second half of FY 2017, when the impact of the entry of *Crestor* generic medicines in the US will annualise.

The Company presents Core EPS guidance. It is unable to provide guidance on a Reported/GAAP basis because the Company cannot reliably forecast material elements of the Reported/GAAP result, including the fair-value adjustments arising on acquisition-related liabilities, intangible-asset impairment charges and legal-settlement provisions. Please refer to the section 'Cautionary Statements Regarding Forward-Looking Statements' at the end of this announcement.

In addition to the guidance listed above, the Company also provides indications in other areas of the Income Statement. The sum of Externalisation Revenue and Other Operating Income in FY 2017 is anticipated to be ahead of that in FY 2016. Sustainable and ongoing income⁴ is expected to increase further as a proportion of Externalisation Revenue in FY 2017. Core R&D costs are expected to be broadly in line with those in FY 2016 and the Company anticipates a further reduction in Core SG&A costs, reflecting the evolving shape of the business. A full explanation of these items is listed in the Operating & Financial Review.

FY 2017 Currency Impact

Based only on average exchange rates in January 2017 and the Company's published currency sensitivities, there is expected to be a low single-digit percentage adverse impact from currency movements on Total Revenue and Core EPS in the year. Further details on currency sensitivities are contained within the Operating and Financial Review.

Notes

- 1. All growth rates and guidance are shown at constant exchange rates (CER) unless specified otherwise.
- 2. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
- 3. The term 'blockbuster' is defined as a medicine with Product Sales in excess of \$1bn over a period of 12 months.
- 4. Sustainable and ongoing income is defined as Externalisation Revenue excluding upfront receipts.



Pipeline: Forthcoming Major News Flow

Innovation is critical to addressing unmet patient needs and is at the heart of the Company's growth strategy. The focus on research and development is designed to yield strong results from the pipeline.

H1 2017	Faslodex - breast cancer (1st line): Regulatory decision (JP) Lynparza - ovarian cancer (2nd line): Regulatory submission Lynparza - breast cancer: Data readout Tagrisso - lung cancer (AURA3): Regulatory decision (US) durvalumab - bladder cancer: Regulatory decision (US) durva +/- treme - lung cancer (ARCTIC): Data readout acalabrutinib - blood cancer: Data readout, regulatory submission (US) (Phase II)# Bydureon - autoinjector: Regulatory submission (US) saxagliptin/dapagliflozin - type-2 diabetes: Regulatory decision (US) ZS-9 (sodium zirconium cyclosilicate) - hyperkalaemia: Regulatory decision (US, EU) Bevespi - COPD: Regulatory submission (EU) benralizumab - severe, uncontrolled asthma: Regulatory submission (JP)
Mid-2017	durva +/- treme - lung cancer (MYSTIC): Data readout
H2 2017	Faslodex - breast cancer (1st line): Regulatory decision (US, EU) Lynparza - breast cancer: Regulatory submission Lynparza - ovarian cancer (1st line): Data readout Tagrisso - lung cancer: Regulatory decision (CN) Tagrisso - lung cancer (AURA3): Regulatory decision (EU) Tagrisso - lung cancer (1st line): Data readout durvalumab - lung cancer (PACIFIC): Data readout, regulatory submission durva +/- treme - lung cancer (MYSTIC): Regulatory submission durva +/- treme - lung cancer (ARCTIC): Regulatory submission durva +/- treme - lung cancer (KESTREL): Data readout moxetumomab - leukaemia: Data readout benralizumab - severe, uncontrolled asthma: Regulatory decision (US) tralokinumab - severe, uncontrolled asthma: Data readout
2018	Lynparza - ovarian cancer (1st line): Regulatory submission Tagrisso - lung cancer (1st line): Regulatory submission durva + treme - lung cancer (NEPTUNE): Data readout durva +/- treme - head & neck cancer (KESTREL): Regulatory submission durva +/- treme - head & neck cancer (EAGLE): Data readout, regulatory submission durva +/- treme - bladder cancer (DANUBE): Data readout, regulatory submission moxetumomab - leukaemia: Regulatory submission selumetinib - thyroid cancer: Data readout, regulatory submission Brilinta - type-2 diabetes / coronary artery disease: Data readout, regulatory submission Bydureon - cardiovascular (CV) outcomes trial: Data readout, regulatory submission Duaklir - COPD: Regulatory submission (US) benralizumab - severe, uncontrolled asthma: Regulatory decision (EU) tralokinumab - severe, uncontrolled asthma: Regulatory submission PT010 - COPD: Data readout, regulatory submission anifrolumab - lupus: Data readout

The term 'data readout' in this section refers to Phase III data readouts, unless specified otherwise. *Potential fast-to-market opportunity ahead of randomised, controlled trials.



Results Presentation

A presentation and accompanying live webcast for investors and analysts, hosted by management, will begin at 12.30pm UK time today. Details can be accessed via <u>astrazeneca.com/investors</u>.

Reporting Calendar

The Company intends to publish its first quarter financial results on 27 April 2017.

About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - Oncology, Cardiovascular & Metabolic Diseases and Respiratory. The Company also is selectively active in the areas of autoimmunity, neuroscience and infection. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit www.astrazeneca.com and follow us on Twitter @AstraZeneca.

Media Enquiries

Esra Erkal-Paler	UK/Global	+44 203 749 5638
Neil Burrows	UK/Global	+44 203 749 5637
Vanessa Rhodes	UK/Global	+44 203 749 5736
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677
Investor Relations		
Thomas Kudsk Larsen		+44 203 749 5712
Thomas Kudsk Larsen Craig Marks	Finance, Fixed Income, M&A	+44 203 749 5712 +44 7881 615 764
	Finance, Fixed Income, M&A Oncology	
Craig Marks		+44 7881 615 764
Craig Marks Henry Wheeler	Oncology	+44 7881 615 764 +44 203 749 5797
Craig Marks Henry Wheeler Mitchell Chan	Oncology Oncology	+44 7881 615 764 +44 203 749 5797 +1 240 477 3771
Craig Marks Henry Wheeler Mitchell Chan Lindsey Trickett	Oncology Oncology Cardiovascular & Metabolic Diseases	+44 7881 615 764 +44 203 749 5797 +1 240 477 3771 +1 240 543 7970



Operating And Financial Review

All narrative on growth and results in this section is based on CER unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the twelve and three-month periods to 31 December 2016 (the year and the quarter, respectively) compared to the twelve and three-month periods to 31 December 2015.

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 intangible assets, including impairment reversals but excluding any charges relating to IT assets
- charges and provisions related to global restructuring programmes (this will include such charges that relate to the impact of global restructuring programmes on 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

Details on the nature of these measures are provided on page 64 of the <u>Annual Report</u> and Form 20-F Information 2015.

Total Revenue

	FY	2016	Q4 2016		
	\$m	\$m % CER change \$m % CER cha			
Product Sales	21,319	(8)	5,260	(15)	
Externalisation Revenue	1,683	59	325	77	
Total Revenue	23,002	(5)	5,585	(12)	

Based on actual exchange rates, Total Revenue declined by 7% in the year and by 13% in the quarter.

Product Sales

The level of decline in Product Sales was driven by the impact of the entry of *Crestor* generic medicines in the US, as well as the reducing impact of *Nexium* generic medicines in the US. Sales of *Crestor* and *Nexium* in the US declined by 57% and 39%, respectively. Overall US Product Sales declined by 22% in the year to \$7,365m (Q4 2016: Down by 37% to \$1,618m). Product Sales in Europe declined by 3% in the year to \$5,064m (Q4 2016: Down by 3% to \$1,332m).

Within Product Sales, the Growth Platforms grew by 5% in the year, representing 63% of Total Revenue:

	FY 2	2016	Q4 2016		
Growth Platform	Product Sales (\$m)	% CER change	Product Sales (\$m)	% CER change	
Emerging Markets	5,794	6	1,486	7	
Respiratory	4,753	(3)	1,210	(5)	
Diabetes	2,427	11	598	3	
Japan	2,184	(3)	591	(5)	
Brilinta	839	39	236	37	
New Oncology ¹	664	n/m	216	n/m	
Total ²	14,491	5	3,728	3	

¹New Oncology comprises Lynparza, Iressa (US) and Tagrisso.

²Total Product Sales for Growth Platforms adjusted to remove duplication on a medicine and regional basis.



Externalisation Revenue

Where AstraZeneca retains a significant economic interest in medicines or potential new medicines, income from transactions is reported as Externalisation Revenue in the Company's financial statements. The table below illustrates the level of sustainable and ongoing income¹ within the total of Externalisation Revenue. Sustainable and ongoing income is anticipated to grow as a proportion of Externalisation Revenue over time.

		FY 2016				Q4 2016			
	¢m	% o f	% ch	ange	¢	% of	% change		
	\$m	Total	CER	Actual	\$m	Total	CER	Actual	
Royalties ²	119	7	69	58	45	14	222	230	
Milestones	237	14	35	33	10	3	(87)	(87)	
Sub-total Sustainable and Ongoing Externalisation Revenue	356	21	45	40	55	17	(37)	(40)	
Upfront Receipts	1,327	79	63	63	270	83	172	171	
Total Externalisation Revenue	1,683	100	59	58	325	100	77	69	

¹Sustainable and ongoing income is defined as Externalisation Revenue excluding upfront receipts.

²Royalties in FY 2016 included those derived from the Aspen Global Incorporated (Aspen) transaction highlighted below.

Externalisation Revenue recognised in the year amounted to \$1,683m. Highlights included:

Medicine	Partner	Region	\$m
Anaesthetics	Aspen - initial revenue	Global (excl. US)	520
<u>Plendil</u>	China Medical System Holdings Ltd - commercialisation rights - initial revenue	China	298
<u>Toprol-XL</u>	Aralez Pharmaceuticals Trading DAC (Aralez) - initial revenue	US	175
<u>Tralokinumab - atopic</u> <u>dermatitis</u>	LEO Pharma A/S (LEO Pharma) - initial revenue	Global	115
AZD3293	Eli Lilly and Company (Lilly) - milestone revenue	Global	100
Nexium OTC 20mg	Pfizer Inc. (Pfizer) - milestone revenue	Global	93
<u>Moventig</u>	ProStrakan Group plc - commercialisation rights - initial and milestone revenue	EU	78
Others			304
Total			1,683

Statements



Examples of sustainable and ongoing Externalisation Revenue streams are shown below:

Announcement Date	Medicine	Partner	Region	Externalisation Revenue	ncial
<u>4 October 2016</u>	Toprol-XL	Aralez	US	 Initial \$175m milestone Up to \$48m milestone and sales- related revenue Mid-teen percentage royalties on sales 	Operating & Financial Review
<u>1 July 2016</u>	Tralokinumab - atopic dermatitis	LEO Pharma	Global	 Initial \$115m milestone Up to \$1bn in commercially-related milestones Up to mid-teen tiered percentage royalties on sales 	Corporate & Business Development
<u>9 June 2016</u>	Anaesthetics	Aspen	Global (excl. US)	 Initial \$520m milestone Up to \$250m in sales-related revenue Double-digit percentage trademark royalties on sales 	Research & Development
<u>1 September 2015</u>	Brodalumab - psoriasis	Valeant Pharmaceuticals International, Inc. (Valeant)	Global, later amended to US	 Initial \$100m milestone Pre-launch milestone up to \$170m Sales-related royalties up to \$175m 	Development Pipeline
<u>19 March 2015</u>	Movantik	Daiichi Sankyo	US	 Initial \$200m milestone Up to \$625m in Product Sales- related revenue 	Preliminary Financial Statements

Product Sales

The performance of key medicines is shown below, with a geographical split shown in Notes 8 and 9.

		FY 2	2016			Q4 2016	
	\$m	% of	% ch	ange	\$m	% cł	nange
	φIII	Total	CER	Actual	φIII	CER	Actual
Oncology							
Iressa	513	2	(5)	(6)	118	(11)	(9)
Tagrisso	423	2	n/m	n/m	147	n/m	n/m
Lynparza	218	1	n/m	n/m	62	72	72
Legacy:							
Faslodex	830	4	19	18	222	19	20
Zoladex	816	4	-	-	235	13	19
Casodex	247	1	(9)	(7)	60	(8)	(5)
Arimidex	232	1	(6)	(7)	57	(7)	(5)
Others	104	-	(26)	(21)	29	-	12
Total Oncology	3,383	16	20	20	930	26	30
Cardiovascular & Metabolic Diseases							
Brilinta	839	4	39	36	236	37	36
Farxiga	835	4	72	70	239	57	57
Onglyza	720	3	(6)	(8)	149	(21)	(22)
Bydureon	578	3	-	-	142	(8)	(8)
Byetta	254	1	(19)	(20)	55	(22)	(24)
Legacy:							
Crestor	3,401	16	(32)	(32)	631	(53)	(52)
Seloken/Toprol-XL	737	3	9	4	178	14	11
Atacand	315	1	(8)	(13)	81	(5)	(6)
Others	437	2	(26)	(28)	100	(31)	(32)
Total Cardiovascular & Metabolic	8,116	38	(13)	(1.4)	1,811	(26)	(26)
Diseases	0,110	30	(13)	(14)	1,011	(20)	(20)
Respiratory							
Symbicort	2,989	14	(10)	(12)	740	(13)	(14)
Pulmicort	1,061	5	8	5	288	8	5
Tudorza/Eklira	170	1	(9)	(11)	36	(23)	(23)
Daliresp/Daxas	154	1	48	48	41	28	28
Duaklir	63	-	n/m	n/m	19	58	58
Others	316	1	27	22	86	37	32
Total Respiratory	4,753	22	(3)	(5)	1,210	(5)	(6)
Other							
Nexium	2,032	10	(18)	(19)	491	(15)	(13)
Seroquel XR	735	3	(27)	(28)	118	(51)	(51)
Synagis	677	3	2	2	302	10	10
Losec/Prilosec	276	1	(17)	(19)	59	(23)	(23)
FluMist/Fluenz	104	-	(59)	(64)	67	(60)	(65)
Movantik/Moventig	91	-	n/m	n/m	26	73	73
Others	1,152	5	(20)	(23)	246	(34)	(35)
Total Other	5,067	24	(19)	(20)	1,309	(25)	(25)
Total Product Sales	21,319	100	(8)	(10)	5,260	(15)	(15)

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Preliminary Financial Statements

AstraZeneca 😕 What science can do

ONCOLOGY

Full-year sales of \$3,383m; up by 20%. Oncology sales represented 16% of Total Product Sales.

Iressa (full-year sales of \$513m; down by 5%)

Sales in the US amounted to \$23m, with sales in Europe declining by 5% to \$120m. The Company prioritised the launch of *Tagrisso* in the year, given its potential impact for patients and the Company. Emerging Markets sales (defined in the Regional Product Sales section on page 13) declined by 10% to \$233m. China sales declined by 16% to \$116m, a result of a new price following national reimbursement listing obtained in June 2016. Strong competition from branded and generic medicines in Korea also contributed to the decline.

Tagrisso (full-year sales of \$423m)

In the second half of the year, sales of *Tagrisso* surpassed those of *Iressa*, with *Tagrisso* becoming the leading AstraZeneca medicine for the treatment of lung cancer. Regulatory approvals were granted in a number of markets, including Brazil, Hong Kong, Singapore, Taiwan and the United Arab Emirates; the Company anticipates additional regulatory approvals and reimbursement decisions in due course. To date, *Tagrisso* has received regulatory approval in 46 countries worldwide.

Sales in the US amounted to \$254m. After regulatory approval in the EU and Japan earlier in the year, sales in the year were \$76m in Europe and \$82m in Japan.

On 27 December 2016, a third-party, blood-based companion-diagnostic test for *Tagrisso* was approved in Japan. The test is designed to confirm the presence of a T790M mutation in patients. Similarly, the blood-based companion-diagnostic partner test for *Tagrisso* was approved in the US on 29 September 2016.

