

#### AstraZeneca PLC

9 November 2017 07:00

#### Year-To-Date and Q3 2017 Results

An improved sales performance as the pipeline-driven transformation gathered pace

**Financial Summary** 

	YTD 2017			Q3 2017			
	¢m	% ch	ange	\$m	% change		
	\$m	Actual	CER <sup>1</sup>	ФШ	Actual	CER	
Total Revenue	16,688	(4)	(3)	6,232	9	10	
Product Sales	14,665	(9)	(8)	4,882	(3)	(2)	
Externalisation Revenue	2,023	49	50	1,350	n/m	n/m	
Reported Operating Profit	2,991	26	16	1,149	12	9	
Core Operating Profit <sup>2</sup>	5,068	8	5	1,853	9	9	
Reported Earnings Per Share (EPS)	\$1.34	3	(4)	\$0.54	(32)	(33)	
Core EPS	\$2.98	(4)	(7)	\$1.12	(15)	(17)	

The difference in growth rates between Operating Profit and EPS included the impact of a one-off tax benefit in Q3 2016.

#### **Financial Highlights**

- Receding impact from losses of exclusivity: Product Sales declined by 3% (2% at CER) in the quarter
- Externalisation Revenue: \$2,023m, including \$997m received in the quarter from the MSD<sup>3</sup> collaboration
- Cost discipline continued:
  - Reported R&D costs declined by 3% (1% at CER) to \$4,206m; Core R&D costs declined by 5% (2% at CER) to \$3,956m
  - Reported SG&A costs declined by 11% (9% at CER) to \$7,155m; Core SG&A costs declined by 7% (5% at CER) to \$5,678m
- The Company now anticipates a 2017 Core EPS performance towards the favourable end of the guidance range of a low to mid teens percentage decline

#### **Commercial Highlights**

The Growth Platforms grew by 3% (4% at CER) and represented 66% of Total Revenue:

- Emerging Markets: 5% growth (7% at CER). China sales in the quarter increased by 12% (14% at CER)
- Respiratory: 5% decline (3% at CER). Symbicort faced continued pressures in the US
- New CVMD<sup>4</sup>: 5% growth. Brilinta sales up by 29% (31% at CER); Farxiga sales up by 24%
- Japan: 3% growth (5% at CER). Underpinned by the growth of Tagrisso, Symbicort and Nexium
- New Oncology<sup>5</sup>: 96% growth (97% at CER). An encouraging performance by *Tagrisso*; *Lynparza* US sales up by 9% in the quarter

#### **Achieving Scientific Leadership**

The table below highlights the development of the late-stage pipeline since 27 July 2017:

Regulatory Approvals	Faslodex - breast cancer (1st line) (US) Lynparza - ovarian cancer (2nd line, 4th line/tablets) (US) Calquence (acalabrutinib) - blood cancer (mantle cell lymphoma (MCL), 2nd line) (US) Brilinta - prior myocardial infarction (MI) (CN) Farxiga + Bydureon - type-2 diabetes (US, EU) Bydureon BCise (autoinjector) - type-2 diabetes (US) Symbicort - chronic obstructive pulmonary disease (COPD) exacerbations (US)
Regulatory Submission Acceptances	Lynparza - breast cancer (US, JP) (Priority Reviews) Imfinzi - locally-advanced, unresectable lung cancer (US/Priority Review, EU, JP) Bydureon BCise - type-2 diabetes (EU)
Major Phase III Data Readouts	moxetumomab pasudotox - leukaemia (met primary endpoint)  Duaklir - COPD (met primary endpoint)  tralokinumab - severe, uncontrolled asthma (did not meet primary endpoints)
Other Major Developments	Tagrisso - lung cancer (1st line): Breakthrough Therapy Designation (US) Imfinzi - locally-advanced, unresectable lung cancer: Breakthrough Therapy Designation (US)



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

"Our financial performance in the quarter was in line with expectations, reflecting good commercial execution, including strong growth in Emerging Markets with standout sales in China.

It was, however, the raft of news flow and approvals that was most notable. In particular, the positive developments for *Tagrisso* and *Imfinzi* in lung cancer and benralizumab and tezepelumab in asthma offset the disappointment of the first readout from the MYSTIC trial. The Accelerated Approval for *Calquence* in the treatment of an aggressive form of blood cancer was an important milestone for a medicine that will be the cornerstone of our presence in blood cancers. Further, the new strategic collaboration with MSD offers significant opportunities to maximise the potential of *Lynparza*.

This impressive momentum is set to continue with regulatory and data milestones that have the potential to show how our science-led strategy and pipeline-driven transformation are delivering for patients and shareholders."

#### FY 2017 Guidance: Updated

The Company provides guidance on Total Revenue and Core EPS only and today refines the guidance for Core EPS. This refinement primarily reflects the impact of the aforementioned MSD collaboration, for which the accounting treatment was finalised in the guarter.

All commentary in this section is at CER.

	Updated Guidance	Prior Guidance
Total Revenue	A low to mid single-digit percentage decline	A low to mid single-digit percentage decline
Core EPS	Towards the favourable end of a low to mid teens percentage decline*	A low to mid teens percentage decline

<sup>\*</sup>The Core EPS guidance anticipates a normalised effective Core tax rate in FY 2017 of 17-19% (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, with year-on-year Product Sales comparisons easing in the second half of the year, following the entry of multiple *Crestor* generic medicines in the US market in July 2016.

The Company presents Core EPS guidance only at CER. It is unable to provide guidance on a Reported/GAAP<sup>6</sup> 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 unchanged guidance above, the Company also provides unchanged indications in other areas of the Income Statement. The sum of Externalisation Revenue and Other Operating Income and Expense in FY 2017 is anticipated to be ahead of that in FY 2016. Sustainable and ongoing income<sup>7</sup> is expected to increase further as a proportion of total Externalisation Revenue in FY 2017 (FY 2016: 21%). 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 in FY 2017, reflecting the evolving shape of the business. A full explanation is listed in the Operating & Financial Review.

#### **FY 2017 Currency Impact**

Based only on average exchange rates in the first nine months of 2017 (year to date, YTD 2017) and the Company's published currency sensitivities, the Company continues to expect a low single-digit percentage adverse impact from currency movements on Total Revenue and a minimal impact on Core EPS. Further details on currency sensitivities are contained within the Operating and Financial Review.



#### Notes

- 1. Constant exchange rates. These are non-GAAP measures because they remove the effects of currency movements from Reported results.
- 2. Core financial measures. These are non-GAAP measures because, unlike Reported performance, they cannot be derived directly from the information in the Group Financial Statements. See the Operating and Financial Review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
- 3. Merck & Co., Inc., Kenilworth, NJ, US (known as MSD outside the US and Canada)
- 4. New Cardiovascular and Metabolic Diseases, incorporating *Brilinta* and Diabetes.
- 5. New Oncology, comprising Lynparza, Tagrisso, Iressa (US), Imfinzi and, in due course, Calquence.
- 6. Generally Accepted Accounting Principles.
- 7. Sustainable and ongoing income is defined as Externalisation Revenue, excluding initial revenue.

All growth rates are shown at actual exchange rates, unless stated otherwise. Only one rate of growth is shown if the actual and constant exchange rates of growth are identical. All commentary in this announcement refers to the performance in the year to date, unless stated otherwise.



**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.

Q4 2017	Tagrisso - lung cancer (1st line): Regulatory submission benralizumab - severe, uncontrolled asthma: Regulatory decision (US)
H1 2018	Lynparza - ovarian cancer (2nd line): Regulatory decision (EU, JP) Lynparza - ovarian cancer (1st line): Data readout Lynparza - breast cancer: Regulatory decision (US), regulatory submission (EU)  Imfinzi - lung cancer (PACIFIC): Regulatory decision (US) Imfinzi +/- treme - lung cancer (ARCTIC): Data readout, regulatory submission Imfinzi +/- treme - lung cancer (MYSTIC): Data readout (final overall survival) Imfinzi +/- treme - head & neck cancer (KESTREL): Data readout Imfinzi +/- treme - head & neck cancer (EAGLE): Data readout moxetumomab pasudotox - leukaemia: Regulatory submission selumetinib - thyroid cancer: Data readout, regulatory submission  Bevespi - COPD: Regulatory submission (JP) Duaklir - COPD: Regulatory submission (US) benralizumab - severe, uncontrolled asthma: Regulatory decision (EU, JP) PT010 - COPD: Data readout
H2 2018	Lynparza - breast cancer: Regulatory decision (JP) Lynparza - ovarian cancer (1st line): Regulatory submission  Imfinzi - lung cancer (PACIFIC): Regulatory decision (EU, JP) Imfinzi + treme - lung cancer (MYSTIC): Regulatory submission Imfinzi + treme - lung cancer (NEPTUNE): Data readout, regulatory submission Imfinzi +/- treme - head & neck cancer (KESTREL): Regulatory submission Imfinzi +/- treme - head & neck cancer (EAGLE): Regulatory submission  Farxiga - type-2 diabetes (DECLARE): Data readout Bydureon BCise - type-2 diabetes: Regulatory decision (EU) roxadustat - anaemia: Regulatory submission (US)  Bevespi - COPD: Regulatory decision (EU) benralizumab - COPD: Data readout, regulatory submission PT010 - COPD: Regulatory submission (JP) anifrolumab - lupus: Data readout

The term 'data readout' in this section refers to Phase III data readouts.



#### **Conference Call**

A conference call and webcast for investors and analysts, hosted by management, will begin at 12:00 UK time today. Details can be accessed via <u>astrazeneca.com/investors</u>.

# **Reporting Calendar**

The Company intends to publish its full-year and fourth-quarter financial results on 2 February 2018.

#### 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, CVMD 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 <a href="www.astrazeneca.com">www.astrazeneca.com</a> and follow us on Twitter @AstraZeneca.