Lynparza (full-year sales of \$218m)

Lynparza was available to patients in 31 countries by the end of 2016, with regulatory reviews underway in seven additional countries including Russia, Brazil and Singapore. Almost 5,000 patients globally have been prescribed *Lynparza* since the first launch in December 2014. Sales in the US increased by 81% in the year to \$127m; *Lynparza* now has a high market penetration. Sales in Europe increased to \$81m, following a number of successful launches.

Legacy: Faslodex (full-year sales of \$830m; up by 19%)

Sales in the US in the year increased by 23% to \$438m, mainly driven by an expanded label in March 2016 for 2nd-line advanced or metastatic breast cancer, in combination with palbociclib. Europe full-year sales increased by 11% to \$228m. An increase in demand in Japan led to sales growth of 12% to \$63m. China sales, up by 91% to \$20m, supported Emerging Markets sales of \$96m, representing an increase of 25%.

Legacy: Zoladex (full-year sales of \$816m; stable)

The stable performance was attributed to Europe sales (down by 4% to \$156m) and Established Rest Of World (ROW) sales (down by 7% to \$270m) being offset by favourable sales performances in the US (up by 25% to \$35m) and Emerging Markets (up by 6% to \$355m).

CARDIOVASCULAR & METABOLIC DISEASES

Full-year sales of \$8,116m; down by 13%.

Cardiovascular & Metabolic Diseases sales represented 38% of Total Product Sales.

Brilinta (full-year sales of \$839m; up by 39%)

Sales of *Brilinta* in the US were \$348m, representing an increase of 45%. The performance reflected updated preferred guidelines from the American College of Cardiology and the American Heart Association in the first half of the year; *Brilinta* remained the branded oral anti-platelet market leader in the US. *Brilinta*'s new-to-brand weekly prescription market share jumped to around 15% at the end of the year, representing an increase of around three percentage points.

Full-year sales of *Brilique* in Europe increased by 15% to \$258m, reflecting indication leadership across a number of markets. In the year, the German Institute for Quality and Efficiency in Healthcare (IQWiG) gave its assessment

Operating & Financial Review

Preliminary Financial

Statements

of the additional benefit from *Brilique* at the 60mg dose as tested in the PEGASUS trial, as did the National Institute for Health and Clinical Excellence in England, UK.

Emerging Markets full-year sales grew by 80% to \$189m, with China sales more than doubling. China represented 47% of Emerging Markets sales of the medicine at \$89m, despite it not being included on the National Reimbursement Drug List. The Company anticipates inclusion in due course. Growth was underpinned by a combination of strong levels of hospital-listing expansion and increased use in existing hospitals.

Farxiga (full-year sales of \$835m; up by 72%)

In the year, sales of *Farxiga* surpassed those of *Onglyza* and *Farxiga* became the leading AstraZeneca medicine for the treatment of diabetes, consolidating its position as global leader in the SGLT2 class.

Sales of *Farxiga* in the US increased by 75% to \$457m, primarily reflecting overall market growth and a higher net price. A stronger emphasis on promotional activity and improved levels of patient access resulted in market-share growth. Full-year sales of *Forxiga* in Europe increased by 52% to \$187m, as the medicine continued to lead the growing class. Emerging Markets sales increased by 96% to \$133m, driven by ongoing launches and improved access. In particular, strong performances were seen in the Asia-Pacific region (up by 108% to \$52m), Brazil (up by 50% to \$28m), and the Middle East, Africa & Others region (up to \$32m).

Onglyza (full-year sales of \$720m; down by 6%)

Sales in the US declined by 10% to \$376m, as the Company prioritised sales and marketing resources towards *Farxiga*. Continued competitive pressures in the DPP-4 class led to lower market share but were partially offset by reduced levels of utilisation of patient-access programmes. Full-year sales in Europe declined by 5% to \$132m and by 4% in Emerging Markets to \$142m, again reflecting the Company's focus on *Farxiga*.

In the quarter, global sales declined by 21%, due to adverse pressures on the DPP-4 class and reflecting an acceleration of the previously-mentioned market dynamics.

Bydureon/Byetta (full-year sales of \$832m; down by 7%)

Combined full-year US sales for *Bydureon/Byetta* were \$627m. *Bydureon* sales in the US declined by 4% to \$463m, representing 74% of total *Bydureon/Byetta* US sales. Around 75% of sales came from the new dualchamber pen compared to the prior tray presentation. The decline in US *Byetta* sales of 22% to \$164m was attributed to the Company's promotional focus on *Bydureon*. The decline in both *Bydureon* and *Byetta* US sales reflected lower net pricing; a regulatory submission for the new *Bydureon* autoinjector is anticipated in the US in the first half of 2017.

Full-year sales in Europe increased by 3% to \$145m, reflecting the Company's ongoing effort to expand its Diabetes presence. Full-year sales of *Byetta* and *Bydureon* in Emerging Markets increased by 13% to \$24m and decreased by 25% to \$4m, respectively. On 10 October 2016, AstraZeneca entered into a strategic collaboration with 3SBio Inc. (3SBio) for the rights to commercialise *Bydureon* and *Byetta* in the Chinese market. The agreement allowed the Company to benefit from 3SBio's established local expertise in injectable medicines as well as focus on its oral type-2 diabetes medicines.

Legacy: Crestor (full-year sales of \$3,401m; down by 32%)

In the US, *Crestor* full-year sales declined by 57% to \$1,223m, reflecting the market entry of *Crestor* generic medicines. Sales in the quarter declined by 88% to \$95m. In Europe, full-year sales declined by 4% to \$866m, reflecting the increasing use of generic medicines. In contrast, *Crestor* consolidated its position as the leading statin in Japan, with full-year sales stable at \$521m. Full-year sales in China grew by 27% to \$311m, while Russia sales grew by 28% to \$29m.

RESPIRATORY

Full-year sales of \$4,753m; down by 3%. Respiratory sales represented 22% of Total Product Sales.

Symbicort (full-year sales of \$2,989m; down by 10%)

Full-year sales in the US declined by 18% to \$1,242m. This primarily reflected the impact of the continued effects of pricing pressure from managed-care access within the ICS/LABA class. Competition also remained intense from other classes. In Europe, full-year sales declined by 12% to \$909m, primarily a result of competition from

branded and analogue medicines. The performance improved during the year, with Q4 2016 sales in Europe declining by only 3% to \$230m.

In contrast, full-year Emerging Markets sales grew by 10% to \$402m, reflecting sales growth in China of 32% to \$156m and Latin America (ex-Brazil) sales growth of 12% to \$37m.

Symbicort continued to lead the global market by volume within the class; the medicine provides a platform for the launch of *Bevespi* and potential launch of benralizumab.

Pulmicort (full-year sales of \$1,061m; up by 8%)

Pulmicort returned to being a blockbuster medicine in the year.

Strong underlying volume growth in Emerging Markets drove a 21% sales increase in that region to \$698m. Emerging Markets, representing 66% of *Pulmicort* sales, more than offset sales declines in the US, Europe and Established ROW. China sales increased by 24% to \$570m and represented 54% of sales of *Pulmicort*. Volume demand in China partly reflected the long-term increase in China of acute chronic obstructive pulmonary disease (COPD) and paediatric asthma. AstraZeneca continued its expansion of treatment centres and provided increased access to home-based patient-care systems.

Tudorza/Eklira (full-year sales of \$170m; down by 9%)

Sales in the US declined by 25% to \$77m, reflecting adverse market demand, limited Medicare Part D access and the focus on the launch of *Bevespi*. Sales in Europe increased by 9% to \$83m.

Daliresp/Daxas (full-year sales of \$154m; up by 48%)

Sales in the US increased by 29% to \$134m in the year, driven primarily by favourable market penetration. US sales represented 87% of global sales. ROW sales rights were added in May 2016 and, since completion, *Daxas* sales in Europe amounted to \$15m.

Duaklir (full-year sales of \$63m)

Duaklir has been launched successfully in excess of 25 countries; sales more than doubled in the year. This followed the strategic transaction with Almirall, S.A., which was completed in October 2014.

<u>Bevespi</u>

Bevespi Aerosphere inhalation aerosol was launched commercially in the US in January 2017 and is available in pharmacies for the long-term, maintenance treatment of airflow obstruction in patients with COPD. It is the only LAMA/LABA combination treatment to be delivered in a pressurised metered-dose inhaler (pMDI) and the first FDA-approved therapy to be formulated with AstraZeneca's co-suspension delivery technology, a focus of the Company's future-platform development for respiratory-disease combination therapies. *Bevespi* also demonstrated a 381mL improvement in peak inspiratory capacity, a potentially differentiating factor.

OTHER

Full-year sales of \$5,067m; down by 19%. Other sales represented 24% of Total Product Sales.

Nexium (full-year sales of \$2,032m; down by 18%)

Sales in the US declined by 39% to \$554m in the year, reflecting lower demand and inventory de-stocking, which followed the loss of exclusivity in 2015. Sales in Europe declined by 11% to \$251m, and Emerging Markets sales decreased 3% to \$690m. Japan sales declined by 4% to \$436m, reflecting the mandated biennial price reduction, effective from April 2016.

Seroquel XR (full-year sales of \$735m; down by 27%)

Sales of *Seroquel XR* in the US declined by 28% to \$515m in the year (Q4 2016: Down by 60% to \$71m). Since 1 November 2016, two companies have launched generic medicines in the US. Full-year sales of *Seroquel XR* in Europe declined by 32% to \$134m reflecting the impact of generic-medicine competition.

Synagis (full-year sales of \$677m; up by 2%)

Sales in the US increased by 14% to \$325m for the full year due to greater market demand. Sales to AbbVie Inc., which is responsible for the commercialisation of *Synagis* in over 80 countries outside the US, declined by 7% to \$352m.



<u>FluMist/Fluenz (full-year sales of \$104m; down by 59%)</u> The Company confirmed on 23 June 2016 that the Advisory Committee on Immunization Practices (ACIP) of the US Centers for Disease Control and Prevention had provided its interim recommendation not to use FluMist Quadrivalent Live Attenuated Influenza Vaccine (FluMist Quadrivalent) in the US for the 2016-2017 influenza season.

The Company wrote down the value of its inventory of FluMist by \$47m in the year, which was reflected within the Cost of Sales. Full-year sales of FluMist in the US declined by 84% to \$33m. Europe sales increased by 3% in the year to \$64m.

Regional Product Sales

		FY 2016				Q4 2016			
	\$m	% of Total	% cł CER	nange Actual	\$m	% ch CER	ange Actual		
US	7,365	35	(22)	(22)	1,618	(37)	(37)		
Europe	5,064	24	(3)	(5)	1,332	(3)	(6)		
Established ROW ¹	3,096	15	(4)	2	824	(6)	5		
Japan	2,184	10	(3)	8	591	(5)	9		
Canada	497	2	(2)	(7)	126	(5)	(6)		
Other Established ROW	415	2	(10)	(12)	107	(10)	(4)		
Emerging Markets ²	5,794	27	6	-	1,486	7	4		
China	2,636	12	10	4	609	8	2		
Ex. China	3,158	15	3	(4)	877	6	5		
Total	21,319	100	(8)	(10)	5,260	(15)	(15)		

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 (full-year sales of \$7,365m; down by 22%)

The full-year decline in US sales reflected the competition from *Crestor* generic medicines that entered the US market from July 2016. Unfavourable managed-care pricing and continued competitive intensity also impacted sales of *Symbicort*.

Europe (full-year sales of \$5,064m; down by 3%)

Strong growth in sales of *Forxiga* (up by 52% to \$187m) and *Brilique* (up by 15% to \$258m) was more than offset by a 12% decline in *Symbicort* sales to \$909m. However, *Symbicort* maintained its position as the number one ICS/LABA medicine by volume, despite competition from branded and analogue medicines. *Lynparza* and *Tagrisso* sales increased to \$81m and \$76m respectively.

Established ROW (full-year sales of \$3,096m; down by 4%)

Full-year sales of *Forxiga* in Established ROW increased by 72% to \$58m. *Nexium* sales declined by 10% to \$537m.

Japan sales declined by 3% to \$2,184m, reflecting the biennial price reduction, effective from April 2016, of around 6%. The decline was partly mitigated by stable sales of *Crestor* of \$521m in the year. Since the launch of *Tagrisso* in Japan in May 2016, sales amounted to \$82m.

Emerging Markets (full-year sales of \$5,794m; up by 6%) Emerging Markets, representing 27% of global Product Sales, is the second-largest sales region for AstraZeneca.

Sales growth for the year in Emerging Markets was impacted by challenging macro-economic conditions in Latin America, where ex-Brazil full-year sales declined by 7% to \$516m. The effect of reductions in Saudi Arabian governmental healthcare spending, as well as the reduction of AstraZeneca's activities in Venezuela, also adversely impacted sales. China sales, however, grew by 10% to \$2,636m, representing 45% of Emerging Markets sales in the year.

Sales in Brazil increased by 2% to \$348m, reflecting the strong performances of *Forxiga* (up by 50% to \$28m), Oncology medicines (up by 1% to \$82m) and *Seloken* (up by 6% to \$63m). Russia sales increased by 13% to \$233m, led by strong performances in Cardiovascular & Metabolic Diseases medicine sales (up by 38% to \$80m).



A number of AstraZeneca medicines were externalised or disposed of in the year, adversely impacting the level of Product Sales:

Medicine	Region	Externalisation / Disposal Completion Date	FY 2015 Impacted Region Product Sales (\$m)
<u>Bydureon &</u> <u>Byetta</u>	China	11 October 2016	15
Anaesthetics	Global (excl. US)	1 September 2016	594
<u>Plendil</u>	China	29 February 2016	189
<u>Moventig</u>	Europe	1 March 2016	1
<u>Toprol-XL</u>	US	31 October 2016	89
<u>Imdur</u>	Global (excl. US)	3 May 2016	55
Total			943

Operating & Financial Review

Corporate & Business Development

Research & Development

Development Pipeline

Preliminary Financial Statements

Financial Performance

	Repo	orted	% cł	nange	Co	re	% change	
Year	FY 2016	FY 2015	CER	Actual	FY 2016	FY 2015	CER	Actual
Product Sales	21,319	23,641	(8)	(10)	21,319	23,641	(8)	(10)
Externalisation Revenue	1,683	1,067	59	58	1,683	1,067	59	58
Total Revenue	23,002	24,708	(5)	(7)	23,002	24,708	(5)	(7)
Cost of Sales	(4,126)	(4,646)	(7)	(11)	(3,872)	(4,119)	(2)	(6)
Gross Profit	18,876	20,062	(5)	(6)	19,130	20,589	(6)	(7)
Gross Margin ¹	80.8%	80.3%	-0.1	+0.5	82.0%	82.6%	-1.1	-0.6
Distribution Expense	(326)	(339)	1	(4)	(326)	(339)	1	(4)
% Total Revenue	1.4%	1.4%	-	-	1.4%	1.4%	-	-
R&D Expense	(5,890)	(5,997)	2	(2)	(5,631)	(5,603)	5	-
% Total Revenue	25.6%	24.3%	-2	-1	24.5%	22.7%	-2	-2
SG&A Expense	(9,413)	(11,112)	(12)	(15)	(8,169)	(9,265)	(9)	(12)
% Total Revenue	40.9%	45.0%	+3	+4	35.5%	37.5%	+1	+2
Other Operating Income	1,655	1,500	12	10	1,717	1,520	14	13
% Total Revenue	7.2%	6.1%	+1	+1	7.5%	6.2%	+1	+1
Operating Profit	4,902	4,114	9	19	6,721	6,902	(7)	(3)
% Total Revenue	21.3%	16.7%	+3	+5	29.2%	27.9%	-	+1
Net Finance Expense	(1,317)	(1,029)	37	28	(661)	(505)	46	31
Joint Ventures	(33)	(16)			(33)	(16)		
Profit Before Tax	3,552	3,069	-	16	6,027	6,381	(11)	(6)
Taxation	(146)	(243)			(658)	(990)		
Tax Rate %	4%	8%			11%	16%		
Profit After Tax	3,406	2,826	6	21	5,369	5,391	(6)	-
Non-controlling Interests	93	(1)			86	(1)		
Net Profit	3,499	2,825	9	24	5,455	5,390	(5)	1
Weighted Average Shares	1,265	1,264			1,265	1,264		
Earnings Per Share (\$)	2.77	2.23	9	24	4.31	4.26	(5)	1

¹ Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales ² All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions.

15

	Repo	orted	% ch	ange	Со	.e	% ch	ange
Quarter	Q4 2016	Q4 2015	CER	Actual	Q4 2016	Q4 2015	CER	Actual
Product Sales	5,260	6,207	(15)	(15)	5,260	6,207	(15)	(15)
Externalisation Revenue	325	192	77	69	325	192	77	69
Total Revenue	5,585	6,399	(12)	(13)	5,585	6,399	(12)	(13)
Cost of Sales	(1,160)	(1,269)	(2)	(9)	(1,087)	(1,209)	(4)	(10)
Gross Profit	4,425	5,130	(15)	(14)	4,498	5,190	(14)	(13)
Gross Margin ¹	77.9%	79.6%	-3.1	-1.7	79.3%	80.5%	-2.6	-1.2
Distribution Expense	(83)	(99)	(11)	(16)	(83)	(99)	(11)	(16)
% Total Revenue	1.5%	1.5%	-	-	1.5%	1.5%	-	-
R&D Expense	(1,543)	(1,746)	(5)	(12)	(1,481)	(1,567)	2	(5)
% Total Revenue	27.6%	27.3%	-2	-	26.5%	24.5%	-4	-2
SG&A Expense	(1,386)	(2,668)	(44)	(48)	(2,050)	(2,461)	(14)	(17)
% Total Revenue	24.8%	41.7%	+15	+17	36.7%	38.5%	+1	+2
Other Operating Income	1,120	471	n/m	n/m	1,142	493	n/m	n/m
% Total Revenue	20.1%	7.4%	+13	+13	20.4%	7.7%	+13	+13
Operating Profit	2,533	1,088	n/m	n/m	2,026	1,556	15	30
% Total Revenue	45.4%	17.0%	+23	+28	36.3%	24.3%	+8	+12
Net Finance Expense	(339)	(279)	36	22	(172)	(150)	36	15
Joint Ventures	(11)	(7)			(11)	(7)		
Profit Before Tax	2,183	802	n/m	n/m	1,843	1,399	13	32
Taxation	(366)	6			(333)	(200)		
Tax Rate %	17%	(1)%			18%	14%		
Profit After Tax	1,817	808	91	n/m	1,510	1,199	7	26
Non-controlling Interests	25	-			23	-		
Net Profit	1,842	808	94	n/m	1,533	1,199	9	28
Weighted Average Shares	1,265	1,264			1,265	1,264		
Earnings Per Share (\$)	1.46	0.63	93	n/m	1.21	0.94	9	29

¹ Gross Margin reflects Gross Profit derived from Product Sales, divided by Product Sales ² All financial figures, except Earnings Per Share, are in \$ millions (\$m). Weighted Average Shares are in millions

Corporate & Business Development

Research & Development

Operating & Financial Review



Reconciliation Of Reported To Core Performance

FY 2016	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other ¹	Core
	\$m	\$m	\$m	\$m	\$m	\$m
Cost of Sales	(4,126)	130	124	-	-	(3,872)
R&D Expense	(5,890)	178	81	-	-	(5,631)
SG&A Expense	(9,413)	823	1,000	(627)	48	(8,169)
Other Operating Income	1,655	(24)	86	-	-	1,717
Net Finance Expense	(1,317)	-	-	389	267	(661)
Taxation	(146)	(232)	(307)	23	4	(658)
Non-controlling Interests	93	(7)	-	-	-	86
Total		868	984	(215)	319	

Q4 2016	Reported \$m	Restructuring \$m	Intangible Asset Amortisation & Impairments \$m	Diabetes Alliance \$m	Other ¹ \$m	Core \$m
Cost of Sales	(1,160)	43	30	φili	- -	۹۱۱ (1,087)
CUSE OF Sales	(1,100)	43		-	-	(1,007)
R&D Expense	(1,543)	32	30	-	-	(1,481)
SG&A Expense	(1,386)	319	246	(938)	(291)	(2,050)
Other Operating Income	1,120	-	22	-	-	1,142
Net Finance Expense	(339)	-	-	97	70	(172)
Taxation	(366)	(82)	(86)	162	39	(333)
Non-controlling Interests	25	(2)	-	-	-	23
Total		310	242	(679)	(182)	

¹ Other adjustments include provision charges related to certain legal matters (see Note 7) and fair-value adjustments arising on acquisition-related liabilities (see Note 6).



Profit And Loss Commentary

Gross Profit

Reported Gross Profit declined by 5% in the year to \$18,876m reflecting the market entry of *Crestor* generic medicines in the US. Excluding the impact of Externalisation Revenue, the Reported Gross Profit Margin was broadly stable at 80.8%, with lower restructuring and amortisation charges offset by an adverse impact from the mix of sales and a write-down of *FluMist* inventory in the US. Excluding these lower restructuring and amortisation charges, Core Gross Profit declined by 6% in the year to \$19,130m and, excluding the impact of externalisation, the Core Gross Profit margin declined by one percentage point to 82.0%.

In the quarter, Reported Gross Profit declined by 15% to \$4,425m and Reported Gross Margin declined by three percentage points to 77.9%. Excluding restructuring and amortisation charges, Core Gross Profit declined by 14% to \$4,498m and the Core Gross Margin declined by three percentage points to 79.3%.

Operating Expenses: R&D

Reported R&D costs increased by 2% in the year to \$5,890m (Q4 2016: \$1,543m, a decline of 5%). The full-year increase reflected the number of potential new medicines in pivotal trials as well as the absorption of the R&D costs of ZS Pharma and Acerta Pharma. These costs were partially offset by lower restructuring costs and impairment charges. Without the impact of ZS Pharma and Acerta Pharma, Reported R&D costs in the year would have declined by 3%.

Excluding the impact of lower restructuring and impairment charges, Core R&D costs increased by 5% in the year to \$5,631m (Q4 2016: \$1,481m, an increase of 2%). Without the impact of the previously-mentioned investments in ZS Pharma and Acerta Pharma, Core R&D costs in the year would have declined by 1%. This compares to the 21% increase in Core R&D costs in FY 2015.

Operating Expenses: SG&A

Reported SG&A costs declined by 12% in the year to \$9,413m, reflecting the evolving shape of the business. The decline was also driven by efficiency savings in sales and marketing operations and further reductions in IT costs. These actions included a material reduction in the sales and head-office structure in the US marketing business. Reported SG&A costs declined by 44% in the quarter to \$1,386m, reflecting the fair-value adjustment to acquisition-related liabilities.

Core SG&A costs declined by 9% in the year to \$8,169m, in line with full-year expectations of a material reduction. Core SG&A costs declined by 14% in the quarter to \$2,050m.

Other Operating Income

Where AstraZeneca does not retain a significant economic interest in medicines or potential new medicines, income from transactions is reported as Other Operating Income in the Company's financial statements.

\$m Sale of the small-molecule antibiotics business to 368 Pfizer net of carrying values disposed and other costs to sell Sale of the ex-US rights to Rhinocort Aqua to Cilag 321 GmbH International (Cilag) Sale of ex-US rights of Imdur 183 Crestor royalties 165 Out-licensing of a potential medicine (MEDI2070) 148 for inflammatory diseases to Allergan plc (Allergan) net, reflecting an agreement with Amgen Inc. (Amgen) **HPV** royalties 134 Other 336 Total 1,655

Reported Other Operating Income of \$1,655m in the year included:



Reported Operating Profit increased by 9% in the year to \$4,902m. The Reported Operating Margin increased by three percentage points to 21% of Total Revenue.

Core Operating Profit declined by 7% in the year to \$6,721m. The Core Operating Margin was stable at 29% of Total Revenue.

Net Finance Expense

Reported Net Finance Expense increased by 37% in the year to \$1,317m, reflecting an increase in Net Debt that was driven by the acquisition of ZS Pharma and the majority investment in Acerta Pharma. Excluding the discount unwind on acquisition-related liabilities, Core Net Finance Expense increased by 46% in the year to \$661m.

Taxation

Excluding a one-off benefit of \$453m following agreements between the Canadian tax authority and the UK and Swedish tax authorities in respect of transfer pricing arrangements for the 13-year period from 2004-2016, the Reported and Core tax rates for the year were 17% and 18% respectively. Including the impact of this benefit, the Reported and Core tax rates for the year were 4% and 11% respectively. The cash tax paid for the year was \$412m, which was 12% of Reported Profit Before Tax and 7% of Core Profit Before Tax.

The Reported and Core tax rates in FY 2015 were 22% and 21% respectively when excluding a one-off tax benefit of \$186m following the agreement of US federal tax liabilities of open years up to 2008, other provision releases and the benefit of the UK patent box. Including the impact of these benefits, the Reported and Core tax rates in FY 2015 were 8% and 16% respectively.

Earnings Per Share (EPS)

Reported EPS of \$2.77 in the year represented growth of 9%; this included a gain of \$0.76 on the revaluation of acquisition-related liabilities. Core EPS in the year declined by 5% to \$4.31, driven by the same rate of decline in Total Revenue. Both Reported and Core EPS in the year included a non-recurring benefit of \$0.36, following the previously-mentioned agreements between the Canadian tax authority and the UK and Swedish tax authorities.

Dividends

The Board has declared a second interim dividend of \$1.90 per share (150.2 pence, 16.57 SEK) bringing the dividend per share for the full year to \$2.80 (218.9 pence, 24.38 SEK). The Board reaffirms its commitment to the Company's progressive dividend policy.

For holders of the Company's American Depositary Shares (ADSs), the \$1.90 per Ordinary Share equates to \$0.95 per ADS. Two ADSs equal one Ordinary Share.

Productivity

AstraZeneca's evolution and the changing shape of the business have enabled productivity improvements through the implementation of restructuring initiatives. These included those announced on 29 April 2016. Restructuring charges of \$1,107m were incurred in the year. The Company remains on track to realise benefits and incur costs in line with prior announcements.

Cash Flow And Balance Sheet

Cash Flow

The Company generated a net cash inflow from operating activities of \$4,145m in the year, compared with \$3,324m in the comparative period. The increase reflected improved cash management performance and one-off tax refunds.

Net cash outflows from investing activities were \$3,969m compared with \$4,239m in the comparative period. The outflows partly reflected the net cash outflow of \$2,383m in relation to the majority investment in Acerta Pharma, as well as \$1,446m for the purchase of property, plant and equipment.

Net cash outflows from financing activities were \$1,324m, incorporating \$2,491m of new long-term loans, net of dividend payments in the year of \$3,561m. This compared to an inflow of \$878m in the comparative period.



The cash payment of contingent consideration in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$242m in the year. The consideration is based on a tiered structure, whereby a higher royalty rate is applied until a specified level of sales is achieved in the year; thereafter a lower rate is applied to the remaining sales in the year and settled in the guarter following the application of the charge. From FY 2017 a single annual rate will be applied.

Capital Expenditure

Capital expenditure amounted to \$1,449m in the year, representing an increase of 3%; the majority of capital expenditure was in maintenance. Investment in AstraZeneca's return to growth continued, with an element of capital expenditure split between expansion of biologics manufacturing capacity and the impending completion of the R&D centre and global headquarters in Cambridge, UK.

Debt and Capital Structure

At 31 December 2016, outstanding gross debt (interest-bearing loans and borrowings) was \$16,808m (31 December 2015; \$15.053m). Of the gross debt outstanding at 31 December 2016. \$2.307m was due within one year (31 December 2015: \$916m). The Company's net debt position at 31 December 2016 was \$10,657m (31 December 2015: \$7,762m).

Shares in Issue

During the year, 1.1 million shares were issued in respect of share option exercises for consideration of \$47m. The total number of shares in issue as at 31 December 2016 was 1,265 million.

Capital Allocation

The Board's aim is to continue to strike a balance between the interests of the business, financial creditors and the Company's shareholders. After providing for investment in the business, supporting the progressive dividend policy and maintaining a strong, investment-grade credit rating, the Board will keep under review potential investment in immediately earnings-accretive, value-enhancing opportunities. The Board reconfirms the continued suspension of the share repurchase programme.

Sensitivity: Foreign-Exchange Rates

The Company provides the following currency sensitivity information:

		Average Exchange Rates Versus USD			Impact Of 5% Strengthening In Exchange Rate Versus USD (\$m) ²		
Currency	Primary Relevance	FY 2016	YTD 2017 ¹	change %	Total Revenue	Core Operating Profit	
EUR	Product Sales	0.90	0.94	-4%	+179	+123	
JPY	Product Sales	108.84	115.14	-5%	+104	+71	
CNY	Product Sales	6.65	6.87	-3%	+131	+74	
SEK	Costs	8.56	8.97	-5%	+7	-98	
GBP	Costs	0.74	0.81	-9%	+29	-131	
Other ³					+194	+124	

¹Based on average daily spot rates between 1st January and 30th January 2017

²Based on 2016 actual results at 2016 actual exchange rates

³Other important currencies include AUD, BRL, CAD, KRW and RUB

Currency Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 31 December 2016, AstraZeneca had hedged 96% of forecast short-term currency exposure that arises between the booking and settlement dates on Product Sales and non-local currency purchases.



Corporate And Business Development Update

The highlights of the Company's corporate and business development activities since the prior results announcement are shown below:

a) Sale Of Small-Molecule Antibiotics Business

On 24 August 2016, the Company announced that it had entered into an agreement with Pfizer to sell the commercialisation and development rights to its small-molecule antibiotics business and late-stage pipeline in most markets outside the US. The transaction closed in the quarter. As AstraZeneca will not maintain a significant ongoing interest in the late-stage, small-molecule antibiotics business, all payments were and will be reported as Other Operating Income in the Company's financial statements. This includes the upfront payment of \$550m and an unconditional payment of \$175m in 2019 (both recognised net of the carrying value of assets disposed and other costs to sell in 2016). The future payments include the milestones of up to \$250m, sales-related payments of up to \$600m and recurring double-digit royalties on sales of *Zavicefta* and ATM AVI.

b) Sale Of Respiratory Medicine Rhinocort Aqua (Nasal Spray)

On 7 October 2016, the Company announced that it had entered an agreement with Cilag, an affiliate of Johnson & Johnson, for the divestment of the rights to *Rhinocort Aqua* outside the US. The transaction closed in the quarter.

c) Externalisation Of Beta-Blocker Medicine Toprol-XL

On 31 October 2016, the Company completed an agreement with Aralez Pharmaceuticals Trading DAC, a subsidiary of Aralez Pharmaceuticals Inc., for the rights to branded and authorised generic *Toprol-XL* (metoprolol succinate) in the US. AstraZeneca will retain a significant ongoing interest in *Toprol-XL* through retained ownership of the medicine in ROW markets and product supply to Aralez. Therefore, the upfront payment of \$175m, milestones and sales-related payments of up to \$48m and mid-teen percentage royalties was and will be reported as Externalisation Revenue in the Company's financial statements.

d) Licensing Agreement: Monoclonal Antibody MEDI2070 (Crohn's Disease)

On 3 October 2016, the Company announced that MedImmune, its global biologics research and development arm, had entered a licensing agreement with Allergan for the global rights to MEDI2070 (moderate-to-severe Crohn's disease). The transaction closed in the quarter. AstraZeneca retained \$148m of the upfront payment and will retain up to approximately \$847m in future potential milestones, as well as the tiered royalty payments of up to low double-digit percent, following payment to Amgen under the provisions of the original agreement.

e) Externalisation Of Diabetes Medicines Bydureon And Byetta In China

On 10 October 2016, AstraZeneca entered a strategic collaboration with 3SBio for the rights to commercialise *Bydureon* and *Byetta* in the Chinese market. The agreement allowed the Company to benefit from 3SBio's established expertise in injectable medicines and also focus resources on AstraZeneca's oral diabetes franchise, including *Onglyza*, which is already marketed in China, as well as *Forxiga* and *Kombiglyze*, which are anticipated to launch in China in 2017. The transaction closed in the quarter.