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# **Operating and Financial Review**

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All narrative on growth and results in this section is based on actual exchange rates, unless stated otherwise. Financial figures are in US\$ millions (\$m). The performance shown in this announcement covers the nine and three-month periods to 30 September 2017 (the year to date (YTD 2017) or the quarter (Q3 2017), respectively) compared to the nine and three-month periods to 30 September 2016 (YTD 2016 and Q3 2016, respectively). All commentary in the Operating and Financial Review relates to the year to date, unless stated otherwise. Core financial measures, EBITDA and Net Debt are non-GAAP financial measures because they cannot be derived directly from the Group Condensed Consolidated Financial Statements. Management believes that these non-GAAP financial measures, when provided in combination with Reported results, will provide investors with helpful supplementary information to better understand the financial performance and position of the Company on a comparable basis from period to period. These non-GAAP financial measures are not a substitute for, or superior to, financial measures prepared in accordance with GAAP. 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 Core financial measures are provided on page 64 of the <u>Annual Report</u> and Form 20-F Information 2016. Reference should be made to the reconciliation of Core to Reported financial information included therein and in the Reconciliation of Reported to Core Financial Measures table included in the Financial Performance section of this announcement.

EBITDA is defined as Reported Profit Before Tax after adding back Net Finance Expense, Joint Ventures and Associates and charges for depreciation, amortisation and impairment. Reference should be made to the Reconciliation of Reported Profit Before Tax to EBITDA included in the Financial Performance section of this announcement.

Net Debt is defined as interest-bearing loans and borrowings net of cash and cash equivalents, other investments and net derivative financial instruments. Reference should be made to the Reconciliation of Interest-Bearing Loans and Borrowings to Net Debt included in the Cash Flow and Balance Sheet section of this announcement.

The Company strongly encourages readers not to rely on any single financial measure, but to review AstraZeneca's financial statements, including the notes thereto, and other publicly-filed Company reports, carefully and in their entirety.

#### **Total Revenue**

		YTD 2017			Q3 2017	
	¢m	% ch	ange	¢m.	% ch	ange
	\$m	Actual	CER	\$m	Actual	CER
Total Revenue	16,688	(4)	(3)	6,232	9	10
Product Sales	14,665	(9)	(8)	4,882	(3)	(2)
Externalisation Revenue	2,023	49	50	1,350	n/m	n/m

#### **Product Sales**

The receding effects of the *Crestor* and *Seroquel XR* losses of exclusivity in the US impacted Product Sales in the year to date. Global Product Sales declined by 9% (8% at CER) from \$16,059m to \$14,665m. Of the \$1,394m difference, \$999m was represented by a 36% decline (35% at CER) in *Crestor* sales; \$393m was represented by a 64% decline in *Seroquel XR* sales.

Emerging Markets sales grew by 5% (7% at CER) to \$4,519m; Emerging Markets represented AstraZeneca's largest sales region in the year to date. China sales increased by 6% (10% at CER) to \$2,142m in the year to date. In the quarter, China sales increased by 12% (14% at CER) to \$723m, reflecting a strong underlying performance. US sales declined by 23% to \$4,399m and were, alongside the effects of the *Crestor* and *Seroquel XR* losses of exclusivity, also impacted by the sales of *Symbicort*, which declined by 15% to \$811m. Product Sales in Europe declined by 7% (6% at CER) to \$3,460m.

Representing 66% of Total Revenue, the Growth Platforms grew by 3% (4% at CER) to \$11,055m:

	YTD 2017			Q3 2017			
	¢ m	% ch	ange	¢ m	% change		
	\$m	Actual	CER	\$m	Actual	CER	
Emerging Markets	4,519	5	7	1,515	9	10	
Respiratory	3,372	(5)	(3)	1,092	(2)	(2)	
New CVMD	2,543	5	5	873	7	7	
Japan	1,645	3	5	578	(3)	4	
New Oncology	876	96	97	339	72	73	
Total*	11,055	3	4	3,760	5	6	

<sup>\*</sup>Total Product Sales for Growth Platforms are adjusted to remove duplication on a medicine and regional basis.

#### **Externalisation Revenue**

Where AstraZeneca retains a significant ongoing interest in medicines or potential new medicines, income arising from externalisation agreements is reported as Externalisation Revenue in the Company's financial statements.

A breakdown of Externalisation Revenue in the year to date is shown below:

Medicine	Partner	Region	\$m
Lynparza & selumetinib	MSD - initial revenue	Global	997
<u>Zoladex</u>	TerSera Therapeutics LLC (TerSera) - initial revenue	US and Canada	250
<u>anaesthetics</u>	Aspen Global, Inc. (Aspen) - milestone revenue	Global (excl.US)	150
Siliq	Valeant Pharmaceuticals International, Inc. (Valeant) - milestone revenue	US	130
MEDI8897	Sanofi Pasteur, Inc. (Sanofi Pasteur) - initial revenue	Global	127
Tudorza/Duaklir	Circassia Pharmaceuticals plc (Circassia) - initial revenue	US	64
lanabecestat	Eli Lilly and Company (Lilly) - milestone revenue	Global	50
MEDI1341	Takeda Pharmaceutical Company Limited (Takeda) - initial revenue	Global	50
Other			205
Total			2,023

The following table illustrates the level of sustainable and ongoing income within the total of Externalisation Revenue. The Company anticipates that sustainable and ongoing income will grow as a proportion of Externalisation Revenue over time.

YTD 2017					Q3 2017			
	\$m	% of	% change		\$m	% of	% change	
	фііі	total	Actual	CER	ΨΠ	total	Actual	CER
Royalties	100	5	22	25	31	2	14	57
Milestones/Other	431	21	104	109	272	20	n/m	n/m
Total Sustainable and Ongoing Externalisation Revenue	531	26	81	85	303	22	n/m	n/m
Initial Revenue	1,492	74	40	39	1,047	78	63	60
Total Externalisation Revenue	2,023	100	49	49	1,350	100	n/m	n/m

A number of AstraZeneca medicines were externalised or disposed after 30 September 2016, thus adversely impacting the overall year-on-year Product Sales performance in the year to date:

Medicine				in ons	
	Region	Completion	YTD 2016	YTD 2017*	Difference
			\$m	\$m	\$m
<u>Toprol-XL</u>	US	October 2016	81	34	(47)
Bydureon/Byetta	China	October 2016	9	-	(9)
antibiotics	Global (excl. US)	December 2016	143	28	(115)
<u>Zoladex</u>	US and Canada	March 2017	50	24	(26)
<u>Seloken</u>	Europe	June 2017	67	48	(19)
<u>Zomig</u>	Global (excl. Japan)	June 2017	56	45	(11)
Total			406	179	(227)
Proportion of YTD 2017 Product Sales					-2%

<sup>\*</sup>YTD 2017 Product Sales here comprise sales made to partners under manufacturing and supply agreements.

Examples of sustainable and ongoing income, as part of Externalisation Revenue, are shown below:

Announcement	Medicine	Partner	Region	Externalisation Revenue
July 2017	Lynparza	MSD	Global	<ul> <li>Initial \$1.0bn revenue</li> <li>Up to \$0.75bn for certain licence options</li> <li>Up to \$6.15bn in regulatory and sales milestones</li> </ul>
<u>March 2017</u>	MEDI8897	Sanofi Pasteur	Global	<ul> <li>Initial €120m revenue</li> <li>Up to €495m in sales and development-related milestones</li> </ul>
February 2017	Zoladex	TerSera	US and Canada	<ul> <li>Initial \$250m revenue</li> <li>Up to \$70m in sales-related milestones</li> <li>Mid-teen percentage royalties on sales</li> </ul>
October 2016	Toprol-XL	Aralez Pharmaceuticals Inc.	US	<ul> <li>Initial \$175m revenue</li> <li>Up to \$48m milestone and sales-related revenue</li> <li>Mid-teen percentage royalties on sales</li> </ul>
July 2016	tralokinumab - atopic dermatitis	LEO Pharma A/S (LEO Pharma)	Global	<ul> <li>Initial \$115m revenue</li> <li>Up to \$1bn in commercially-related milestones</li> <li>Up to mid-teen tiered percentage royalties on sales</li> </ul>
September 2015	Siliq	Valeant	Global, later amended to US	<ul> <li>Initial \$100m revenue</li> <li>Pre-launch milestone of \$130m</li> <li>Sales-related royalties up to \$175m</li> <li>Profit sharing</li> </ul>
March 2015	Movantik	Daiichi Sankyo Company, Ltd (Daiichi Sankyo)	US	<ul> <li>Initial \$200m revenue</li> <li>Up to \$625m in sales-related revenue</li> </ul>

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# **Product Sales**

The performance of key medicines is shown below, with a geographical split shown in Note 6 and 7.