Under the terms of the collaboration agreement, 3SBio made an upfront payment of \$50m and will pay development milestones of up to a further \$50m for the exclusive rights to commercialise *Bydureon* and *Byetta* in the Chinese market (excluding Hong Kong) for an initial period of 20 years. AstraZeneca will retain a significant ongoing interest in *Bydureon* and *Byetta* through retained ownership of the medicines in other markets and will manufacture and supply these medicines to 3SBio for an agreed purchase price.

f) MEDI1814 (Alzheimer's Disease)

AstraZeneca continues to collaborate with Lilly in the development of medicines for patients impacted by Alzheimer's disease (AD). Building on the current collaboration for the BACE inhibitor, AZD3293, currently in two Phase III trials, the companies are now also co-developing MEDI1814, an antibody selective for amyloid-beta 42 (Aβ42), which is currently in Phase I development as a potential disease-modifying treatment for AD. The build-up of plaque in the brain containing the peptide amyloid-beta (Aβ) is one of the pathological hallmarks of AD. MEDI1814 binds selectively to Aβ42, which is believed to be a more toxic Aβ species. In pre-clinical models, MEDI1814 dose-dependently reduces levels of this peptide, potentially slowing the progression of AD.



g) Senior Executive Team Changes

In January 2017, Leon Wang was appointed to the newly-created SET role of Executive Vice-President, Asia Pacific, with responsibility for the Company's activities in China and Hong Kong, Asia Area, Australia and New Zealand. Leon joined AstraZeneca China in 2013 as a Vice-President and became President in 2014. Under his leadership China became AstraZeneca's second-largest market worldwide. Leon has twenty years of experience in the pharmaceutical industry.

As Executive Vice-President, International West, Mark Mallon retains responsibility for AstraZeneca's businesses in Russia, Latin America, and the Middle East and Africa in addition to his role as EVP, Global Product and Portfolio Strategy, Global Medical Affairs & Corporate Affairs.

It was announced in January 2017 that Luke Miels, formerly Executive Vice-President, Europe would leave AstraZeneca to take up a senior position with a main competitor.

22



Research and Development Update

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

Since the results announcement on 10 November 2016 (the period):

Regulatory Submission Acceptances	8	 durvalumab - bladder cancer (US) <i>Tagrisso</i> - lung cancer (AURA3 trial) (US, EU) <i>Faslodex</i> - breast cancer (1L) (US, EU) roxadustat - anaemia (CN) (rolling submission) benralizumab - severe, uncontrolled asthma (US, EU)
Other Key Developments	2	 Priority Review Designation: durvalumab (US) Priority Review Designation: <i>Tagrisso</i> (US)
New Molecular Entities (NMEs) In Phase III Trials Or Under Regulatory Review*#	12	 Oncology durvalumab* - multiple cancers durva + treme - multiple cancers acalabrutinib - blood cancers moxetumomab pasudotox - leukaemia selumetinib - thyroid cancer Cardiovascular & Metabolic Diseases ZS-9* - hyperkalaemia roxadustat* - anaemia Respiratory benralizumab* - severe, uncontrolled asthma tralokinumab - severe, uncontrolled asthma PT010 - COPD Other anifrolumab - lupus AZD3293 - Alzheimer's disease
Projects in clinical pipeline [#] #As at 2 February 2017	120	

#As at 2 February 2017



ONCOLOGY

AstraZeneca has a deep-rooted heritage in Oncology and offers a growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. At least six new Oncology medicines are expected to be launched between 2014 and 2020, of which two have already been launched (*Lynparza* and *Tagrisso*). A broad pipeline of small molecules and biologics is in development and the Company is committed to advancing Oncology as one of AstraZeneca's Growth Platforms primarily focused on lung, ovarian, breast and blood cancers.

In addition to its own existing cancer medicine capabilities, the Company is actively pursuing innovative collaborations and investments that are designed to accelerate the delivery of AstraZeneca's strategy, as illustrated by the Company's majority investment in Acerta Pharma in haematology that closed in 2016.

At three recent medical meetings, ASH (American Society of Hematology), WCLC (World Conference on Lung Cancer) and the San Antonio Breast Cancer Symposium, AstraZeneca highlighted its continued momentum in Oncology with a total of 50 abstracts, including 15 oral presentations. Abstracts and presentations provided a comprehensive update on recent data from *Faslodex*, *Iressa*, *Tagrisso* and the Company's emerging presence in blood cancers, through acalabrutinib.

a) Faslodex (breast cancer)

During the period, the Company received regulatory submission acceptances for *Faslodex* in 1st-line metastatic breast cancer in the US and the EU. The submissions were based on the Phase III FALCON trial that compared *Faslodex* 500mg to *Arimidex* 1mg for the treatment of locally-advanced or metastatic breast cancer, in post-menopausal women who have not had prior hormonal treatment for hormone receptor-positive breast cancer. *Faslodex* demonstrated superiority compared with *Arimidex* and met its primary endpoint of extended progression-free survival (PFS).

b) Tagrisso (lung cancer)

In December 2016, data from the AURA3 trial were presented at WCLC. AURA3 was the first randomised and controlled trial for *Tagrisso* and tested the medicine in 2nd-line treatment of patients with epidermal growth factor receptor (EGFR) T790M mutation-positive locally-advanced or metastatic NSCLC against standard-of-care (SoC) platinum-based doublet chemotherapy. The trial showed that *Tagrisso* significantly improved PFS by 5.7 months with a hazard ratio of 0.30 (equal to a risk reduction of 70%).

Additionally, in the 34% of patients with central nervous system (CNS) metastases at baseline, PFS was also significantly greater (4.3 months, hazard ratio 0.32) with *Tagrisso*. The medicine's ability to provide benefit in patients with CNS metastases is encouraging and *Tagrisso* continues to be tested in the BLOOM trial. Based on results from AURA3, regulatory submissions were made in the US and EU during the period; acceptances were received on both submissions and Priority Review Designation was obtained in the US.

c) Durvalumab (multiple cancers)

In December 2016, AstraZeneca received FDA acceptance with Priority Review status of the Biologics License Application (BLA) for durvalumab in patients with locally-advanced or metastatic urothelial carcinoma, whose disease has progressed during or after one standard platinum-based regimen. This acceptance was based on the results of the urothelial cancer cohort of Study 1108 and follows the FDA's Breakthrough Therapy Designation for durvalumab in bladder cancer in February 2016. The Prescription Drug User Fee Act (PDUFA) date is in the second quarter of 2017.

The Company is also advancing durvalumab alone and in combination with tremelimumab in bladder cancer.

Operating & Financial Review



METASTATIC UROTHELIAL BLADDER CANCER

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
Combination	therapy					
DANUBE	111	1st Line	Cisplatin chemo- therapy- eligible/ ineligible bladder cancer	durvalumab, durva + treme vs SoC chemotherapy	FPD ¹ Q4 2015 First data anticipated 2018	Ongoing

The Company continues to advance multiple monotherapy trials of durvalumab and combination trials of durvalumab with tremelimumab and other potential new medicines in Immuno-Oncology (IO). An update on key AstraZeneca-sponsored ongoing trials with durvalumab outside bladder cancer is provided below:

LUNG CANCER

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
Monotherapy						
ADJUVANT ²		N/A	Stage lb-IIIa NSCLC	durvalumab vs placebo	FPD Q1 2015 First data anticipated 2020	Ongoing
PACIFIC	111	N/A	Stage III unresectable NSCLC	durvalumab vs placebo	FPD Q2 2014 LPCD ³ Q2 2016 First data anticipated H2 2017	Recruitment completed
PEARL	111	1st line	NSCLC (Asia)	durvalumab vs SoC chemotherapy	First data anticipated 2020	Initiating
Combination th	nerapy		-	·		
MYSTIC		1st line	NSCLC	durvalumab, durva + treme vs SoC chemotherapy	FPD Q3 2015 LPCD Q3 2016 First data anticipated mid-2017	Recruitment completed
NEPTUNE	III	1st line	NSCLC	durva + treme vs SoC chemotherapy	FPD Q4 2015 First data anticipated 2018	Ongoing

Operating & Financial Review

-		1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab	-	Ongoing in safety lead-in Phase I/II trial
ARCTIC		3rd line	PD-L1 neg. NSCLC	durvalumab, tremelimumab, durva + treme vs SoC chemotherapy	FPD Q2 2015 LPCD Q3 2016 First data anticipated H1 2017	Recruitment completed
CASPIAN	111	1st line	Small-cell lung cancer	durvalumab + SoC, durva + treme + SoC vs SoC chemotherapy	-	Initiating

¹ FPD = First Patient Dosed

² Conducted by the National Cancer Institute of Canada

³LPCD = Last Patient Commenced Dosing

On 17 January 2017, the Company provided an update on its late-stage IO clinical-development programme in 1st-line NSCLC, including a refinement of the Phase III MYSTIC trial. The trial was initially designed to assess the benefit of durvalumab monotherapy and durvalumab and tremelimumab (durva + treme) combination therapy versus SoC chemotherapy, focused on PFS.

The MYSTIC trial will now assess PFS and overall survival (OS) endpoints in patients with PDL1-expressing tumours for both durvalumab monotherapy and the combination of durva + treme, as well as in 'all comers' for the combination of durva + treme, versus SoC chemotherapy. While the focus remains on exploring the benefit of durva + treme as combination therapy, the Company has updated the endpoints of the MYSTIC trial to include OS and PFS in durvalumab monotherapy. This is based on recent internal and external data, including durvalumab's strong efficacy in monotherapy presented at recent medical meetings, as well as significant opportunities in the competitive landscape.

The estimated primary completion date was updated to reflect both an increase in patient recruitment (as reported in February 2016 with the inclusion of OS as a co-primary endpoint) and the event-based nature of the trial. As a result, the Company anticipates MYSTIC PFS data in mid-2017 and final OS data, at the latest, in 2018. MYSTIC also includes several undisclosed interim analyses for OS.

Additionally, the ongoing Phase III NEPTUNE trial will be expanded with local patients to support regulatory submission of durva + treme combination therapy in China for 1st-line NSCLC patients, without delaying the anticipated OS data readout in 2018 from the global cohort, which is approaching full recruitment. The Company has also initiated the new Phase III PEARL trial of durvalumab monotherapy versus SoC chemotherapy in 1st-line NSCLC patients, whose tumours express PD-L1. The PEARL trial focuses on Asian countries, primarily China, due to the prevalence of NSCLC in the region.

At WCLC, AstraZeneca presented safety findings from the safety lead-in Phase Ib trial of durvalumab with or without tremelimumab in combination with doublet chemotherapy. The conclusion of this trial was that in a PD-L1 unselected patient population, durvalumab and tremelimumab can be safely combined with full doses of pemetrexed/cisplatin chemotherapy.

Operating & Financial

AstraZeneca 😕 What science can do

METASTATIC OR RECURRENT HEAD AND NECK CANCER

Name	Phase	Line of Treatment	Population	Design	Timelines	Status			
Combination th	Combination therapy								
KESTREL		1st line	HNSCC*	durvalumab, durva + treme vs SoC	FPD Q4 2015 First data anticipated H2 2017	Ongoing			
EAGLE	111	2nd line	HNSCC	durvalumab, durva + treme vs SoC	FPD Q4 2015 First data anticipated 2018	Ongoing			

*Head and Neck Squamous Cell Carcinoma

As communicated on 15 December 2016, the Company has reviewed data from the CONDOR trial, a randomised, but non-controlled Phase II trial in 2nd-line PDL1-negative HNSCC patients. While the data show efficacy and safety of the experimental medicines, AstraZeneca does not believe that a non-controlled trial can facilitate a regulatory submission for accelerated approval in a setting where a PD1-targeted medicine was approved during 2016, based on an OS benefit in all-comers.

On 22 November 2016, AstraZeneca announced that the FDA had lifted the partial clinical hold on the enrolment of new patients with HNSCC for clinical trials of durvalumab as monotherapy and in combination with tremelimumab or other potential new medicines. The partial clinical hold on new patient enrolment was communicated on 27 October 2016, after preliminary findings from ongoing clinical trials related specifically to HNSCC. The FDA lifted the hold following a review of the comprehensive analysis provided by AstraZeneca of bleeding events that were observed as part of the routine safety monitoring of the Phase III KESTREL and EAGLE trials.

d) Acalabrutinib (blood cancers)

Less than a year after announcing a majority investment in Acerta Pharma, AstraZeneca provided new clinical data on acalabrutinib, a highly-selective, potent Bruton tyrosine-kinase (BTK) inhibitor in Phase III development for B-cell malignancies. At the 2016 ASH annual meeting, two oral presentations were shared on acalabrutinib, in patients with Richter's transformation and in patients with ibrutinib intolerance, both Phase I/II trials.

In patients with Richter's transformation, acalabrutinib monotherapy produced a partial or complete response in 38% of patients, with a median time on treatment of 3.4 months. In 21 Richter-transformation patients evaluable for efficacy measures in the trial, median PFS was 2.1 months and the median duration of response was 5.2 months. Acalabrutinib monotherapy demonstrated a tolerable safety profile in patients with Richter's transformation and these data suggested that further investigation, in combination with immunotherapy or other targeted therapies, is warranted.

Acalabrutinib was well tolerated in ibrutinib-intolerant patients, with a total of 12 of 33 (36%) patients experiencing adverse event (AE) recurrence, most of which reduced or had the same severity as before; no patients discontinued treatment because of a recurrent AE. This safety profile was coupled with promising activity (objective response rate of 79%) and response duration (81% of responding patients had a duration of response ≥12 months).

AstraZeneca 😕 What science can do

Preliminary Financial

Statements



CARDIOVASCULAR & METABOLIC DISEASES

This therapy area includes a broad type-2 diabetes portfolio, differentiated devices and unique small and largemolecule programmes to reduce morbidity, mortality and organ damage across CV disease, diabetes and chronic kidney disease (CKD) indications.

a) Bydureon (type-2 diabetes)

During the period, the DURATION-7 trial met its primary endpoint of a reduction in blood glucose (HbA1c) at 28 weeks as well as key secondary endpoints. No new safety findings were observed and the overall rates of AEs and serious AEs were low in both groups.

DURATION-7 was a multi-centre, randomised, double-blind, placebo-controlled, parallel group, Phase III trial that evaluated the safety and efficacy of once-weekly *Bydureon* therapy added to titrated basal insulin glargine, compared with placebo added to titrated basal insulin glargine, in patients with type-2 diabetes who have inadequate glycaemic control on basal insulin glargine with or without metformin.

b) Type-2 diabetes medicines in CV outcomes trials

As the field of type-2 diabetes medicines evolves, with multiple outcomes trials producing data, AstraZeneca continues to assess both *Farxiga* and *Bydureon* for potential long-term CV benefits. Two significant type-2 diabetes outcomes trials are progressing:

Medicine	Trial	Mode of Action	Number of Patients	Primary Endpoint	Timeline
Bydureon	EXSCEL	GLP-1 agonist	~14,000	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	Latest 2018 (final analysis)
Farxiga	DECLARE	SGLT2 inhibitor	~17,000*	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	Latest 2019 (final analysis)

*Includes ~10,000 patients who have had no prior index event (primary prevention) and ~7,000 patients who have suffered an index event (secondary prevention).

c) Roxadustat (anaemia)

Roxadustat is a potential first-in-class oral HIF-PH inhibitor in Phase III development for the treatment of anaemia in CKD patients. AstraZeneca, FibroGen, Inc. (FibroGen) and Astellas Pharma Inc. are jointly undertaking an extensive worldwide Phase III trial programme, enrolling more than 8,000 patients.