rne periorman	ce of key medicines is	SHOWIT BOIL	YTD 2	•	moar opii	Q3 2017			
Therapy	Medicine		1	ı					
Area		\$m	% of total*	% cha	CER	\$m	% of total	% cha	CER
	Tagrisso	651	4	136	138	248	5	86	89
	Iressa	398	3	130	2	137	3	10	10
	Lynparza	197	1	26	26	81	2	40	36
	Imfinzi	197	_	n/m	n/m	-		40	30
	Legacy:	ı	-	11/111	11/111	_	-	_	-
Oncology	Faslodex	703	5	16	16	241	5	16	16
Officology	Zoladex	548	4	(6)	(5)	185	4	(7)	(6)
	Casodex	161	1	(14)	(12)	51	1	(18)	(16)
	Arimidex	160	1	(9)	(6)	54	1	(4)	(2)
	Others	85	1	13	16	29	1	7	15
	Total Oncology	2,904	20	18	19	1,026	21	18	19
	Brilinta	780	5	29	31	284	6	37	36
	Farxiga	742	5	24	24	285	6	30	29
	Onglyza	431	3	(25)	(25)	127	3	(25)	(25)
	Bydureon	427	3	(2)	(2)	128	3	(12)	(12)
	Byetta	128	1	(36)	(35)	39	1	(36)	(36)
0)/440	Symlin	35	-	30	30	10	-	(9)	(9)
CVMD	-	35	-	30	30	10	-	(9)	(9)
	Legacy:	1 771	10	(26)	(25)	E90	10	(16)	(4.4)
	Crestor	1,771	12	(36)	(35)	580	12	(16)	(14)
	Seloken/Toprol-XL	527	4	(6)	(4)	160	3	(14)	(12)
	Atacand	227	2	(3)	(1)	80	2	10	11
	Others	259	2	(16)	(14)	80	2	(6)	(5)
	Total CVMD	5,327	36	(16)	(14)	1,773	36	(4)	(4)
	Symbicort	2,051	14	(9)	(8)	668	14	(4)	(4)
	Pulmicort	805	5	4	7	242	5	8	9
	Daliresp/Daxas	145	1	28	28	53	1	26	26
Respiratory	Tudorza/Eklira	108	1	(19)	(18)	37	1	(21)	(21)
	Duaklir	56	-	27	30	21	-	50	43
	Bevespi	8	-	n/m	n/m	4	-	n/m	n/m
	Others	199	1	(13)	(12)	67	1	(22)	(22)
	Total Respiratory	3,372	23	(5)	(3)	1,092	22	(2)	(2)

Therapy		YTD 2017				Q3 2017			
Area	Medicine	\$m	% of	% change		\$m	% of	% change	
		ФШ	total*	Actual	CER	ΨΠ	total	Actual	CER
	Nexium	1,525	10	(1)	-	469	10	(9)	(7)
	Synagis	453	3	21	21	153	3	47	47
	Losec/Prilosec	202	1	(7)	(5)	66	1	(8)	(8)
Other	Seroquel XR	224	2	(64)	(64)	62	1	(67)	(68)
Other	Movantik/Moventig	92	1	42	42	30	1	20	20
	FluMist/Fluenz	20	-	(46)	(46)	20	-	(23)	(23)
	Others	546	4	(40)	(39)	191	4	(30)	(29)
	Total Other	3,062	21	(19)	(18)	991	20	(18)	(17)
	Total Product Sales	14,665	100	(9)	(8)	4,882	100	(3)	(2)

\*Due to rounding, the sum of individual brand percentages may not agree to totals.

# **Product Sales Summary**

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#### **ONCOLOGY**

Product Sales of \$2,904m; an increase of 18% (19% at CER). Oncology Product Sales represented 20% of total Product Sales, up from 15% in the first nine months of 2016.

## **Lung Cancer**

#### **Tagrisso**

Product Sales of \$651m; an increase of 136% (138% at CER).

Within Emerging Markets, *Tagrisso* was approved in China in March 2017 as the first AstraZeneca medicine under the China FDA's Priority Review pathway. Sales in the US and Europe were \$277m and \$124m, respectively. Sales grew by 54% year-on-year in the US, with progress in T790M-mutation testing rates accompanied by the launch of a new diagnostic-testing voucher programme for patients. In Europe, where *Tagrisso* was launched in 2016, sales of \$124m were driven by a continued uptake and positive reimbursement decisions, most recently in Italy, Portugal and Sweden.

Testing rates in Japan, where *Tagrisso* was also launched in 2016, exceeded 90%, with year-to-date sales of \$158m (FY 2016: \$82m) reflecting a high penetration rate in the currently-approved 2nd-line T790M-mutation setting. Sequential quarterly sales declined in the quarter in Japan, reflecting the one-time impact of the ending of the Ryotanki restriction in Q2 2017. This regulation in Japan restricts prescriptions for medicines in their first year on the market to just two weeks of supply.

To date, *Tagrisso* has received regulatory approval in over 50 countries.

# <u>Iressa</u>

Product Sales of \$398m; an increase of 1% (2% at CER).

Emerging Markets sales increased by 7% (8% at CER) to \$200m. China Product Sales increased by 17% (22% at CER) to \$115m, reflecting an improvement in patient access following the National Negotiation process in 2016. Iressa was subsequently included on the National Reimbursement Drug List (NRDL). Other Emerging Markets sales were negatively impacted by competition from branded and generic medicines, including in South Korea.



Sales in the US increased by 69% to \$27m and declined in Europe by 12% to \$80m. Given the significant future potential of *Tagrisso*, the Company continues to prioritise the ongoing launch of *Tagrisso* in established markets over commercial support for *Iressa*.

#### **Other Cancers**

#### Lynparza

Product Sales of \$197m; an increase of 26%.

*Lynparza* was available to patients in over 30 countries by the end of the period, with regulatory reviews underway in additional countries. On 17 August 2017, *Lynparza* received an additional, broad approval in the US, namely for patients regardless of BRCA-mutation status, for the treatment of 2nd-line ovarian cancer with a new tablet formulation. This was in addition to the full approval for the later-line treatment of patients with BRCA-mutant ovarian cancer. This was followed by an immediate encouraging uplift in new-patient starts.

US sales declined by 9% in the year to date to \$87m, reflecting the introduction of competing poly ADP ribose polymerase (PARP)-inhibitor medicines in earlier lines of treatment that were approved in broader patient populations. Encouraging progress was made in the quarter, however, with sales growth of 9% reflecting the aforementioned approval for the treatment of 2nd-line ovarian cancer. Sales in Europe increased by 68% (70% at CER) to \$94m, following a number of successful launches.

On 27 July 2017, AstraZeneca and MSD announced a global strategic oncology collaboration to co-develop *Lynparza* and potential medicine selumetinib for multiple cancer types. The companies intend to develop *Lynparza* and selumetinib jointly, both in monotherapy and in combination with other potential medicines. Independently, the companies will develop *Lynparza* and selumetinib in combination with their respective PD-L1 and PD-1 medicines, *Imfinzi* and pembrolizumab, separately. MSD is planning to co-commercialise *Lynparza* and potential medicine selumetinib with the Company in due course.

#### Imfinzi

Product Sales of \$1m; launched in the US on 1 May 2017.

Approved under the US FDA's Accelerated-Approval pathway and launched on the same day as a fast-to-market, limited commercial opportunity, *Imfinzi* is currently indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (bladder cancer) who have disease progression during or following platinum-containing chemotherapy, or whose disease has progressed within 12 months of receiving platinum-containing chemotherapy before (neo-adjuvant) or after (adjuvant) surgery. At present, there are five immunotherapy medicines approved for the treatment of bladder cancer in the US. The Company is actively preparing for the potential launch of *Imfinzi* in locally-advanced, unresectable non-small cell lung cancer (NSCLC) in H1 2018, given US FDA regulatory submission acceptance received in October 2017.

# Legacy: Faslodex

Product Sales of \$703m; an increase of 16%.

China sales grew by 29% (36% at CER) to \$18m in the year to date, which followed the recent successful negotiation and subsequent inclusion on the NRDL; overall *Faslodex* Emerging Markets sales grew by 26% (23% at CER) to \$88m. In May 2017, the Company received a label extension for *Faslodex* in Russia in the 1st-line monotherapy setting, based on data from the FALCON trial. Russia sales grew by 50% in the year to date (30% at CER) to \$15m.

US sales increased by 15% to \$368m, mainly reflecting a continued strong uptake of the combination with palbociclib, a medicine approved for the treatment of hormone-receptor-positive (HR+) breast cancer. Europe sales increased by 15% (16% at CER) to \$194m.

In June 2017, a label extension based upon the FALCON trial in the 1st-line setting was approved in Japan; sales grew by 11% (13% at CER) in the year to date to \$50m.



#### Legacy: Zoladex

Product Sales of \$548m; a decline of 6% (5% at CER).

Emerging Markets sales growth of 9% (10% at CER) to \$260m particularly reflected an increase in China sales of 21% (26% at CER) to \$127m. Sales in Europe declined by 11% (8% at CER) to \$104m. Sales in Established Rest Of World (ROW, comprising Japan, Canada, Australia and New Zealand) declined by 16% (15% at CER) to \$168m, driven by lower levels of use. On 31 March 2017, the Company completed an agreement with TerSera for the commercial rights to *Zoladex* in the US and Canada.

#### **CVMD**

Product Sales of \$5,327m; a decline of 16% (14% at CER). CVMD Product Sales represented 36% of total Product Sales, down from 39% in the first nine months of 2016.

#### Brilinta

Product Sales of \$780m; an increase of 29% (31% at CER).

Emerging Markets sales of *Brilinta* in the year to date grew by 29% (32% at CER) to \$175m, with China Product Sales increasing by 32% (38% at CER) to \$86m. This was followed by the recent successful negotiation and subsequent inclusion of *Brilinta* on the NRDL. Growth in Emerging Markets was reflected in a continued outperformance of the growth of the oral anti-platelet market. Strong sales growth was delivered in many markets, including other parts of Asia Pacific, as well as in Russia.

US sales of *Brilinta*, at \$355m, represented an increase of 46% in the year to date, including growth of 67% in the quarter; *Brilinta* achieved record total-prescription market share of 6.8% at the end of the period. Days-of-therapy volume market-share data was particularly encouraging. The performance reflected the growth in demand, driven by updated preferred guidelines from the American College of Cardiology and the American Heart Association in 2016, as well as the narrowing of a competitor's label; *Brilinta* remained the branded oral antiplatelet market leader in the US. Sales of *Brilique* in Europe increased by 11% (13% at CER) to \$213m, reflecting indication leadership across a number of markets.

#### Farxiga

Product Sales of \$742m; an increase of 24%.

Emerging Markets sales increased by 74% (72% at CER) to \$160m, reflecting ongoing launches and improved levels of patient access. In March 2017, *Forxiga* became the first sodium-glucose co-transporter 2 (SGLT2) inhibitor medicine to be approved in China.

US sales increased by 4% to \$339m, with sales subdued by the impact of affordability programmes. Given recent changes to these programmes, the Company saw a diminished impact on sales in the quarter; importantly, Farxiga's market share in the SGLT2 class remained stable in the period. Overall, the SGLT2 class gained market share from other classes of type-2 diabetes medicines, supported by growing evidence around the cardiovascular (CV) benefits of the class.

Sales in Europe increased by 26% (27% at CER) to \$171m as the medicine continued to lead the growing class. In Japan, where Ono Pharmaceutical Co., Ltd is a partner and records in-market sales, sales to the partner amounted to \$31m.

#### Onglyza

Product Sales of \$431m; a decline of 25%.

The performance reflected adverse pressures on the dipeptidyl peptidase-4 (DPP-4) class and an acceleration of ongoing Diabetes market dynamics. Sales in Emerging Markets declined by 15% (16% at CER) to \$93m as the Company focused on *Farxiga*. *Onglyza*, however, entered the NRDL in China in the period with year-to-date growth of 41% (47% at CER) to \$24m.

US sales declined by 29% to \$217m. Continued competitive pressures and a lower market share were only partially offset by the favourable impact of lower utilisation of patient-access programmes. Sales in Europe



declined by 24% (23% at CER) to \$78m. In Japan, in-market sales are recorded by Kyowa Hakko Kirin Co., Ltd, to whom sales totalled \$10m.

#### Bydureon/Byetta

Product Sales of \$555m; a decline of 13% (12% at CER).

Combined sales of *Bydureon* and *Byetta* in Emerging Markets were \$5m and \$9m, respectively. In 2016, AstraZeneca entered a strategic collaboration with 3SBio Inc. for the rights to commercialise *Bydureon* and *Byetta* in China. Combined US sales for *Bydureon* and *Byetta* were \$424m, despite intense levels of competition. *Bydureon* US sales declined by 2% to \$343m, representing 81% of total US *Bydureon* and *Byetta* sales. The fall in US *Byetta* sales continued in the year to date; the decline of 36% to \$81m reflected the Company's promotional focus on once-weekly *Bydureon* over twice-daily *Byetta*. Combined sales in Europe declined by 19% (17% at CER) to \$91m.

#### Legacy: Crestor

Product Sales of \$1,771m; a decline of 36% (35% at CER).

Sales in China grew by 15% (19% at CER) to \$273m. In the US, sales declined by 78% to \$246m, reflecting the market entry in July 2016 of multiple *Crestor* generic medicines. In the quarter, the US performance was flattered by a managed-market adjustment. In Europe, sales declined by 22% (21% at CER) to \$514m, reflecting the increasing presence of generic medicines. In Japan, where Shionogi Co. Ltd is a partner, *Crestor* maintained its position as the leading statin, with growth of 1% (2% at CER) to \$394m despite the entry in the quarter of the first *Crestor* competitor. Multiple *Crestor* generics are expected to launch in Japan in due course.

#### **RESPIRATORY**

Product Sales of \$3,372m; a decline of 5% (3% at CER). Respiratory Product Sales represented 23% of total Product Sales, up from 22% in the first nine months of 2016.

#### Symbicort

Product Sales of \$2,051m; a decline of 9% (8% at CER).

*Symbicort* continued to lead the global market by volume within the inhaled corticosteroids (ICS) / Long-Acting Beta Agonist (LABA) class. Emerging Markets sales grew by 7% (8% at CER) to \$322m, reflecting growth in China of 13% (18% at CER) to \$136m and in Latin America (ex-Brazil), where sales grew by 27% (31% at CER) to \$33m.

In contrast, US sales declined by 15% to \$811m, in line with expectations of continued challenging conditions; these conditions were a result of the impact of managed-care access programmes on pricing within the class. Competition also remained intense from other classes, such as Long-Acting Muscarinic Antagonist (LAMA) / LABA combination medicines. In Europe, sales declined by 13% (11% at CER) to \$590m, reflecting competition from other branded and *Symbicort*-analogue medicines.

In Japan, where Astellas Pharma Co. Ltd assists as a promotional partner, sales increased by 3% (5% at CER) to \$151m.

#### **Pulmicort**

Product Sales of \$805m; an increase of 4% (7% at CER).

Emerging Markets sales increased by 14% (19% at CER) to \$571m, reflecting strong underlying volume growth, with sales in China, Middle East and North Africa particularly encouraging. Emerging Markets represented 71% of global sales. China sales increased by 13% (18% at CER) to \$463m and represented 58% of global sales. Usage in China continued to increase, with the increasing prevalence of acute COPD and paediatric asthma accompanied by continued investment by the Company in new hospital nebulisation centres. Legacy sales in the US and Europe declined by 22% to \$107m and by 10% to \$66m, respectively.



#### Daliresp/Daxas

Product Sales of \$145m; an increase of 28%.

US sales, representing 86% of global sales, increased by 23% to \$124m, driven by favourable pricing and greater use of the medicine which is the only oral, selective, long-acting inhibitor of the enzyme phosphodiesterase-4, an inflammatory agent in COPD. Sales outside the US increased by 75% to \$21m.

#### Tudorza/Eklira

Product Sales of \$108m; a decline of 19% (18% at CER).

Sales in the US declined by 23% to \$47m, reflecting lower use of inhaled monotherapy medicines for COPD and the Company's commercial focus on the launch of *Bevespi Aerosphere*. On 17 March 2017, AstraZeneca announced that it had entered a strategic collaboration with Circassia for the development and commercialisation of *Tudorza* in the US. Circassia began its promotion of *Tudorza* in the US in May 2017; AstraZeneca will continue to book Product Sales in the US. Sales in Europe declined by 15% (14% at CER) to \$55m.

#### Duaklir

Product Sales of \$56m; an increase of 27% (30% at CER).

Duaklir, the Company's first inhaled dual bronchodilator, is now available for patients in over 25 countries. The growth in sales in the year to date was favourably impacted by the performances in Germany and the UK and the recent launch in Italy. Duaklir is expected to be submitted for US regulatory review in H1 2018. Duaklir is a registered trademark in certain European countries. The US trademark is to be confirmed.

#### Bevespi

Product Sales of \$8m; launched in 2017.

Bevespi Aerosphere was launched commercially in the US during the first quarter of 2017. Prescriptions in the period tracked in line with other LAMA/LABA launches. The overall LAMA/LABA class in the US, however, continued to grow more slowly than anticipated. Bevespi Aerosphere was the first product launched using the Company's Aerosphere co-suspension Delivery Technology delivered in a pressurised metered-dose inhaler (pMDI).

#### **OTHER**

Product Sales of \$3,062m; a decline of 19% (18% at CER). Other Product Sales represented 21% of total Product Sales, down from 23% in the first nine months of 2016.

#### Nexium

Product Sales of \$1,525m; 1% decline (stable at CER).

Emerging Markets sales declined by 5% (2% at CER) to \$516m; however, sales increased by 6% to \$442m in the US. The latter performance was flattered by returns adjustments related to the loss of exclusivity in 2015. Sales in Europe declined by 7% to \$176m. In Japan, where Daiichi Sankyo is a partner, sales increased by 6% (8% at CER) to \$330m.

#### Synagis

Product Sales of \$453m; an increase of 21%.

US sales increased by 6% to \$182m, despite restrictive guidelines from the American Academy of Pediatrics Committee on Infectious Diseases, which reduced the number of patients eligible for preventative therapy with *Synagis*. Product Sales to AbbVie Inc., which is responsible for the commercialisation of *Synagis* in over 80 countries outside the US, increased by 33% to \$271m, flattered by an element of true-up adjustments.



# Seroquel XR

Product Sales of \$224m; a decline of 64%.

Sales of *Seroquel XR* in the US declined by 77% to \$103m. Since November 2016, several competitors have launched generic *Seroquel XR* medicines in the US. Sales of *Seroquel XR* in Europe declined by 42% to \$61m, also reflecting the impact of generic-medicine competition.

#### FluMist/Fluenz

Product Sales of \$20m; a decrease of 46%.

FluMist is approved by the FDA for the 2017-2018 influenza season and will be available in the US. No US sales of FluMist were recorded in the quarter, however, due to the adverse US Advisory Committee on Immunization Practices (ACIP) recommendation for use during the 2017-2018 influenza season. FluMist continues to be recommended for use outside the US.

Sales in Europe declined by 14% to \$18m primarily driven by lower usage rates in Germany that reflected the competitive environment and parity recommendations for injectable vaccines, which more than offset the favourable impact of the UK National Immunisation Programme. *Fluenz* is the vaccine of choice in the UK for children aged 2-17 years.

# **Regional Product Sales**

		YTD 2017				Q3 2017			
	¢	6m % of	% ch	ange	¢	% of	% ch	ange	
	\$m	total1	Actual	CER	\$m	total	Actual	CER	
Emerging Markets <sup>2</sup>	4,519	31	5	7	1,515	31	9	10	
China	2,142	15	6	10	723	15	12	14	
Ex. China	2,377	16	4	5	792	16	5	7	
US	4,399	30	(23)	(23)	1,386	28	(10)	(10)	
Europe	3,460	24	(7)	(6)	1,188	24	(6)	(8)	
Established ROW	2,287	16	1	1	793	16	(4)	-	
Japan	1,645	11	3	5	578	12	(3)	4	
Canada	353	2	(5)	(6)	115	2	(9)	(10)	
Other Established ROW	289	2	(6)	(9)	100	2	(6)	(10)	
Total	14,665	100	(9)	(8)	4,882	100	(3)	(2)	

Due to rounding, the sum of individual brand percentages may not agree to totals.

#### **Emerging Markets**

Product Sales of \$4,519m; an increase of 5% (7% at CER).