In addition to evaluating efficacy, the US/global programme is designed to demonstrate the CV safety of roxadustat in comparison to epoetin alfa in dialysis patients (based on data pooled from four clinical trials) and in comparison to placebo in non-dialysis patients (based on data pooled from three clinical trials). AstraZeneca and FibroGen anticipate data readout and US regulatory submission in 2018.

FibroGen is responsible for development and regulatory activities in China, and recently announced that the submission process had initiated and is expected to complete in the second or third quarter of 2017.

Additionally, on 30 January 2017, FibroGen reported positive results from two Phase III clinical trials of roxadustat in China. The two Phase III clinical trials evaluated roxadustat for anaemia in CKD in patients on dialysis and not on dialysis. Both Phase III trials met their primary efficacy endpoints, confirming earlier results. Initial analysis suggests that adverse events were consistent with previous clinical trials of roxadustat in the CKD patient population.



RESPIRATORY

AstraZeneca's Respiratory portfolio is aimed at transforming the treatment of asthma and COPD through combination inhaled therapies, biologics for the unmet medical needs of specific patient populations and an early pipeline focused on disease modification. The growing range of medicines includes up to four launches between 2017 and 2020. The capability in inhalation technology spans both pMDIs and dry-powder inhalers to serve patient needs, as well as the innovative *Aerosphere* co-suspension delivery technology, a focus of AstraZeneca's future-platform development for respiratory-disease combination therapies.

a) Symbicort (asthma, COPD)

During the period, the Company received EU approval for *Symbicort* SMART (*Symbicort* Maintenance And Reliever Therapy) for adolescent asthma patients (aged 12 to <18 years). The SMART regimen for adolescents is the same as for adult patients, with a daily maintenance dose of *Symbicort Turbuhaler* plus additional doses as needed in response to symptoms. *Symbicort* SMART is a key component of the Company's commitment to 'patient-adjusted therapy' in treating asthma.

On 26 January 2017, AstraZeneca announced that the FDA had granted six months of paediatric exclusivity for *Symbicort*, based on the evaluation of trials conducted in children with asthma aged six up to 12 years.

b) Benralizumab (severe, uncontrolled asthma)

During the period, AstraZeneca announced that the FDA accepted a BLA for benralizumab, an anti-eosinophil monoclonal antibody (mAb), with a PDUFA date anticipated in Q4 2017. The Company also announced that the European Medicines Agency accepted the Marketing Authorisation Application (MAA) for benralizumab.

The BLA and MAA submissions, for the treatment of patients with severe, uncontrolled asthma with an eosinophilic phenotype, were based on the results of the pivotal Phase III trials, SIROCCO and CALIMA, that demonstrated that adding benralizumab to SoC significantly reduced exacerbations and improved lung function and asthma symptoms. To date, five positive Phase III trials (BISE, SIROCCO, CALIMA, GREGALE and ZONDA) have supported the efficacy and safety profile of benralizumab.



ASTRAZENECA DEVELOPMENT PIPELINE 31 DECEMBER 2016

AstraZeneca-sponsored or -directed trials

Phase III / Pivotal Phase II / Registration

New Molecular Entities (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.

Mechanism	Area Under	Date Commenced	Estima	Date /		
	Investigation	Phase	US	EU	Japan	China
EGFR inhibitor	≥2nd-line advanced EGFRm T790M NSCLC		Launched (Breakthrough Therapy, Priority Review, Orphan drug)	Launched (Accelerated assessment)	Launched	Accepted
EGFR inhibitor	≥2nd-line advanced EGFRm T790M NSCLC		Accepted (Priority Review)	Accepted		
PD-L1 mAb	≥2nd-line advanced bladder cancer		Accepted (Breakthrough Therapy & Priority Review)			
BTK inhibitor	B-cell malignancy	Q1 2015	H1 2017 (Orphan drug)			
BTK inhibitor	1st-line CLL	Q3 2015	2020 (Orphan drug)	2020 (Orphan drug)		
BTK inhibitor	r/r CLL, high risk	Q4 2015	2020 (Orphan drug)	2020 (Orphan drug)		
MEK inhibitor	differentiated thyroid cancer	Q3 2013	2018 (Orphan drug)	2018		
anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	2018 (Orphan drug)			
PD-L1 mAb	stage III NSCLC	Q2 2014	H2 2017	H2 2017	H2 2017	
PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	H2 2017	H2 2017	H2 2017	
PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	H2 2017	H2 2017	H2 2017	
PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	2020
PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	2018	2018	2018	
PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC	Q4 2015	2018	2018	2018	
PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2018	2018	2018	
	EGFR inhibitor EGFR inhibitor PD-L1 mAb BTK inhibitor BTK inhibitor PD-L1 mAb + CTLA-4 mAb PD-L1 mAb + CTLA-4 mAb PD-L1 mAb + CTLA-4 mAb	MechanismInvestigationEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCPD-L1 mAb BTK inhibitor≥2nd-line advanced bladder cancerBTK inhibitorB-cell malignancyBTK inhibitorB-cell malignancyBTK inhibitorIst-line CLLBTK inhibitorIst-line CLLBTK inhibitorIst-line CLLBTK inhibitorfr/r CLL, high riskMEK inhibitordifferentiated thyroid canceranti-CD22 recombinant immunotoxinhairy cell leukaemiaPD-L1 mAb CTLA-4 mAb3rd-line NSCLCPD-L1 mAb + CTLA-4 mAb1st-line HNSCCPD-L1 mAb + CTLA-4 mAb2nd-line HNSCCPD-L1 mAb + CTLA-4 mAb2nd-line HNSCC	MechanismArea Under InvestigationCommenced PhaseEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCEGFR inhibitor≥2nd-line advanced EGFRm T790M NSCLCPD-L1 mAb BTK inhibitor≥2nd-line advanced bladder cancerBTK inhibitorB-cell malignancyQ1 2015BTK inhibitorIst-line CLLQ3 2015BTK inhibitorfr/r CLL, high riskQ4 2015MEK inhibitorfr/r CLL, high riskQ2 2013MEK inhibitordifferentiated thyroid cancerQ3 2013anti-CD22 recombinant immunotoxinhairy cell leukaemiaQ2 2014PD-L1 mAb CTLA-4 mAb3rd-line NSCLCQ2 2015PD-L1 mAb + CTLA-4 mAb1st-line NSCLCQ3 2015PD-L1 mAb + CTLA-4 mAb1st-line NSCLCQ4 2015PD-L1 mAb + CTLA-4 mAb1st-line NSCLCQ4 2015PD-L1 mAb + CTLA-4 mAb1st-line HNSCCQ4 2015PD-L1 mAb + CTLA-4 mAb2nd-line HNSCCQ4 2015	MechanismArea Under InvestigationCommenced PhaseEGFR inhibitor22nd-line advanced EGFRm T790M NSCLCLaunched (Breakthrough Therapy, Priority Review, Orphan drug)EGFR inhibitor22nd-line advanced EGFRm T790M NSCLCAccepted (Priority Review)PD-L1 mAb BTK inhibitor22nd-line advanced bladder cancerAccepted (Breakthrough Therapy, Priority Review)BTK inhibitorB-cell malignancyQ1 2015H1 2017 (Orphan drug)BTK inhibitor1st-line CLLQ3 20152020 (Orphan drug)BTK inhibitor1st-line CLLQ3 20132018 (Orphan drug)BTK inhibitorr/r CLL, high riskQ4 20152020 (Orphan drug)MEK inhibitorr/r CLL, high riskQ2 20132018 (Orphan drug)PD-L1 mAb + CTLA-4 mAb3rd-line NSCLCQ2 2015H2 2017PD-L1 mAb + CTLA-4 mAb1st-line NSCLCQ4 20152019PD-L1 mAb + CTLA-4 mAb1st-line HNSCCQ4 20152018PD-L1 mAb + CTLA-4 mAb2nd-line HNSCCQ4 2015 <td>MechanismArea Under InvestigationCommenced PhaseSubmissionEGFR inhibitor>2nd-line advanced EGFRm T790M NSCLCLaunched (Breakthrough Therapy, Piontly Review)Launched (Accelerated assessment)EGFR inhibitor>2nd-line advanced EGFRm T790M NSCLCAccepted (Piority Review)Accepted (Breakthrough Therapy, Piontly Review)PD-L1 mAb BTK inhibitor>2nd-line advanced bladder cancerAccepted (Breakthrough Therapy, Priority Review)Accepted (Orphan drug)BTK inhibitor9-cell malignancyQ1 2015 (Orphan drug)2020 (Orphan drug)BTK inhibitor1st-line CLLQ3 2015 (Orphan drug)2020 (Orphan drug)BTK inhibitordifferentiated thyroid cancerQ3 2013 (Orphan drug)2018 (Orphan drug)MEK inhibitordifferentiated thyroid cancerQ2 2013 (Orphan drug)2018 (Orphan drug)MEK inhibitordifferentiated thyroid cancerQ2 2013 (Orphan drug)2018 (Orphan drug)PD-L1 mAb CTLA-4 mAb3rd-line NSCLC Stale III NSCLCQ2 2015 Q2 2015H2 2017 H2 2017H2 2017 H2 2017PD-L1 mAb + CTLA-4 mAb1st-line HNSCC Q4 2015Q4 2015 20182018 20182018 2018PD-L1 mAb + CTLA-4 mAb1st-line HNSCC Q4 2015Q4 2015 20182018 20182018 2018PD-L1 mAb + CTLA-4 mAb1st-line HNSCC Q4 2015Q4 2015 20182018 20182018 2018</td> <td>MechanismArea Under InvestigationCommenced PhaseSubmission StatusEGFR inhibitor22nd-line advanced EGFRm T790M NSCLCLaunched (Breakthrough Therapy-Printry Review, Orphan drug)Launched (Accepted (Printry Review)Launched (Accepted (Printry Review)Launched (Accepted (Breakthrough Therapy-Printry Review)Launched (Accepted (Breakthrough Therapy & Printry Review)Launched (Accepted (Breakthrough Therapy & Printry Review)Launched (Accepted (Breakthrough (Orphan drug))BTK inhibitorB-cell ration cancerQ1 2015 (Q2 2015 (Q2 2020 (Orphan drug))Accepted (Orphan drug)Accepted (Orphan drug)BTK inhibitorrtr CLL, high riskQ4 2015 (Q2 2013 (Orphan drug))2018 (Orphan drug)2018 (Orphan drug)BTK inhibitorrtr CLL, high riskQ2 2013 (Q2 2013 (Orphan drug))2018 (Orphan drug)2018 (Q2 2017PD-L1 mAb CTLA-4 mAbst</td>	MechanismArea Under InvestigationCommenced PhaseSubmissionEGFR inhibitor>2nd-line advanced EGFRm T790M NSCLCLaunched (Breakthrough Therapy, Piontly Review)Launched (Accelerated assessment)EGFR inhibitor>2nd-line advanced EGFRm T790M NSCLCAccepted (Piority Review)Accepted (Breakthrough Therapy, Piontly Review)PD-L1 mAb BTK inhibitor>2nd-line advanced bladder cancerAccepted (Breakthrough Therapy, Priority Review)Accepted (Orphan drug)BTK inhibitor9-cell malignancyQ1 2015 (Orphan drug)2020 (Orphan drug)BTK inhibitor1st-line CLLQ3 2015 (Orphan drug)2020 (Orphan drug)BTK inhibitordifferentiated thyroid cancerQ3 2013 (Orphan drug)2018 (Orphan drug)MEK inhibitordifferentiated thyroid cancerQ2 2013 (Orphan drug)2018 (Orphan drug)MEK inhibitordifferentiated thyroid cancerQ2 2013 (Orphan drug)2018 (Orphan drug)PD-L1 mAb CTLA-4 mAb3rd-line NSCLC Stale III NSCLCQ2 2015 Q2 2015H2 2017 H2 2017H2 2017 H2 2017PD-L1 mAb + CTLA-4 mAb1st-line HNSCC Q4 2015Q4 2015 20182018 20182018 2018PD-L1 mAb + CTLA-4 mAb1st-line HNSCC Q4 2015Q4 2015 20182018 20182018 2018PD-L1 mAb + CTLA-4 mAb1st-line HNSCC Q4 2015Q4 2015 20182018 20182018 2018	MechanismArea Under InvestigationCommenced PhaseSubmission StatusEGFR inhibitor22nd-line advanced EGFRm T790M NSCLCLaunched (Breakthrough Therapy-Printry Review, Orphan drug)Launched (Accepted (Printry Review)Launched (Accepted (Printry Review)Launched (Accepted (Breakthrough Therapy-Printry Review)Launched (Accepted (Breakthrough Therapy & Printry Review)Launched (Accepted (Breakthrough Therapy & Printry Review)Launched (Accepted (Breakthrough (Orphan drug))BTK inhibitorB-cell ration cancerQ1 2015 (Q2 2015 (Q2 2020 (Orphan drug))Accepted (Orphan drug)Accepted (Orphan drug)BTK inhibitorrtr CLL, high riskQ4 2015 (Q2 2013 (Orphan drug))2018 (Orphan drug)2018 (Orphan drug)BTK inhibitorrtr CLL, high riskQ2 2013 (Q2 2013 (Orphan drug))2018 (Orphan drug)2018 (Q2 2017PD-L1 mAb CTLA-4 mAbst

Compound	Mechanism	Area Under Investigation	Date Commenced	Estimated Regulatory Acceptance Date / Submission Status				
			Phase	US	EU	Japan	China	
Cardiovascular	& Metabolic Dis	seases						
Brilinta ¹	P2Y12 receptor antagonist	arterial thrombosis		Launched	Launched	Approved	Launched	
Farxiga ²	SGLT2 inhibitor	type-2 diabetes		Launched	Launched	Launched	Accepted	
Epanova [#]	omega-3 carboxylic acids	severe hypertriglyceride mia		Approved		2018		
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		Accepted	Accepted			
roxadustat [#] OLYMPUS (US) ROCKIES (US)	hypoxia- inducible factor prolyl hydroxylase inhibitor	anaemia in CKD/ESRD	Q3 2014	2018			Initiated ³	
Respiratory								
Bevespi Aerosphere (PT003)	LABA/LAMA	COPD		Launched ⁴	H1 2017	2018	2018	
benralizumab [#] CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe asthma		Accepted	Accepted	H1 2017	2020	
benralizumab [#] TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	2018	2018	2019		
PT010	LABA/LAMA/I CS	COPD	Q3 2015	2018	2018	2018	2019	
tralokinumab STRATOS 1,2 TROPOS MESOS	IL-13 mAb	severe asthma	Q3 2014	2018	2018	2018		
Other								
anifrolumab [#] TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019		
AZD3293 [#] AMARANTH DAYBREAK- ALZ	beta- secretase inhibitor	Alzheimer's disease	Q2 2016	2020 (Fast Track)	2020	2020		

Registrational Phase II trial Collaboration ¶ #

1 2 3

Brilinta in the US and Japan; Brilique in ROW Farxiga in the US; Forxiga in ROW Rolling New Drug Application (NDA) regulatory submission initiated in Q4 2016 Bevespi Aerosphere (glycopyrrolate and formoterol fumarate) inhalation aerosol was launched commercially in the US in January 2017 4