China sales grew by 6% (10% at CER) to \$2,142m, representing 47% of total Emerging Markets sales. *Onglyza* and *Iressa* were included on the NRDL in China in the period, as were *Brilinta*, *Faslodex* and *Seroquel XR*, following price negotiation. *Crestor* also had its 2nd-line usage restriction removed and *Zoladex* was reclassified from the hormone and endocrine classification to oncology, which is expected to continue to support growth.

Sales in Latin America were impacted by ongoing economic conditions, with sales in Latin America (ex-Brazil) declining by 8% (6% at CER) to \$335m. Brazil sales increased by 3% (but declined by 8% at CER) to \$274m. Russia sales increased by 10% (but declined by 7% at CER) to \$170m.

<sup>&</sup>lt;sup>2</sup> Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.



Despite this, the Growth Platforms in Emerging Markets grew by 17% (20% at CER) to \$1,503m. Sales of *Symbicort* grew by 7% (8% at CER) to \$322m, reflecting higher prescription demand. *Tagrisso* launches in Emerging Markets led to year-to-date sales of \$85m. *Tagrisso* was launched in China in April 2017; China sales of *Tagrisso* totalled \$53m in the year to date. *Brilinta* also received provincial reimbursement listing in China for the period across more than 15 provinces.

#### US

Product Sales of \$4,399m; a decline of 23%.

The decline in sales reflected generic-medicine launches that impacted sales of *Crestor* and *Seroquel XR*. Unfavourable managed-care pricing and continued competitive intensity impacted sales of *Symbicort*, which declined by 15% to \$811m. The New Oncology Growth Platform in the US, however, grew by 34% to \$392m, primarily reflecting encouraging *Tagrisso* sales growth of 54% to \$277m in the year to date (YTD 2016: \$180m). *Brilinta* grew by 46% in the US to \$355m. The New CVMD Growth Platform declined by 1% in the US to \$1,370m, reflecting the competitive environment in Diabetes.

#### **Europe**

Product Sales of \$3,460m; a decline of 7% (6% at CER).

The New Oncology Growth Platform in Europe grew by 108% (110% at CER) to \$218m, partly driven by *Tagrisso* sales of \$124m. *Lynparza* sales of \$94m represented growth of 68% (70% at CER). *Forxiga* sales growth of 26% (27% at CER) to \$171m was accompanied by *Brilique* growth of 11% (13% at CER) to \$213m. These performances were more than offset by declines in other areas, including a 13% decline (11% at CER) in *Symbicort* sales to \$590m. *Symbicort* maintained its position, however, as the number one ICS/LABA medicine, despite competition from branded and analogue medicines. *Crestor* sales declined by 22% (21% at CER) to \$514m, reflecting the increasing presence of generic medicines.

#### **Established ROW**

Product Sales of \$2,287m; an increase of 1%.

Japan sales increased by 3% (5% at CER) to \$1,645m, partly reflecting sales of *Symbicort* and the launch of *Tagrisso*. *Symbicort* sales in Japan increased by 3% (5% at CER) to \$151m and, following the launch in Japan in May 2016, *Tagrisso* sales in the year to date amounted to \$158m. The first *Crestor* competitor medicine was launched in Q3 2017, with full generic competition anticipated from Q4 2017. Despite the magnitude of the impact of brand equity in the Japanese market, the Company anticipates an impact from generic competition on *Crestor* Japan sales. *Nexium* sales in Japan increased by 6% (8% at CER) to \$330m and sales of *Forxiga* increased by 55% (60% at CER) to \$31m.

# Financial Performance

Other Operating Income and Expense

% Total Revenue

**Operating Profit** 

% Total Revenue

**Profit Before Tax** 

Profit After Tax

Earnings Per Share

**Taxation** 

Tax Rate

Net Finance Expense

Joint Ventures and Associates

YTD 2017 **YTD 2016** Actual **CER** % change \$m \$m **Total Revenue** 16,688 17,417 (4)(3)Product Sales 14,665 16,059 (9)(8)Externalisation Revenue 49 50 2,023 1,358 Cost of Sales (3,093)(2,966)4 9 **Gross Profit** 13,595 14,451 (6)(5)Gross Margin\* 80.3% 81.7% -1 -2 Distribution Expense (225)(243)(8)(4)% Total Revenue 1.3% 1.4% R&D Expense (4,206)(4,347)(3)(1) % Total Revenue 25.2% 25.0% -1 SG&A Expense (7,155)(8,027)(11)(9)% Total Revenue 42.9% 46.1% +3 +3

982

5.9%

2,991

17.9%

(1,128)

(43)

1,820

(213)12%

1,607

\$1.34

535

3.1%

2,369

13.6%

(978)

(22)

1,369

220

(16)%

1,589

\$1.31

83

+3

26

+4

15

89

33

1

3

86

+3

16

+3

4

89

24

(6)

(4)

Reported

<sup>\*</sup> Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. YTD 2017 Cost of Sales included \$200m of costs relating to externalisation activities, which is excluded from the calculation of Gross Margin (YTD 2016: \$32m).

AstraZeneca What science can do

		Reported				
	Q3 2017	Q3 2016	Actual	CER		
	\$m	\$m	% ch	inge		
Total Revenue	6,232	5,699	9	10		
Product Sales	4,882	5,025	(3)	(2)		
Externalisation Revenue	1,350	674	n/m	n/m		
Cost of Sales	(1,249)	(900)	39	40		
Gross Profit	4,983	4,799	4	4		
Gross Margin*	77.7%	82.2%	-4	-4		
Distribution Expense	(76)	(76)	(1)	1		
% Total Revenue	1.2%	1.3%	-	-		
R&D Expense	(1,404)	(1,402)	-	1		
% Total Revenue	22.5%	24.6%	+2	+2		
SG&A Expense	(2,497)	(2,403)	4	5		
% Total Revenue	40.1%	42.2%	+2	+2		
Other Operating Income and Expense	143	110	29	29		
% Total Revenue	2.3%	1.9%	-	-		
Operating Profit	1,149	1,028	12	9		
% Total Revenue	18.4%	18.0%	-	-		
Net Finance Expense	(386)	(342)	13	5		
Joint Ventures and Associates	(17)	(10)	60	60		
Profit Before Tax	746	676	10	11		
Taxation	(97)	319				
Tax Rate	13%	(47)%				
Profit After Tax	649	995	(35)	(36)		
Earnings Per Share	\$0.54	\$0.80	(32)	(33)		

<sup>\*</sup> Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales. Q3 2017 Cost of Sales included \$159m of costs relating to externalisation activities (Q3 2016: \$4m), which is excluded from the calculation of Gross Margin.

Reconciliation of Reported Profit Before Tax to EBITDA

		YTD 2017		Q3 2017			
	¢	% change		¢	% change		
	\$m	Actual	CER	\$m	Actual	CER	
Reported Profit Before Tax	1,820	33	24	746	10	11	
Net Finance Expense	1,128	15	4	386	13	5	
Joint Ventures and Associates	43	89	89	17	60	60	
Depreciation, Amortisation and Impairment	1,929	9	12	655	7	7	
EBITDA*	4,920	19	15	1,804	10	9	

<sup>\*</sup> The Company uses EBITDA as a non-GAAP measure in addition to its Core Financial Measures.

Reconciliation of Reported to Core Financial Measures

			Intangible Asset	Diabetes			Cor	е
YTD 2017	Reported	Restructuring	Amortisation & Impairments	Alliance	Other <sup>1</sup>	Core <sup>2</sup>	Actual	CER
	\$m	\$m	\$m	\$m	\$m	\$m	% cha	nge
Gross Profit	13,595	128	103	-	-	13,826	(6)	(5)
Gross Margin <sup>3</sup>	80.3%	-	-	-	-	81.8%	-1	-1
Distribution Expense	(225)	-	-	-	-	(225)	(8)	(4)
R&D Expense	(4,206)	177	73	-	-	(3,956)	(5)	(2)
SG&A Expense	(7,155)	265	773	235	204	(5,678)	(7)	(5)
Other Operating Income and Expense	982	75	44	-	-	1,101	91	94
Operating Profit	2,991	645	993	235	204	5,068	8	5
% Total Revenue	17.9%	-	-	-	-	30.4%	+3	+2
Net Finance Expense	(1,128)	-	-	234	368	(526)	8	5
Taxation	(213)	(135)	(240)	(144)	(86)	(818)	n/m	n/m
Earnings Per Share	\$1.34	\$0.40	\$0.59	\$0.26	\$0.39	\$2.98	(4)	(7)

Other adjustments include discount unwind on acquisition-related liabilities (see Note 4), provision charges related to certain legal matters (see Note 5) and foreign-exchange gains and losses relating to the classification of certain non-structural intra-group loans.

<sup>2</sup> Each of the measures in the Core column in the above table are non-GAAP measures.

<sup>&</sup>lt;sup>3</sup> Gross Margin as a percentage of Product Sales reflects gross profit derived from Product Sales, divided by Product Sales. YTD 2017 Cost of Sales includes \$200m of costs relating to externalisation activities (YTD 2016: \$32m), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

			Intangible Asset	Diabetes			Co	re
Q3 2017	Reported	Restructuring	Amortisation & Impairments	Alliance	Other <sup>1</sup>	Core <sup>2</sup>	Actual	CER
	\$m	\$m	\$m	\$m	\$m	\$m	% ch	ange
Gross Profit	4,983	47	45	-	-	5,075	4	4
Gross Margin <sup>3</sup>	77.7%	-	-	-	-	79.6%	-4	-4
Distribution Expense	(76)	-	-	-	-	(76)	(1)	1
R&D Expense	(1,404)	35	30	-	-	(1,339)	-	-
SG&A Expense	(2,497)	68	265	102	112	(1,950)	3	4
Other Operating Income and Expense	143	(1)	1	-	-	143	32	32
Operating Profit	1,149	149	341	102	112	1,853	9	9
% Total Revenue	18.4%	-	-	-	-	29.7%	-	-
Net Finance Expense	(386)	-	-	70	147	(169)	(2)	3
Taxation	(97)	(31)	(78)	(37)	(46)	(289)	n/m	n/m
Earnings Per Share	\$0.54	\$0.09	\$0.21	\$0.11	\$0.17	\$1.12	(15)	(17)

<sup>&</sup>lt;sup>1</sup> Other adjustments include discount unwind on acquisition-related liabilities (see Note 4), provision charges related to certain legal matters (see Note 5) and foreign-exchange gains and losses relating to the classification of certain non-structural intra-group loans.