What science can do

Operating & Financial Review

AstraZeneca

Corporate & Business Development



Phases I and II

NMEs and significant additional indications

Compound Mechanism		Area Under Investigation	Phase	Date Commenced Phase
Oncology				
durvalumab [#]	PD-L1 mAb	solid tumours	II	Q3 2014
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	Hepatocellular carcinoma (liver cancer)		Q4 2016
durvalumab# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
durvalumab [#] + AZD5069	PD-L1 mAb + CXCR2	HNSCC	II	Q3 2015
durvalumab [#] + AZD9150 [#] durvalumab [#] + dabrafenib +	PD-L1 mAb + STAT3 inhibitor PD-L1 mAb+ BRAF inhibitor +	melanoma	II	Q1 2014
trametinib durvalumab [#] + AZD1775 [#]	MEK inhibitor PD-L1 mAb + Wee1 inhibitor	solid tumours		Q4 2015
durvalumab [#] + MEDI0680	PD-L1 mAb + Wee1 inhibitor PD-L1 mAb + PD-1 mAb	solid tumours	1	Q4 2015 Q3 2016
durvalumab# or durvalumab# + (tremelimumab or AZD9150#)	PD-L1 mAb or PD-L1 mAb + (CTLA-4 mAb or STAT3 inhibitor)	diffuse large B-cell lymphoma		Q3 2016
durvalumab [#] + Iressa	PD-L1 mAb+ EGFR inhibitor	NSCLC	1	Q2 2014
durvalumab# + MEDI0562#	PD-L1 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
durvalumab# + MEDI9447	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
durvalumab# + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
durvalumab# + selumetinib	PD-L1 mAb + MEK inhibitor	solid tumours	I	Q4 2015
durvalumab [#] + tremelimumab	PD-L1 mAb + CTLA-4 mAb	solid tumours	1	Q4 2013
tremelimumab + MEDI0562 [#]	CTLA-4 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
Lynparza + AZD6738	PARP inhibitor + ATR inhibitor	gastric cancer	II	Q3 2016
Lynparza + AZD1775 [#]	PARP inhibitor + Wee1 inhibitor	solid tumours	I	Q3 2015
savolitinib [#]	MET inhibitor	papillary renal cell carcinoma	II	Q2 2014
<i>Tagrisso</i> + (selumetinib [#] or savolitinib [#]) TATTON	EGFR inhibitor + (MEK inhibitor or MET inhibitor)	advanced EGFRm NSCLC	11	Q2 2016
Tagrisso BLOOM	EGFR inhibitor	CNS metastases in advanced EGFRm NSCLC	11	Q4 2015
AZD1775 [#] + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer		Q4 2012
AZD1775 [#]	Wee1 inhibitor	solid tumours	II	Q1 2016
vistusertib (AZD2014)	mTOR inhibitor	solid tumours		Q1 2013
AZD5363#	AKT inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR inhibitor	solid tumours	II	Q4 2011
MEDI-573 [#]	IGF mAb	metastatic breast cancer	II	Q2 2012
AZD0156	ATM inhibitor	solid tumours	I	Q4 2015
AZD2811 [#]	Aurora B inhibitor	solid tumours		Q4 2015
AZD4635	A2aR inhibitor	solid tumours	1	Q2 2016
AZD6738	ATR inhibitor	solid tumours	Ι	Q4 2013
AZD8186	PI3k inhibitor	solid tumours		Q2 2013
AZD9150 [#]	STAT3 inhibitor	haematological malignancies	I	Q1 2012
AZD9496	selective oestrogen receptor downregulator (SERD)	ER+ breast cancer	I	Q4 2014
MEDI-565 [#]	CEA BITE mAb	solid tumours	I	Q1 2011

Operating & Financial Review

		Area Under Investigation	Phase	Date Commenced Phase
MED10562#	humanised OX40 agonist	solid tumours	I	Q1 2015
MED10680	PD-1 mAb	solid tumours	I	Q4 2013
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI4276	HER2 bispecific ADC mAb	solid tumours	1	Q4 2015
MEDI9197 [#]	TLR 7/8 agonist	solid tumours		Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
			•	40 2010
Cardiovascular & Metabol		1		
MED10382	GLP-1/ glucagon dual agonist	diabetes / obesity	II	Q3 2016
MEDI4166	PCSK9/GLP-1 mAb + peptide fusion	diabetes / cardiovascular	II	Q1 2016
MEDI6012	LCAT	ACS	II	Q4 2015
AZD4076	anti-miR103/107	non-alcoholic fatty liver		Q4 2016
	oligonucleotide	disease/non-alcoholic steatohepatitis (NASH)		Q+2010
AZD4831	Myeloperoxidase	Heart failure with a preserved ejection fraction	Ι	Q3 2016
AZD5718	FLAP	CAD	I	Q1 2016
AZD8601#	VEGF-A	cardiovascular	1	Q1 2017
MEDI8111	Rh-factor II	trauma / bleeding		Q1 2014
Respiratory			•	
tezepelumab [#]	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
abediterol#	LABA	asthma/COPD	II	Q4 2007
AZD7594	inhaled SGRM	asthma/COPD		Q3 2015
AZD9412 [#]	inhaled interferon beta	asthma/COPD	 	Q3 2015
PT010	LABA/LAMA/ICS	asthma	 	Q2 2014
AZD1419 [#]	TLR9 agonist	asthma		Q4 2016
AZD8871 [#]	MABA	COPD		Q1 2017
AZD0284	Inhaled RORg	psoriasis	 	Q4 2016
AZD5634	inhaled ENaC	cystic fibrosis	I	Q1 2016
		-	1	
AZD7594+abediterol#	Inhaled SGRM+LABA	asthma/COPD	<u> </u>	Q4 2016
AZD7986 [#]	DPP1	COPD	I	Q4 2014
AZD9567	oral SGRM	rheumatoid arthritis		Q4 2015
Other				1
anifrolumab#	IFN-alphaR mAb	lupus nephritis	II	Q4 2015
anifrolumab [#]	IFN-alphaR mAb	systemic lupus erythematosus (subcutaneous)	Ι	Q4 2015
inebilizumab [#]	CD19 mAb	neuromyelitis optica	II	Q1 2015 (Orphan drug)
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	11	Q1 2010
verinurad ¹	selective uric acid	chronic treatment of		Q3 2013
volinaraa	reabsorption inhibitor (URAT-	hyperuricemia in patients with gout		
MEDI5872 [#]	B7RP1 mAb	primary Sjögren's syndrome	II	Q3 2016
AZD3241	myeloperoxidase inhibitor	multiple system atrophy	II	Q2 2015 (Orphan drug)
MEDI3902	Psl/PcrV bispecific mAb	prevention of nosocomial pseudomonas pneumonia	II	Q2 2016 (Fast Track, US)
MEDI4893	mAb binding to S. aureus toxin	hospital-acquired pneumonia / serious <i>S.</i> <i>aureus</i> infection	II	Q4 2014 (Fast Track, US)

AstraZeneca What science can do

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
MED18852	influenza A mAb	influenza A treatment	II	Q4 2015 (Fast Track, US)
MED18897 [#]	RSV mAb-YTE	passive RSV prophylaxis	Ш	Q1 2015 (Fast Track, US)
MED10700 [#]	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	Ι	Q1 2016
MEDI1814 ^{#2}	amyloid beta mAb	Alzheimer's disease		Q2 2014
MED14920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	Ι	Q2 2014
MEDI7352	NGF/TNF bispecific mAb	osteoarthritis pain	Ι	Q1 2016
MEDI7734	ILT7 mAb	myositis	I	Q3 2016
MEDI9314	IL-4R mAb	atopic dermatitis	I	Q1 2016

Collaboration
1 Planning to initiate a programme for CKD
2 Co-development collaboration with Eli Lilly for MEDI1814

Significant Lifecycle Management

Compound	Mechanism	Area Under Investigation	Date Commenced	Estimated Regulatory Acceptance Date / Submission Status			
-		investigation	Phase	US	EU	Japan	China
Oncology			•				
<i>Faslodex</i> FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer		Accepted	Accepted	Accepted	H2 2017
<i>Lynparza</i> OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	H2 2017	H2 2017	H2 2017	
Lynparza SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	H1 2017 (Fast Track)	H1 2017	H2 2017	
<i>Lynparza</i> SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	2018	2018	2018	
<i>Lynparza</i> SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	2018			
<i>Lynparza</i> POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2018	2018		
Lynparza	PARP inhibitor	prostate cancer	Q3 2014	(Breakthrough Therapy)			
<i>Lynparza</i> OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
<i>Tagrisso</i> FLAURA	EGFR inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	H2 2017	H2 2017	H2 2017	H2 2017
<i>Tagrisso</i> ADAURA	EGFR inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
Cardiovascular	& Metabolic Dis	eases					
<i>Brilinta</i> 1 PEGASUS- TIMI 54	P2Y12 receptor antagonist	outcomes trial in patients with prior myocardial infarction		Launched (Priority Review)	Launched	Approved	Accepted
Brilinta ¹ THEMIS	P2Y12 receptor antagonist	outcomes trial in patients with type-2 diabetes and CAD, but without a previous history of myocardial infarction or stroke	Q1 2014	2018	2018	2018	2019

Operating & Financial Review

AstraZeneca What science can do

Compound	Mechanism	Area Under Investigation	Date Commenced	Submission Status			
			Phase	US	EU	Japan	China
<i>Brilinta</i> ¹ HESTIA	P2Y12 receptor antagonist	prevention of vaso- occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2020	2020		
Onglyza SAVOR-TIMI 53	DPP-4 inhibitor	type-2 diabetes outcomes trial		Launched	Launched		Accepted
Kombiglyze XR/Komboglyze ²	DPP-4 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		Accepted
<i>Farxiga</i> ³ DECLARE- TIMI 58	SGLT2 inhibitor	type-2 diabetes outcomes trial	Q2 2013	2020	2020		
Farxiga ³	SGLT2 inhibitor	type-1 diabetes	Q4 2014	2018	2018	2018	
Xigduo XR/ Xigduo⁴	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		
Qtern (saxagliptin/ dapagliflozin FDC)	DPP-4 inhibitor/ SGLT2 inhibitor FDC	type-2 diabetes		Accepted	Approved		
<i>Bydureon</i> weekly suspension	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	H1 2017	H2 2017		
Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	2018	2018		2018
Epanova STRENGTH	omega-3 carboxylic acids	outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridemia plus low HDL- cholesterol	Q4 2014	2020	2020	2020	2020
Respiratory							
Symbicort SYGMA	ICS/LABA	as-needed use in mild asthma	Q4 2014		2018		2019
Symbicort	ICS/LABA	breath actuated Inhaler asthma/COPD		2018			
Duaklir Genuair [#]	LAMA/LABA	COPD		2018	Launched		2019
Other	T	I	r	I			
Nexium	proton pump inhibitor	stress ulcer prophylaxis					Submitted
Nexium	proton pump inhibitor	paediatrics		Launched	Launched	Accepted	
linaclotide#	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)					Accepted

Date

Corporate & Business Development

Operating & Financial Review

Collaboration

1

Brilinta in the US and Japan; Brilique in ROW Kombiglyze XR in the US; Komboglyze in the EU Farxiga in the US; Forxiga in ROW Xigduo XR in the US; Xigduo in the EU

2 3

4



Estimated Regulatory Acceptance Date /



Terminations (discontinued projects between 1 October 2016 and 31 December 2016)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation
NME	durvalumab# + tremelimumab ALPS¶	Safety/Efficacy	metastatic pancreatic ductal carcinoma
NME	MEDI7510	Safety/Efficacy	Prevention of respiratory syncytial virus disease in older patients

Completed Projects / Divestitures

0	Maakaniam	Area Under	Completed/	Estimated Regulatory Submission Acceptance [†]				
Compound	Mechanism	Investigation	Divested	US	EU	Japan	China	
MEDI2070 ^{#1}	IL-23 mAb	Crohn's disease	Divested					
Zinforo ^{#2}	extended spectrum cephalosporin with affinity to penicillin-binding proteins	pneumonia/skin infections	Divested		Launched		Submitted	
Zavicefta ^{#2} (CAZ AVI)	cephalosporin/ beta lactamase inhibitor	hospital-acquired pneumonia/ ventilator- associated pneumonia	Divested		Approved			
Zavicefta ^{#2} (CAZ AVI)	cephalosporin/ beta lactamase inhibitor	serious infections, complicated intra- abdominal infection, complicated urinary tract infection	Divested		Approved			
ATM AVI ^{#2}	monobactam/ beta lactamase inhibitor	targeted serious bacterial infections	Divested					
CXL ^{#2}	beta lactamase inhibitor / cephalosporin	methicillin- resistant <i>S.</i> <i>aureus</i>	Divested					
AZD8108	NMDA antagonist	suicidal ideation	Divested					
durvalumab [#] HAWK ^{¶3}	PD-L1 mAb	2nd-line HNSCC (PD-L1 positive)	Completed					
durvalumab [#] + tremelimumab CONDOR ^{¶3}	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC (PD-L1 negative)	Completed					

1 AstraZeneca licensing agreement with Allergan

2 AstraZeneca completed the transaction with Pfizer to sell the commercialisation and development rights to its late-stage, small-molecule antibiotics business in most markets globally outside the US

3 Registrational trials now complete (data will contribute towards subsequent HNSCC regulatory submissions)

Operating & Financial Review



Condensed Consolidated Statement of Comprehensive Income

For the year ended 31 December	2016 \$m	2015 \$m
Product sales	21,319	23,641
Externalisation revenue	1,683	1,067
Total revenue	23,002	24,708
Cost of sales	(4,126)	(4,646)
Gross profit	18,876	20,062
Distribution costs	(326)	(339)
Research and development expense	(5,890)	(5,997)
Selling, general and administrative costs	(9,413)	(11,112)
Other operating income and expense	1,655	1,500
Operating profit	4,902	4,114
Finance income	67	46
Finance expense	(1,384)	(1,075)
Share of after tax losses in associates and joint ventures	(33)	(16)
Profit before tax	3,552	3,069
Taxation	(146)	(243)
Profit for the period	3,406	2,826
Other comprehensive income Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(575)	652
Tax on items that will not be reclassified to profit or loss	136	(199)
	(439)	453
Items that may be reclassified subsequently to profit or loss	(100)	100
Foreign exchange arising on consolidation	(1,050)	(528)
Foreign exchange arising on designating borrowings in net investment hedges	(1,000)	(333)
Fair value movements on cash flow hedges	(115)	(000)
Fair value movements on cash flow hedges transferred to profit or loss	195	-
Fair value movements on derivatives designated in net investment hedges	(4)	14
Amortisation of loss on cash flow hedge	1	1
Net available for sale gains/(losses) taken to equity	139	(32)
Tax on items that may be reclassified subsequently to profit or loss	86	87
· · · · · · · · · · · · · · · · · · ·	(1,339)	(791)
Other comprehensive income for the period, net of tax	(1,778)	(338)
Total comprehensive income for the period	1,628	2,488
Profit attributable to: Owners of the Parent	3,499	2,825
Non-controlling interests	(93)	2,025
	3,406	2,826
Total comprehensive income attributable to:	4 700	0.400
Owners of the Parent	1,722	2,488
Non-controlling interests	(94)	-
	1,628	2,488
Basic earnings per \$0.25 Ordinary Share	\$2.77	\$2.23
Diluted earnings per \$0.25 Ordinary Share	\$2.76	\$2.23
Weighted average number of Ordinary Shares in issue (millions)	1,265	1,264