#### **Profit and Loss Commentary for the Year To Date**

#### **Gross Profit**

Reported Gross Profit declined by 6% (5% at CER) to \$13,595m; Core Gross Profit declined by 6% (5% at CER) to \$13,826m. The \$997m of Externalisation Revenue received as part of the *Lynparza* and selumetinib collaboration with MSD was outweighed by the receding effects of the *Crestor* and *Seroquel XR* loss of exclusivity in the US.

The calculation of the Reported Gross and Core Gross Margins excludes the impact of Externalisation Revenue, thereby reflecting the underlying performance of Product Sales. The Reported Gross Profit Margin declined by one percentage point (two percentage points at CER) to 80.3%. The Core Gross Profit margin declined by one percentage point to 81.8%. The declines primarily reflected the effect of losses of exclusivity, as well as the impact of supply agreements on externalised or divested medicines.

In the quarter, the Reported Gross Profit Margin declined by four percentage points to 77.7%; the Core Gross Profit margin declined by four percentage points to 79.6%. These declines partly reflected the magnitude of the Gross Margins in the comparative period, as well as manufacturing costs. The profit-share element of the aforementioned MSD collaboration was and will continue to be reflected in the Cost of Sales and the calculation

<sup>&</sup>lt;sup>2</sup> Each of the measures in the Core column in the above table are non-GAAP measures.

<sup>&</sup>lt;sup>3</sup> Gross Margin as a percentage of Product Sales reflects gross profit derived from Product Sales, divided by Product Sales. Q3 2017 Cost of Sales included \$159m of costs relating to externalisation activities (Q3 2016: \$4m), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.



of the Reported and Core Gross Margin; this also adversely impacted the Gross Margin performance in the quarter.

### Operating Expenses: R&D

Reported R&D costs declined by 3% (1% at CER) to \$4,206m, with the Company continuing to focus on resource prioritisation and cost discipline. Core R&D costs declined by 5% (2% at CER) to \$3,956m. Core R&D costs over the full year are expected to be broadly in line with those in FY 2016 at CER.

#### Operating Expenses: SG&A

Reported SG&A costs declined by 11% (9% at CER) to \$7,155m, reflecting the evolving shape of the business. Core SG&A costs declined by 7% (5% at CER) to \$5,678m.

In the quarter, Reported SG&A costs increased by 4% (5% at CER) to \$2,497m, reflecting the magnitude of the reduction in Reported SG&A costs in the comparative period, early investment in forthcoming launches and commercial support in Emerging Markets, particularly in China. Core SG&A costs in the quarter increased by 3% (4% at CER) to \$1,950m.

The Company has continued to consolidate its operations used by multiple parts of the business. It is committed to driving simplification and standardisation through centralisation in shared services of back-office and some middle-office activities that are currently performed in various enabling units, including Finance, HR, Procurement and IT. Instead of operating numerous shared-service centres and managing outsourced vendors independently, the recently-launched Global Business Services organisation will, over time, provide integration of governance, locations and business practices to all shared services and outsourcing activities across AstraZeneca.

#### Other Operating Income and Expense

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

Reported Other Operating Income and Expense increased by 83% (86% at CER) to \$982m and included:

- \$301m resulting from the sale of rights to Seloken in Europe to Recordati S.p.A (Recordati)
- \$165m resulting from the sale of the global rights to *Zomig* outside Japan to the Grünenthal Group (Grünenthal)
- \$161m of gains recognised on the sale of short-term investments
- \$73m from the sale of *Prilosec* royalty streams
- A milestone receipt of \$50m in relation to the disposal of Zavicefta to Pfizer Inc.
- Other gains on disposal of intangible assets

Core Other Operating Income and Expense increased by 91% (94% at CER) to \$1,101m, with the difference to Reported Other Operating Income and Expense primarily driven by a restructuring charge taken against land and buildings.

# **Operating Profit**

Reported Operating Profit increased by 26% (16% at CER) to \$2,991m. The Reported Operating Margin increased by four percentage points (three percentage points at CER) at 18% of Total Revenue. Core Operating Profit increased by 8% (5% at CER) to \$5,068m. The Core Operating Margin increased by three percentage points (two percentage points at CER) to 30% of Total Revenue.

# Net Finance Expense

Reported Net Finance Expense increased by 15% to \$1,128m, primarily reflecting an adverse foreign-exchange impact relating to the classification of certain non-structural intra-group loans. Reported Net Finance Expense increased by 4% at CER, reflecting the impact of bond issuances in May 2016 and June 2017. Excluding the discount unwind on acquisition-related liabilities and the adverse foreign-exchange impact, Core Net Finance Expense increased by 8% (5% at CER) to \$526m.



#### **Profit Before Tax**

Reported Profit Before Tax increased by 33% (24% at CER) to \$1,820m, reflecting the higher Operating Profit partly offset by increased interest charges. EBITDA increased by 19% (15% at CER) to \$4,920m.

#### **Taxation**

The Reported and Core Tax Rates for the year to date were 12% and 18% respectively. The Reported Tax Rate was lower than the 2017 UK Corporation Tax Rate of 19.25% mainly due to the impact of tax settlements and non-taxable fair value adjustments relating to contingent consideration on business combinations. The Core Tax Rate was lower than the 2017 UK Corporation Tax Rate of 19.25% mainly due to the impact of tax settlements. The net cash tax paid for the year to date was \$473m, representing 26% of Reported Profit Before Tax and 11% of Core Profit Before Tax.

The Reported and Core Tax Rates for the comparative period were (16%) and 8% respectively. These rates included 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. Excluding this effect, the Reported and Core Tax Rates for the comparative period were 17% and 19% respectively.

#### Earnings Per Share (EPS)

Reported EPS of \$1.34 represented an increase of 3% (a decline of 4% at CER). Core EPS declined by 4% (7% at CER) to \$2.98. The performance was driven by a decline in Total Revenue, partly offset by continued progress on cost control and an increase in Other Operating Income and Expense. The difference in growth rates between Operating Profit and EPS included the impact of a one-off tax benefit in Q3 2016.

#### **Cash Flow and Balance Sheet**

#### Cash Flow

The Company generated a net cash inflow from operating activities of \$2,581m in the year to date, compared with \$2,185m in the comparative period. In Q3 2017, the Company received an upfront cash receipt of \$1.6bn from the global strategic oncology collaboration with MSD, \$997m of which was recorded in Operating Profit, with the remainder deferred to the balance sheet.

	YTD 2017	YTD 2016	Difference
	\$m	\$m	\$m
Reported operating profit	2,991	2,369	622
Depreciation, amortisation and impairment	1,929	1,767	162
(Increase)/decrease in working capital and short-term provisions	(228)	(472)	244
(Gains)/losses on disposal of intangible assets	(735)	(198)	(537)
Fair value movement on contingent consideration arising from business combinations	(62)	132	(194)
Non-cash and other movements	(322)	(479)	157
Interest paid	(519)	(489)	(30)
Tax paid	(473)	(445)	(28)
Net cash inflow from operating activities	2,581	2,185	396

Net cash outflows from investing activities were \$686m in the year to date compared with \$4,572m in the comparative period. The prior-period outflow included an upfront payment as part of the majority investment in Acerta Pharma.



The cash payment of contingent consideration in respect of the Bristol-Myers Squibb Company share of the global Diabetes alliance amounted to \$235m in the year to date, which included a \$100m milestone payment in respect of *Qtern* and royalty payments.

Net cash outflows from financing activities were \$2,924m in the year to date compared to outflows of \$1,020m in the comparative period, which included cash inflows on the issuance of new long-term loans of \$2,483m.

# Capital Expenditure

Capital expenditure amounted to \$849m in the year to date, which included investment in the new global headquarters in Cambridge, UK, as well as strategic manufacturing capacity in the UK, the US, Sweden and China.

#### **Debt and Capital Structure**

At 30 September 2017, outstanding gross debt (interest-bearing loans and borrowings) was \$17,852m. Of the gross debt outstanding at 30 September 2017, \$941m was due within one year. The Company's Net Debt position at 30 September 2017 was \$12,134m.

Reconciliation of Interest-Bearing Loans and Borrowings to Net Debt

	At 30 Sep 2017	At 31 Dec 2016	At 30 Sep 2016
	\$m	\$m	\$m
Cash and cash equivalents	4,036	5,018	3,090
Other investments	1,255	898	927
Net derivatives	427	235	267
Cash, short-term investments and derivatives	5,718	6,151	4,284
Overdrafts and short-term borrowings	(930)	(451)	(1,075)
Finance leases	(12)	(93)	(97)
Current instalments of loans	-	(1,769)	(1,775)
Loans due after one year	(16,910)	(14,495)	(14,736)
Interest-bearing loans and borrowings (gross debt)	(17,852)	(16,808)	(17,683)
Net Debt	(12,134)	(10,657)	(13,399)

#### 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.



# Foreign-Exchange Rates

# Sensitivity

The Company provides the following currency sensitivity information:

		Average Exchange Rates Versus USD			Exchange Rate	Strengthening in ate Versus USD \$m) <sup>1</sup>	
Currency	Primary Relevance	FY 2016	YTD 2017 <sup>2</sup>	% change	Total Revenue	Core Operating Profit	
EUR	Product Sales	0.90	0.90	+1	+179	+123	
JPY	Product Sales	108.84	111.93	-3	+104	+71	
CNY	Product Sales	6.65	6.80	-2	+131	+74	
SEK	Costs	8.56	8.62	-1	+7	-98	
GBP	Costs	0.74	0.78	-6	+29	-131	
Other <sup>3</sup>					+194	+124	

<sup>&</sup>lt;sup>1</sup>Based on 2016 results at 2016 actual exchange rates.

# Foreign-Exchange Hedging

AstraZeneca monitors the impact of adverse currency movements on a portfolio basis, recognising correlation effects. The Company may hedge to protect against adverse impacts on cash flow over the short to medium term. As at 30 September 2017, AstraZeneca had hedged 95% of forecast short-term currency exposure that arises between the booking and settlement dates on Product Sales and non-local currency purchases.

<sup>&</sup>lt;sup>2</sup>Based on average daily spot rates between 1 January and 30 September 2017. <sup>3</sup>Other important currencies include AUD, BRL, CAD, KRW and RUB.



# **Corporate and Business Development Update**

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

# a) AstraZeneca and MSD Establish Strategic Oncology Collaboration

On 27 July 2017, AstraZeneca and MSD announced that they had entered a global strategic oncology collaboration to co-develop and co-commercialise *Lynparza* for multiple cancer types. The companies will develop and commercialise *Lynparza* jointly, both as monotherapy and in combination with other potential medicines. Independently, the companies will develop and commercialise *Lynparza* in combination with their respective PD-L1 and PD-1 medicines. *Imfinzi* and pembrolizumab.

The companies will also jointly develop and commercialise AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase pathway, currently being developed for multiple indications including thyroid cancer.

As part of the agreement, MSD will pay AstraZeneca up to \$8.5bn in total consideration, including \$1.6bn upfront, \$750m for certain licence options and up to \$6.15bn contingent upon successful achievement of future regulatory and sales milestones. The collaboration agreement was completed upon signing. Under the terms of the agreement, AstraZeneca subsequently recorded \$997m under Externalisation Revenue. AstraZeneca books all Product Sales of *Lynparza* and selumetinib; gross profits due to MSD under the collaboration are recorded under Cost of Sales. The initial, regulatory and commercial milestone payments have been and will be recorded as Externalisation Revenue in the Company's financial statements.

# b) AstraZeneca and Aspen Enter Agreement for Remaining Rights to Anaesthetics Medicines

On 14 September 2017, AstraZeneca announced that it had entered into an agreement with Aspen, under which Aspen will acquire the residual rights to the established anaesthetic medicines comprising *Diprivan*, *EMLA*, *Xylocaine*/*Xylocard*/*Xyloproct*, *Marcaine*, *Naropin*, *Carbocaine* and *Citanest*.

AstraZeneca entered into an agreement with Aspen in June 2016, under which Aspen gained the exclusive commercialisation rights to the medicines in markets outside the US. Under the terms of the new agreement, Aspen will pay an upfront consideration of \$555m and up to \$211m in performance-related milestones based on sales and gross margin during the period from 1 September 2017 to 30 November 2019. AstraZeneca will continue to manufacture and supply the medicines to Aspen during a transition period of up to five years.

Under the terms of the original agreement, Aspen made an upfront payment to AstraZeneca of \$520m and agreed to make future Product Sales-related payments of up to \$250m, as well as paying double-digit percentage royalties on Product Sales. AstraZeneca agreed to continue to manufacture and supply the medicines to Aspen on a cost-plus basis for an initial period of 10 years.

The new agreement did not impact the first Product Sales-related payment of \$150m due to AstraZeneca, which was recorded as Externalisation Revenue in the Company's financial statements in the quarter. Under the new agreement, Aspen will no longer pay royalties to AstraZeneca. The remaining \$100m Product Sales-related payment from the original agreement will be made to AstraZeneca in 2018, if the contingent terms are met and will be recorded as Other Operating Income and Expense to reflect the reduced ongoing interest in the medicines as a result of the new agreement. Furthermore, as AstraZeneca will transition the manufacture and supply of the medicines to Aspen and therefore will have a reduced ongoing interest, the \$555m initial and up to \$211m sales and gross margin-related payments from the new agreement will also be recorded as Other Operating Income and Expense in the Company's financial statements. The Company announced completion of the agreement on 1 November 2017.

# c) Agreement for Rights to Zomig in Japan

On 30 September 2017, AstraZeneca entered into an agreement with Sawai Pharmaceuticals Company Ltd (Sawai) for the rights to *Zomig* in Japan. *Zomig* is a legacy medicine indicated for the acute treatment of migraines and cluster headaches, an area of medicine outside AstraZeneca's strategic focus. The divestment of the rights to *Zomig* in Japan follows an agreement entered into in June 2017, under which Grünenthal acquired the rights to the medicine in all other markets. AstraZeneca received initial revenue from Sawai which was recorded as Other Operating Income and Expense in the Company's financial statements.



# d) AstraZeneca and Takeda Establish Collaboration to Develop and Commercialise MEDI1341

On 29 August 2017, AstraZeneca and Takeda announced that they had entered an agreement to jointly develop and commercialise MEDI1341, an antibody currently in development as a potential treatment for Parkinson's disease.

Under the terms of the agreement, AstraZeneca will lead Phase I development, while Takeda will lead future clinical-development activities. The companies will share equally future development and commercialisation costs for MEDI1341, as well as any future revenues. Takeda will pay AstraZeneca up to \$400m, including initial income of \$50m in Q3 2017 and development and sales milestones thereafter, all recorded as Externalisation Revenue in the Company's financial statements. Additional terms of the agreement were not disclosed.

### e) MedImmune and NewLink Announce Collaboration on Immuno-Oncology Combination Clinical Trial

During the period, it was announced that MedImmune, the Company's global biologics research and development arm and NewLink Genetics Corporation (NewLink Genetics) had entered into a clinical collaboration agreement to evaluate the combination of *Imfinzi*, AstraZeneca's PD-L1 monoclonal antibody and indoximod, NewLink Genetics' small molecule IDO pathway inhibitor, along with standard-of-care chemotherapy for patients with metastatic pancreatic cancer. The primary objective for this randomised, placebo-controlled, Phase II trial is to evaluate the immuno-oncology-based combination compared to gemcitabine alone.

# f) AstraZeneca and Incyte Enter Clinical-Trial Collaboration in Early Lung Cancer

On 31 October 2017, the Company announced the expansion of its clinical collaboration with Incyte Corporation (Incyte). As part of the agreement, the companies will evaluate the efficacy and safety of epacadostat, Incyte's investigational selective IDO1 enzyme inhibitor, in combination with *Imfinzi*, compared to *Imfinzi* alone. The exclusive collaboration for the trial population allows for the two companies to conduct a Phase III trial in patients with locally-advanced (Stage III), unresectable NSCLC whose disease has not progressed following platinum-based chemotherapy concurrent with radiation therapy (CRT). This agreement builds on the positive clinical data readout from the PACIFIC trial, published in September 2017.

# g) Senior Executive Team Changes

On 10 October 2017, David Fredrickson was appointed Executive Vice-President, Global Head Oncology Business Unit (OBU), with responsibility for sales, marketing, medical affairs and diagnostics for Oncology medicines globally, as well as Oncology commercial operations in the US, UK, Spain, Italy, Germany and France. Prior to this appointment, Mr. Fredrickson was President and Country Representative, Japan, where he was responsible for, *inter alia*, the launch of *Tagrisso*. Before that, as Vice President, US for Oncology, Infectious Diseases and Neuroscience, he was responsible for the US launches of *Tagrisso*, *Lynparza* and *Iressa*. Mr. Fredrickson also spent a number of years at Roche Holding Ltd.

He became a member of the Senior Executive Team, reporting to the Chief Executive Officer on 10 October 2017. Mr Fredrickson took over leadership of the OBU from Jamie Freedman, who was appointed President, AstraZeneca Canada, effective on the same day.

# Research and Development Update

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A comprehensive table with AstraZeneca's pipeline of medicines in human trials can be found later in this document. Since the results announcement on 27 July 2017 (the period):

Regulatory Approvals	9	<ul> <li>Faslodex - breast cancer (1st line) (US)</li> <li>Lynparza - ovarian cancer (2nd line, 4th line/tablets) (US)</li> <li>Calquence (acalabrutinib) - MCL (2nd line) (US)</li> <li>Brilinta - prior MI (CN)</li> <li>Farxiga + Bydureon - type-2 diabetes (US, EU)</li> <li>Bydureon BCise - type-2 diabetes (US)</li> <li>Symbicort - COPD exacerbations (US)</li> </ul>
Regulatory Submission Acceptances	6	<ul> <li>Lynparza - breast cancer (US, JP) (Priority Reviews)</li> <li>Imfinzi - locally-advanced, unresectable NSCLC ((US/Priority Review), EU, JP)</li> <li>Bydureon BCise - type-2 diabetes (EU)</li> </ul>
Major Phase III Data Readouts	5	<ul> <li>Tagrisso - lung cancer (1st line) (FLAURA) (met primary endpoint)</li> <li>Imfinzi - lung cancer (MYSTIC) (did not meet PFS primary endpoint)</li> <li>moxetumomab pasudotox - leukaemia (met primary endpoint)</li> <li>Duaklir - COPD (met primary endpoint)</li> <li>tralokinumab - severe, uncontrolled asthma (did not meet primary endpoints)</li> </ul>
Other Major Developments	3	<ul> <li>Tagrisso - lung cancer (1st line)         (Breakthrough Therapy Designation, US)</li> <li>Imfinzi - locally-advanced, unresectable lung cancer         (Breakthrough Therapy Designation, US)</li> <li>Calquence - MCL (2nd line)         (Breakthrough Therapy Designation, US)</li> </ul>
New Molecular Entities (NMEs) in Phase III Trials or Under Regulatory Review	11	Oncology - Imfinzi + treme - multiple cancers - moxetumomab pasudotox - leukaemia - selumetinib - thyroid cancer - savolitinib - kidney cancer  CVMD - ZS-9 (sodium zirconium cyclosilicate) - hyperkalaemia* - roxadustat - anaemia*  Respiratory - benralizumab - severe, uncontrolled asthma*, COPD - tralokinumab - severe, uncontrolled asthma - PT010 - COPD  Other - anifrolumab - lupus - lanabecestat - Alzheimer's disease
Projects in Clinical Pipeline	129	

<sup>\*</sup>Under Regulatory Review. The table shown above as at 9 November 2017.