Condensed Consolidated Statement of Comprehensive Income

For the quarter ended 31 December	2016 \$m	2015 \$m
Product sales	5,260	6,207
Externalisation revenue	325	192
Total revenue	5,585	6,399
Cost of sales	(1,160)	(1,269)
Gross profit	4,425	5,130
Distribution costs	(83)	(99)
Research and development expense	(1,543)	(1,746)
Selling, general and administrative costs	(1,386)	(2,668)
Other operating income and expense	1,120	471
Operating profit	2,533	1,088
Finance income	23	13
Finance expense	(362)	(292)
Share of after tax losses in associates and joint ventures	(11)	(7)
Profit before tax	2,183	802
Taxation	(366)	6
Profit for the period	1,817	808
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	552	618
Tax on items that will not be reclassified to profit or loss	(120)	(187)
	432	431
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(360)	(169)
Foreign exchange arising on designating borrowings in net investment hedges	(397)	(11)
Fair value movements on cash flow hedges	(89)	-
Fair value movements on cash flow hedges transferred to profit or loss	154	-
Fair value movements on derivatives designated in net investment hedges	92	(10)
Net available for sale gains taken to equity	13	
Tax on items that may be reclassified subsequently to profit or loss	23	3
	(564)	(156)
Other comprehensive income for the period, net of tax	(132)	275
Total comprehensive income for the period	1,685	1,083
Profit attributable to: Owners of the Parent	1,842	808
Non-controlling interests		
	(25)	- 808
Total comprehensive income attributable to: Owners of the Parent	4 740	4 000
	1,710	1,083
Non-controlling interests	(25) 1,685	- 1,083
	1,000	1,000
Basic earnings per \$0.25 Ordinary Share	\$1.46	\$0.63
Diluted earnings per \$0.25 Ordinary Share	\$1.45	\$0.63
Weighted average number of Ordinary Shares in issue (millions)	1,265	1,264
Diluted weighted average number of Ordinary Shares in issue (millions)	1,266	1,265



Condensed Consolidated Statement of Financial Position

	At 31 Dec 2016 \$m	Restated* At 31 Dec 2015 \$m
ASSETS		
Non-current assets		
Property, plant and equipment	6,848	6,413
Goodwill	11,658	11,800
Intangible assets	27,586	22,646
Derivative financial instruments	343	446
Investments in associates and joint ventures	99	85
Other investments	727	458
Other receivables	901	907
Deferred tax assets	1,102	1,294
	49,264	44,049
Current assets		
Inventories	2,334	2,143
Trade and other receivables	4,573	6,622
Other investments	884	613
Derivative financial instruments	27	2
Income tax receivable	426	387
Cash and cash equivalents	5,018	6,240
	13,262	16,007
Total assets	62,526	60,056
LIABILITIES	02,020	00,000
Current liabilities		
Interest-bearing loans and borrowings	(2,307)	(916)
Trade and other payables	(10,486)	(11,663)
Derivative financial instruments	(10,400)	(11,003)
Provisions		
	(1,065) (1,380)	(798) (1,483)
Income tax payable		
Non-current liabilities	(15,256)	(14,869)
	(14 501)	(11107)
Interest-bearing loans and borrowings	(14,501)	(14,137)
Derivative financial instruments	(117)	(1)
Deferred tax liabilities	(3,956)	(2,665)
Retirement benefit obligations	(2,186)	(1,974)
Provisions	(353)	(444)
Other payables	(9,488)	(7,457)
	(30,601)	(26,678)
Total liabilities	(45,857)	(41,547)
Net assets	16,669	18,509
EQUITY		
Capital and reserves attributable to equity holders		
of the Company		
Share capital	316	316
Share premium account	4,351	4,304
Other reserves	2,047	2,036
Retained earnings	8,140	11,834
	14,854	18,490
Non-controlling interests	1,815	19
Total equity	16,669	18,509

*2015 comparatives have been restated to reflect an adjustment to the acquisition accounting for ZS Pharma (see Note 5).



Condensed Consolidated Statement of Cash Flows

For the year ended 31 December	2016 \$m	2015 \$m
Cash flows from operating activities		
Profit before tax	3,552	3,069
Finance income and expense	1,317	1,029
Share of after tax losses in associates and joint ventures	33	16
Depreciation, amortisation and impairment	2,357	2,852
Decrease/(increase) in working capital and short-term provisions	926	(49
Gain on disposal of intangible assets	(1,301)	(961
Fair value movements on contingent consideration arising from business combinations	(1,158)	(432
Non-cash and other movements	(492)	(350
Cash generated from operations	5,234	5,174
Interest paid	(677)	(496
Tax paid	(412)	(1,354
Net cash inflow from operating activities	4,145	3,324
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	(166)	283
Purchase of property, plant and equipment	(1,446)	(1,328
Disposal of property, plant and equipment	82	47
Purchase of intangible assets	(868)	(1,460
Disposal of intangible assets	1,427	1,130
Purchase of non-current asset investments	(230)	(57
Disposal of non-current asset investments	3	93
Payments to joint ventures	(41)	(45
Upfront payments on business combinations	(2,564)	(2,446
Payment of contingent consideration from business combinations	(293)	(579
Interest received	140	123
Payments made by subsidiaries to non-controlling interests	(13)	-
Net cash outflow from investing activities	(3,969)	(4,239
Net cash inflow/(outflow) before financing activities	176	(915
Cash flows from financing activities		
Proceeds from issue of share capital	47	43
New long-term loans	2,491	5,928
Repayment of loans	-	(884
Dividends paid	(3,561)	(3,486
Hedge contracts relating to dividend payments	18	(51
Repayment of obligations under finance leases	(16)	(42
Movement in short-term borrowings	(303)	(630
Net cash (outflow)/inflow from financing activities	(1,324)	878
Net decrease in cash and cash equivalents in the period	(1,148)	(37
Cash and cash equivalents at the beginning of the period	6,051	6,164
Exchange rate effects	21	(76
Cash and cash equivalents at the end of the period	4,924	6,051
Cash and cash equivalents consists of:		
Cash and cash equivalents	5,018	6,240
Overdrafts	(94)	(189
	4,924	6,051

Condensed Consolidated Statement of Changes in Equity

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m	ancial
At 1 Jan 2015	316	4,261	2,021	13,029	19,627	19	19,646	ing & Fina Review
Profit for the period	-	-	-	2,825	2,825	1	2,826	Operating & Financial Review
Other comprehensive income	-	-	-	(337)	(337)	(1)	(338)	Oper
Transfer to other reserves	-	-	15	(15)	-	-	-	
Transactions with owners:								siness nt
Dividends	-	-	-	(3,537)	(3,537)	-	(3,537)	& Bus pme
Issue of Ordinary Shares	-	43	-	-	43	-	43	Corporate & Business Development
Share-based payments	-	-	-	(131)	(131)	-	(131)	CO
Net movement	-	43	15	(1,195)	(1,137)	-	(1,137)	
At 31 Dec 2015	316	4,304	2,036	11,834	18,490	19	18,509	ent
114 Jan 2010	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m	Research & Development
At 1 Jan 2016	316	4,304	2,036	11,834	18,490	19	18,509	Res
Profit for the period	-	-	-	3,499	3,499	(93)	3,406	
Other comprehensive income	-	-	-	(1,777)	(1,777)	(1)	(1,778)	De
Transfer to other reserves	-	-	11	(11)	-	-	-	Development Pipeline
Transactions with owners:								bmei
Dividends	-	-	-	(3,540)	(3,540)	-	(3,540)	evelo
Dividend paid by subsidiary to non- controlling interest	-	-	-	-	-	(13)	(13)	
Acerta put option	-	-	-	(1,825)	(1,825)	-	(1,825)	
Changes in non- controlling interest	-	-	-	-	-	1,903	1,903	ancial s
Issue of Ordinary Shares	-	47	-	-	47	-	47	Preliminary Financial Statements
Share-based payments	-	-	-	(40)	(40)	-	(40)	elimin Sta
Net movement	-	47	11	(3,694)	(3,636)	1,796	(1,840)	Pre
At 31 Dec 2016	316	4,351	2,047	8,140	14,854	1,815	16,669	

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



Notes to the Interim Financial Statements 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

The preliminary announcement for the year ended 31 December 2016 has been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB).

The annual financial statements of the Group are prepared in accordance with IFRSs as adopted by the EU and as issued by the IASB. The preliminary announcement has been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2015. There have been no significant new or revised accounting standards applied in the 12 months ended 31 December 2016.

Legal proceedings

The information contained in Note 7 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2015 and Interim Financial Statements for the six months ended 30 June 2016 and the Third Quarter and Nine Months Results 2016.

Going concern

The Group has considerable financial resources available. As at 31 December 2016 the Group has \$5.7bn in financial resources (cash balances of \$5bn and undrawn committed bank facilities of \$3bn which are available until April 2021, with only \$2.3bn 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 the foreseeable future. Accordingly, the preliminary announcement has been prepared on a going concern basis.

Financial information

The financial information contained in the preliminary announcement does not constitute statutory accounts of the Group for the years ended 31 December 2016 and 2015 but is derived from those accounts. Statutory accounts for 2015 have been delivered to the registrar of companies and those for 2016 will be delivered in due course. Those accounts have been reported on by the Group's auditors; their report 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. The quarterly information for the three month period to 31 December 2016 and to 31 December 2016 and to 31 December 2016.

2 RESTRUCTURING COSTS

Profit before tax for the year ended 31 December 2016 is stated after charging restructuring costs of \$1,107m (\$394m for the fourth quarter of 2016). These have been charged to profit as follows:

	FY 2016 \$m	FY 2015 \$m	Q4 2016 \$m	Q4 2015 \$m
Cost of sales	130	158	43	34
Research and development expense	178	258	32	78
Selling, general and administrative costs	823	618	319	260
Other operating income and expense	(24)	-	-	-
Total	1,107	1,034	394	372



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 2016 \$m	Cash Flow \$m	Acquisitions \$m	Non-cash & Other \$m	Exchange Movements \$m	At 31 Dec 2016 \$m
Loans due after one year	(14,109)	(2,491)	-	1,793	312	(14,495)
Finance leases due after one year	(28)	-	-	22	-	(6)
Total long-term debt	(14,137)	(2,491)	-	1,815	312	(14,501)
Current instalments of loans	-	-	-	(1,769)	-	(1,769)
Current instalments of finance leases	(67)	16	-	(37)	1	(87)
Total current debt	(67)	16	-	(1,806)	1	(1,856)
Other Investments	613	164	140	54	(73)	898
Net derivative financial instruments	438	(2)	-	(201)	-	235
Cash and cash equivalents	6,240	(1,231)	-	-	9	5,018
Overdrafts	(189)	83	-	-	12	(94)
Short-term borrowings	(660)	303		1	(1)	(357)
	6,442	(683)	140	(146)	(53)	5,700
Net debt	(7,762)	(3,158)	140	(137)	260	(10,657)

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



4 MAJORITY EQUITY INVESTMENT IN ACERTA PHARMA

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

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

AstraZeneca's 55% holding is a controlling interest and Acerta's combination of intangible product rights with an established workforce and their operating processes requires that the transaction is accounted for as a business combination in accordance with IFRS 3.

Goodwill is principally attributable to the value of the specialist knowhow inherent in the acquired workforce and the accounting for deferred taxes. Goodwill is not expected to be deductible for tax purposes. Acerta Pharma's results have been consolidated into the Group's results from 2 February 2016. From the period from acquisition to 31 December 2016, Acerta Pharma had no revenues and its loss after tax was \$212m.

In the period since 2 February 2016, the acquisition accounting has been adjusted to reflect new information regarding the value of net assets acquired with Acerta. This has resulted in an increase in other assets of \$15m, a decrease in deferred tax liabilities of \$50m, and a decrease in goodwill of \$65m.

	Fair value
	\$m
Intangible assets	7,307
Other assets including cash and cash equivalents	253
Deferred tax liabilities	(1,777)
Other liabilities	(90)
Total net assets acquired	5,693
Non-controlling interests	(1,903)
Goodwill	19
Fair value of total consideration	3,809
Less: fair value of deferred consideration	(1,332)
Total upfront consideration	2,477
Less: cash and cash equivalents acquired	(94)
Net cash outflow	2,383

5 ACQUISITION OF ZS PHARMA

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

During 2016, we revised our assessment of the fair values of the assets and liabilities acquired as a result of new information obtained about facts and circumstances that existed at the date of acquisition that impact the value of deferred tax. This has resulted in a reduction to both deferred tax liabilities and goodwill of \$68m.

	Fair value
	\$m
Non-current assets	
Intangible assets	3,162
Property, plant and equipment	21
	3,183
Current assets	169
Current liabilities	(50)
Non-current liabilities	
Deferred tax liabilities	(977)
Other liabilities	(13)
	(990)
Total net assets acquired	2,312
Goodwill	388
Total upfront consideration	2,700
Less: cash and cash equivalents acquired	(73)
Less: deferred upfront consideration	(181)
Net cash outflow	2,446

6 FINANCIAL INSTRUMENTS

As detailed in the Group's most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. As indicated in Note 1, there have been no changes to the accounting policies for financial instruments, including fair value measurement, from those disclosed on pages 146 and 147 of the Company's Annual Report and Form 20-F Information 2015. In addition, there have been no changes of significance to the categorisation or fair value hierarchy of our financial instruments. Financial instruments measured at fair value include \$1,611m of other investments, \$1,719m of loans, and \$235m of derivatives as at 31 December 2016. The total fair value of interest-bearing loans and borrowings at 31 December 2016 which have a carrying value of \$16,808m in the Condensed Consolidated Statement of Financial Position, was \$18,174m. 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	Other	Total	Tota	
	2016 \$m	2016 \$m	2016 \$m	2015 \$m	
At 1 January	5,092	1,319	6,411	6,899	
Settlements	(242)	(51)	(293)	(579)	
Revaluations	(999)	(159)	(1,158)	(432)	
Discount unwind	389	108	497	524	
Foreign exchange	-	-	-	(1)	
At 31 December	4,240	1,217	5,457	6,411	



7 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2015 and as part of the Company's Half-Yearly Financial Report for the six-month period to 30 June 2016 and the Third Quarter and Nine-Month Results 2016 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

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

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

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

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

Matters disclosed in respect of the fourth quarter of 2016 and to 2 February 2017.

Patent litigation

Faslodex (fulvestrant)

US patent proceedings

As previously disclosed, AstraZeneca has filed patent infringement lawsuits in the US District Court in New Jersey (the District Court) relating to four patents listed in the FDA Orange Book with reference to *Faslodex* after AstraZeneca received Paragraph IV notices relating to six Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. In December 2016, AstraZeneca settled the lawsuit against one of the ANDA filers, and the District Court entered a consent judgment in January 2017 which ended that particular lawsuit. AstraZeneca continues to litigate in the District Court against two other ANDA filers.

As previously disclosed, in July 2016, AstraZeneca was served with four petitions for *inter partes* review by the Patent Trial and Appeal Board (PTAB) relating to each of the four Orange Book-listed patents. In December 2016, the PTAB issued an order denying institution of the first of the four petitions. In January 2017, the PTAB terminated the remaining petitions at the request of the parties.

Patent proceedings outside the US

As previously disclosed, in Germany, in July 2015, AstraZeneca was served with complaints filed by Hexal AG (Hexal) and ratiopharm GmbH (ratiopharm) requesting the revocation of the German part of European Patent No. EP 1250138 (the '138 Patent). Following an oral hearing in January 2017, the German Federal Patent Court declared the patent invalid. AstraZeneca intends to appeal. In January 2017, the Regional Court of Düsseldorf suspended the effects of a provisional injunction based on the '138 patent which had been in place against Hexal since February 2016. Hexal is also seeking to lift a provisional injunction based on European Patent No. EP 2266573. In January 2017, the Higher Regional Court of Düsseldorf lifted a provisional injunction based on the '138 patent which had been in place against ratiopharm since September 2016.

As previously disclosed, in China, in March 2014, AstraZeneca received a request for invalidation of the *Faslodex* formulation patent, CN01803546.9, filed by Jiangsu Hansoh Pharmaceutical Co. Ltd. at the Chinese Patent Office. In September 2014, the Patent Re-examination Board of the Chinese Patent Board declared the patent invalid. AstraZeneca appealed to the Beijing IP Court and the appeal was rejected in April 2016. AstraZeneca appealed this decision to the Beijing Higher People's Court and the appeal was rejected in December 2016. AstraZeneca is considering its options.



Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

US patent proceedings

As previously disclosed, in June 2016, the US Court of Appeals for the Federal Circuit denied Mylan Pharmaceuticals Inc.'s (Mylan) petition for rehearing en banc of the decision affirming the denial of Mylan's motion to dismiss for lack of jurisdiction. In September 2016, Mylan filed a petition for writ of certiorari with the Supreme Court of the United States seeking an appeal of that decision and, in January 2017, the writ was denied.

As previously disclosed, in May 2016, the US Patent and Trademark Office (USPTO) instituted an inter partes review brought by Mylan Pharmaceuticals Inc. challenging the validity of US Patent No. RE44,186 (the '186 Patent) (the Mylan IPR). Subsequently, Wockhardt Bio AG, Teva Pharmaceuticals USA Inc., Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, and Amneal Pharmaceuticals LLC also filed petitions for inter partes review challenging the validity of the '186 Patent and joined the Mylan IPR. A hearing in the Mylan IPR was held in January 2017. A decision is awaited.

Crestor (rosuvastatin)

US patent proceedings

As previously disclosed, in December 2015, the US District Court for the District of South Carolina (the District Court) dismissed and entered judgment in AstraZeneca's favour in a patent infringement lawsuit filed by plaintiff Palmetto Pharmaceuticals, LLC (Palmetto), which, among other things, claimed that AstraZeneca's *Crestor* sales induced infringement of Palmetto's patent. Palmetto subsequently appealed. In December 2016, the Federal Circuit Court of Appeals affirmed the District Court's order dismissing the lawsuit.

Patent proceedings outside the US

As previously disclosed, in Japan, in March 2015, an individual filed a patent invalidation request with the Japanese Patent Office (JPO) in relation to the Crestor substance patent. In July 2016, the JPO dismissed the request. The individual has appealed to the Intellectual Property High Court of Japan (the High Court) with the intervention of Nippon Chemiphar Co. Ltd (Nippon). In addition, Nippon commenced a separate patent invalidation request with the JPO in relation to the *Crestor* substance patent. In November 2016, the JPO denied the request. Nippon has appealed to the High Court.

Synagis (palivizumab)

US patent proceedings

In December 2016, UCB BioPharma SPRL (UCB) filed a complaint against MedImmune LLC in the US District Court for the District of Delaware alleging infringement of US Patent No. 7,566,771. The complaint relates to a royalty-bearing license between Celltech R&D LTD and MedImmune which was terminated by MedImmune in 2010.

Losec/Prilosec (omeprazole)

Patent proceedings outside the US

As previously disclosed, in Canada, in 2004, AstraZeneca brought proceedings against Apotex Inc. (Apotex) for infringement of several patents related to *Losec*. In February 2015, the Federal Court of Canada (the Federal Court) found that Apotex had infringed AstraZeneca's *Losec* formulation patent (Canadian Patent No. 1,292,693). Apotex appealed. In January 2017, the Federal Court of Appeal upheld the trial court's findings of infringement and validity. However, the Federal Court upheld one aspect of Apotex's appeal relating to a limitation period defence, which may lower the amount of damages owed by Apotex. A reference to determine patent infringement damages is scheduled to commence in February 2017.

Product liability litigation

Farxiga (dapagliflozin)

As previously disclosed, in the US, AstraZeneca has been named as a defendant in lawsuits involving plaintiffs claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with *Farxiga* and/or *Xigduo XR*. Cases with these allegations have been filed in several jurisdictions. As previously disclosed, in October 2016 one of these cases was dismissed with prejudice in favour of AstraZeneca. Since then, several other cases have been dismissed either voluntarily or by the courts. Motions to dismiss are pending in many of the jurisdictions where AstraZeneca has been served.

As previously disclosed, in the US, counsel for plaintiffs in a product liability action pertaining to *Invokana* (a product in the same class as *Farxiga*) filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking transfer of any currently pending cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation (MDL) proceeding on a class-wide basis. In December 2016, the JPML granted an MDL to only those plaintiffs alleging injury from Invokana.

OnglyzalKombiglyze (saxagliptin)

As previously disclosed, in the US, AstraZeneca is defending various lawsuits filed in state and federal courts involving multiple plaintiffs claiming heart failure, cardiac failure and/or death from treatment with either *Onglyza* or *Kombiglyze*. In December 2016, plaintiffs in the California Superior Court filed a Petition for Coordination with the Judicial Council of California, requesting that all similar, currently pending or subsequently filed cases in California be coordinated for pre-trial purposes.



Nexium (esomeprazole)

As previously disclosed, in the US, AstraZeneca has been defending product liability lawsuits brought in US federal and state courts by approximately 1,900 plaintiffs who alleged that *Nexium* caused osteoporotic injuries, such as bone deterioration, loss of bone density and/or bone fractures, but all such claims have now been dismissed with judgment entered in AstraZeneca's favour. Approximately 270 plaintiffs appealed the dismissal of their claims to the US Court of Appeals for the Ninth Circuit, and fewer than 40 plaintiffs appealed the dismissal of their claims to the California Second Appellate Division. In October 2016, the US Court of Appeals for the Ninth Circuit. In January 2017, the California Second Appellate Division affirmed the dismissal of the less than 40 cases in California state court.

Commercial litigation

Crestor (rosuvastatin calcium)

As previously disclosed, in Israel, in November 2012, a Motion to Certify a Claim as a Class Action and Statement of Claim (together, a Motion to Certify) were filed in the District Court in Tel Aviv, Jaffa, (the District Court) against AstraZeneca and four other pharmaceutical companies for alleged deception and failure to disclose material facts to consumers regarding potential adverse events associated with certain drugs, including *Crestor*. In July 2013, an amended Motion to Certify containing similar allegations to those in the first action were filed in the same District Court against the same defendants. In November 2016, the plaintiff filed a motion to withdraw from the action, which the District Court granted in December 2016. This matter has now concluded.

Nexium Settlement anti-trust litigation

As previously disclosed, AstraZeneca is a defendant in a multidistrict litigation class action and individual lawsuit alleging that AstraZeneca's settlements of certain patent litigation in the US relating to Nexium violated US anti-trust law and various state laws. A trial in the US District Court for the District of Massachusetts (the District Court) commenced in October 2014 and, in December 2014, a jury returned a verdict in favour of AstraZeneca and entered judgment in favour of AstraZeneca in September 2015. The plaintiffs appealed that judgment and, in November 2016, the US Court of Appeals for the First Circuit affirmed the District Court's decision. The plaintiffs petitioned for rehearing and rehearing *en banc*, both of which were denied in January 2017.

Telephone Consumer Protection Act litigation

In December 2016, in the US, AstraZeneca and several other entities were served with a complaint filed in the US District Court for the Southern District of Florida (the District Court) that alleges, among other things, violations of the Telephone Consumer Protection Act caused by the sending of unsolicited advertisements by facsimile. AstraZeneca's motion to dismiss is pending. The plaintiff also made a motion for class certification, which, in January 2017, was denied without prejudice by the District Court.



8 PRODUCT ANALYSIS – FY 2016

	World		US				Established ROW		Emerging Markets	
	FY 2016	CER	FY 2016	CER	FY 2016	CER	FY 2016	CER	FY 2016	CER
	\$m	%	\$m	%	\$m	%	\$m	%	\$m	%
Oncology:										
Iressa	513	(5)	23	n/m	120	(5)	137	(8)	233	(10)
Tagrisso	423	n/m	254	n/m	76	n/m	83	100	10	100
Lynparza	218	n/m	127	81	81	n/m	3	n/m	7	n/m
Legacy:										
Faslodex	830	19	438	23	228	11	68	15	96	25
Zoladex	816	-	35	25	156	(4)	270	(7)	355	6
Casodex	247	(9)	2	100	27	(7)	111	(23)	107	8
Arimidex	232	(6)	14	(26)	37	(24)	71	(18)	110	15
Others	104	(26)	-	n/m	8	(65)	71	7	25	(13)
Total Oncology	3,383	20	893	74	733	18	814	2	943	6
Cardiovascular & Metabolic Diseases:										
Brilinta	839	39	348	45	258	15	44	22	189	80
Farxiga	835	72	457	75	187	52	58	72	133	96
Onglyza	720	(6)	376	(10)	132	(5)	70	11	142	(4)
Bydureon	578	-	463	(4)	100	23	11	25	4	(25)
Byetta	254	(19)	164	(22)	45	(25)	21	(9)	24	13
Legacy:										
Crestor	3,401	(32)	1,223	(57)	866	(4)	591	(5)	721	12
Seloken/Toprol-XL	737	9	95	7	90	(5)	16	25	536	12
Atacand	315	(8)	36	6	97	(8)	20	(20)	162	(9)
Others	437	(26)	40	(27)	119	(17)	50	(21)	228	(30)
Total Cardiovascular & Metabolic Diseases	8,116	(13)	3,202	(31)	1,894	1	881	(1)	2,139	8
Respiratory:	·				· · ·				<u> </u>	
Symbicort	2,989	(10)	1,242	(18)	909	(12)	436	5	402	10
Pulmicort	1,061	8	174	(13)	99	(14)	90	(3)	698	21
Tudorza/ Eklira	170	(9)	77	(25)	83	9	9	-	1	n/m
Daliresp/Daxas	154	48	134	29	15	100	1	n/m	4	n/m
Duaklir	63	n/m	-		60	n/m	2	n/m	1	n/m
Others	316	27	11	(39)	118	38	50	108	137	13
Total Respiratory	4,753	(3)	1,638	(16)	1,284	(4)	588	8	1,243	17
Other:			.,	(14)	.,				.,	
Nexium	2,032	(18)	554	(39)	251	(11)	537	(10)	690	(3)
Seroquel XR	735	(10)	515	(28)	134	(32)	17	(32)	69	(7)
Synagis	677	2	325	14	352	(7)		(02)	-	(,,)
Losec/Prilosec	276	(17)	10	(44)	83	(13)	55	(31)	128	(9)
FluMist/Fluenz	104	(59)	33	(84)	64	3	6	(14)	120	(9) n/m
Novantik/Moventig	91	(39) n/m	90	n/m	-	-	-	(17)	1	-
	1,152	(20)	90 105	(54)	- 269	(21)	198	(27)	580	(4)
Others		. ,				. ,				
Total Other	5,067	(19)	1,632	(31)	1,153	(15)	813	(17)	1,469	(4)
Total Product Sales	21,319	(8)	7,365	(22)	5,064	(3)	3,096	(4)	5,794	6



9 PRODUCT ANALYSIS – Q4 2016

	World		US		Europe		Established ROW		Emerging Markets	
	Q4 2016	CER	Q4 2016	CER	Q4 2016	CER	Q4 2016	CER	Q4 2016	CER
	\$m	%	<u>\$m</u>	%	\$m	%	\$m	%	\$m	%
Oncology:										
Iressa	118	(11)	7	75	29	(6)	36	(6)	46	(22)
Tagrisso	147	n/m	74	n/m	27	n/m	40	100	6	n/m
Lynparza	62	72	31	29	25	127	3	n/m	3	n/m
Legacy:										
Faslodex	222	19	117	23	59	11	20	20	26	23
Zoladex	235	13	8	33	39	2	71	(9)	117	36
Casodex	60	(8)	-	-	8	14	27	(27)	25	13
Arimidex	57	(7)	2	(50)	10	(17)	18	(24)	27	22
Others	29	-		-	4	33	20	6	5	(29)
Total Oncology	930	26	239	61	201	26	235	11	255	16
Cardiovascular & Metabolic Diseases:										
Brilinta	236	37	105	50	66	13	12	10	53	62
Farxiga	239	57	130	69	51	37	17	50	41	56
Onglyza	149	(21)	72	(27)	30	(6)	15	(17)	32	(23)
Bydureon	142	(8)	114	(7)	25	(7)	3	50	-	n/m
Byetta	55	(22)	37	(14)	8	(43)	5	(29)	5	(25)
Legacy:										
Crestor	631	(53)	95	(88)	209	(6)	146	(16)	181	14
Seloken/Toprol-XL	178	14	14	(26)	23	(4)	6	67	135	23
Atacand	81	(5)	8	14	23	(12)	5	25	45	(6)
Others	100	(31)	13	(7)	30	(21)	12	(29)	45	(41)
Total Cardiovascular & Metabolic Diseases	1,811	(26)	588	(52)	465	(3)	221	(11)	537	6
Respiratory:										
Symbicort	740	(13)	284	(31)	230	(3)	126	15	100	5
Pulmicort	288	8	36	(31)	26	(10)	29	-	197	25
Tudorza/Eklira	36	(23)	16	(36)	18	(5)	2	-	-	n/m
Daliresp/Daxas	41	28	33	3	5	100	-	-	3	n/m
Duaklir	19	58	-	-	18	46	1	n/m	-	-
Others	86	37	4	(33)	35	85	17	143	30	(3)
Total Respiratory	1,210	(5)	373	(29)	332	5	175	19	330	16
Other:										
Nexium	491	(15)	135	(23)	61	(19)	148	(5)	147	(12)
Seroquel XR	118	(51)	71	(60)	28	(32)	3	(40)	16	(16)
Synagis	302	10	154	20	148	1	-	-	-	-
Losec/Prilosec	59	(23)	3	100	20	(19)	13	(33)	23	(30)
FluMist/Fluenz	67	(60)	20	(83)	43	(21)	4	(43)	-	-
Movantik/Moventig	26	73	26	73	-	-	-	-	-	-
Others	246	(34)	9	(84)	34	(57)	25	(69)	178	8
Total Other	1,309	(25)	418	(38)	334	(21)	193	(28)	364	(5)
Total Product Sales	5,260	(15)	1,618	(37)	1,332	(3)	824	(6)	1,486	7
	-,	<u> </u>	,	N= 7	,	1-7	-	1.7	,	



Shareholder Information

Announcement of first quarter 2017 results	27 April 2017
Annual General Meeting	27 April 2017
Announcement of half year and second quarter 2017 results	27 July 2017
Announcement of nine months and third quarter 2017 results	9 November 2017

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 2016, payable on 20 March 2017, will be 17 February 2017. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 16 February 2017. American Depositary Shares listed in New York will trade ex-dividend from 15 February 2017.

The record date for the first interim dividend for 2017, payable on 11 September 2017, will be 11 August 2017. Ordinary Shares listed in London and Stockholm will trade ex-dividend from 10 August 2017. American Depositary Shares listed in New York will trade ex-dividend from 9 August 2017.

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 Duaklir Genuair, Duaklir, Eklira, and Tudorza, trademarks of Almirall, S.A.; Toprol-XL, a trademark of Aralez Pharmaceuticals Inc.; Epanova, a trademark of Chrysalis Pharma AG; Rhinocort Aqua, a trademark of Cilag GmbH International (outside the US); Zinforo, a trademark of Forest Laboratories; Invokana, a trademark of Johnson & Johnson/Janssen Pharmaceutica NV; and Zavicefta, a trademark of Pfizer Inc.

Addresses for Correspondence

Registered Office 1 Francis Crick Avenue Cambridge Biomedical Campus, Cambridge CB2 0AA UK	Registrar and Transfer Office Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA UK	Swedish Central Securities Depository Euroclear Sweden AB PO Box 191 SE-101 23 Stockholm Sweden	US Depositary Citibank Shareholder Services PO Box 43077 Providence RI 02940-3077 USA
Tel: +44 (0)20 3749 5000	Tel (freephone in UK): 0800 389 1580	Tel: +46 (0)8 402 9000	Tel: (toll free in the US) +1 (888) 697 8018
	Tel (outside UK): +44 (0)121 415 7033		Tel: (outside the US) +1 (781) 575 4555
			citibank@shareholders- online.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 document/presentation/webcast should be construed as a profit forecast.