#### **ONCOLOGY**

AstraZeneca has a deep-rooted heritage in Oncology and offers a growing line of new medicines that has the potential to transform patients' lives and the Company's future. At least six Oncology medicines are expected to be launched between 2014 and 2020, of which *Lynparza*, *Tagrisso*, *Imfinzi* and *Calquence* are already benefitting patients. An extensive pipeline of small-molecule and biologic medicines is in development and the Company is committed to advancing New Oncology, primarily focused on lung, ovarian, breast and blood cancers, as one of AstraZeneca's five Growth Platforms.

At the recent 2017 European Society of Medical Oncology (ESMO) annual meeting, AstraZeneca presented data from more than 40 abstracts, including two pivotal clinical-trial readouts selected for late-breaking presentation at the Presidential Symposium. Highlights included new data on approved and potential new medicines from the Company's pipeline across multiple scientific platforms and tumour types.

#### a) Faslodex (breast cancer)

On 28 August 2017, the Company announced approval in the US for the expansion of *Faslodex* use into advanced breast-cancer patients not previously treated with endocrine (hormonal) medicines. The US FDA approval was based on data from the Phase III FALCON trial, where *Faslodex* 500mg demonstrated superiority over anastrozole 1mg in the treatment of locally-advanced or metastatic breast cancer in post-menopausal patients who had not received prior hormonal-based medicine for hormone receptor-positive breast cancer. The FALCON trial data showed that *Faslodex* significantly reduced the risk of disease worsening or death by 20%.

During the period, the Company announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) had adopted a positive opinion recommending a new indication for *Faslodex* that will expand its use to include combination therapy with palbociclib. The combination use was designed for the treatment of patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) locally-advanced or metastatic breast cancer or who have received prior endocrine therapy. The CHMP opinion was based on data from the Phase III PALOMA-3 trial which demonstrated that the combination of *Faslodex* 500mg and palbociclib 125mg resulted in a 4.9 month progression-free survival (PFS) improvement over *Faslodex* and placebo.

The Company also announced during the period that the US FDA had approved a new indication for *Faslodex*, expanding the indication to include use with abemaciclib for the treatment of HR+, HER2- advanced or metastatic breast cancer in patients with disease progression after endocrine therapy. The US FDA approval was based on data from the Phase III MONARCH 2 trial, which met the primary endpoint of PFS.

Finally, the Company announced during the period the approval of the supplemental New Drug Application (NDA) of *Faslodex* in combination with palbociclib in Japan, based on data from the PALOMA-3 trial; the approval was for the treatment of pre-menopausal breast cancer patients taking a luteinising hormone-releasing hormone medication.

#### b) Lynparza (multiple cancers)

On 17 August 2017, the Company announced approval in the US for *Lynparza* tablets as a maintenance treatment for patients with platinum-sensitive recurrent ovarian cancer, regardless of BRCA-mutation status. *Lynparza* tablets were also indicated for patients with BRCA-mutated ovarian cancer beyond the 3rd-line setting, with the Accelerated Approval converted to full approval. Data from two randomised trials supported the new approval and the conversion of the prior approval to full approval, originally based on a single-arm trial.

Data from the Phase III SOLO-2 trial confirmed the benefit of *Lynparza* in germline BRCA-mutated (gBRCAm) patients, demonstrating a 70% reduced risk of disease progression or death (HR, hazard ratio, 0.30) and improved PFS to 19.1 vs 5.5 months for placebo by investigator-assessed analysis. Data from the Phase II Study-19 trial showed that *Lynparza* reduced the risk of disease progression or death by 65% and improved PFS compared to placebo in patients of any BRCA status (HR 0.35; median PFS of 8.4 months vs 4.8 months for placebo). Additionally, patients in Study 19, treated with *Lynparza* as a maintenance therapy, had a median overall survival (OS) of 29.8 months vs 27.8 months for placebo (HR 0.73).

During the period, the Company received regulatory submission acceptance in the US for *Lynparza* tablet's supplementary NDA based on the OlympiAD trial data in breast cancer. In the period, the Company also announced the submission of an NDA to Japan's Pharmaceuticals and Medical Devices Agency for the use of *Lynparza* tablets in unresectable or recurrent BRCA-mutated breast cancer, with a decision expected in the second half of 2018. The OlympiAD trial focused on patients with germline BRCA-mutated, HER2- metastatic



breast cancer who had been treated previously with chemotherapy either in the neo-adjuvant, adjuvant or metastatic settings. This followed the Phase III OlympiAD data presented at the 2017 American Society of Clinical Oncology annual meeting. *Lynparza* is the first PARP inhibitor with a regulatory submission outside ovarian cancer.

### c) Tagrisso (lung cancer)

At the recent ESMO Congress's Presidential Symposium, the Company presented positive results from the Phase III FLAURA trial for patients with 1st-line epidermal growth factor receptor (EGFR)-mutated NSCLC. Patients treated with *Tagrisso* had less than half the risk of progression or death compared with patients on erlotinib or gefitinib (HR 0.46). The median PFS was 18.9 months for patients on *Tagrisso* vs. 10.2 months for patients in the comparator arm. FLAURA demonstrated clinically-meaningful preliminary OS data favouring *Tagrisso*, namely a 37% reduction in the risk of death. OS data were 25% mature at the time of the interim analysis and a final OS analysis is planned for a later stage.

Improvements in PFS with *Tagrisso* were consistent across all pre-specified patient subgroups, with at least a 40% reduction in the risk of progression or death, including in patients with or without central nervous system metastases at trial entry, Asian/non-Asian patients, patients with or without prior smoking history and patients with exon 19 deletion/L858R. Patients treated with *Tagrisso* had more than double the median duration of response than those on the comparator arm (17.2 months vs. 8.5 months), while the objective response rates (ORR) were similar.

The US National Comprehensive Cancer Network (NCCN) guidelines were updated on 28 September 2017 to include *Tagrisso* as a category-2A treatment option in NSCLC patients with an EGFR mutation discovered prior to 1st-line treatment. The medicine is not currently approved for treatment in the 1st-line setting.

During the period, the Company and its partner Hutchison China MediTech Limited presented preliminary safety and clinical activity of savolitinib when given in combination with *Tagrisso* in a Phase Ib trial at the International Association for the Study of Lung Cancer 18th World Conference on Lung Cancer in Japan. The trial was conducted in patients with EGFR-mutation-positive NSCLC with mesenchymal epithelial transition (MET)-amplification, who had progressed following 1st-line treatment with a tyrosine kinase inhibitor (TKI). Early data on safety and anti-tumour activity for savolitinib plus *Tagrisso* demonstrated a response according to RECIST 1.1 criteria in 28% of patients previously treated with third-generation T790M-directed EGFR TKIs, including *Tagrisso*. In patients who had progressed after prior treatment with a first- or second-generation EGFR inhibitor, 53% of T790M-negative patients had a partial response, while 57% of T790M-positive patients had a partial response. In the 66 patients treated with savolitinib plus *Tagrisso*, the most common all-causality adverse events of any grade were consistent with the known safety profiles of both therapies, including nausea (44%), vomiting (35%), fatigue (30%), and decreased appetite (30%).

#### d) Imfinzi (lung and other cancers)

The Company continues to advance multiple monotherapy trials of *Imfinzi* and combination trials of *Imfinzi* with tremelimumab and other potential new medicines:

#### **Lung Cancer**

During the period, the Company maintained strong momentum in its early immunotherapy efforts in lung cancer. On 31 July 2017, *Imfinzi* was granted Breakthrough Therapy Designation by the US FDA for patients with locally-advanced, unresectable NSCLC. PACIFIC is a Phase III, randomised, double-blinded, placebo-controlled multicentre trial of *Imfinzi* as sequential treatment in patients with locally-advanced (Stage III) unresectable NSCLC, who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy. PACIFIC trial results presented at the 2017 ESMO annual meeting showed a statistically-significant and clinically-meaningful PFS benefit with *Imfinzi* and also demonstrated a favourable risk/benefit profile. The trial will continue in order to evaluate OS, the other primary endpoint, which is anticipated to be assessed in 2019.

During the period, the US FDA accepted a supplemental Biologics License Application for *Imfinzi* for the treatment of patients with locally-advanced, unresectable NSCLC whose disease has not progressed following platinum-based chemoradiation therapy. The agency granted *Imfinzi* Priority Review status in this potential indication. The Company also recently submitted the data from the PACIFIC trial to the EMA for the same indication and received acceptance of the submission. Additional regulatory submissions for the PACIFIC trial were made and/or accepted in the period in Australia, Brazil, Canada, Japan and Switzerland.



On 28 September 2017, the US NCCN Clinical Practice Guidelines in Oncology were updated to include *Imfinzi* for the treatment of patients with locally-advanced, unresectable NSCLC with no disease progression after two or more cycles of definitive chemoradiation, based on the data from the aforementioned PACIFIC trial. The medicine is not currently approved for treatment in the locally-advanced, unresectable NSCLC setting.

The Company now expects the first data from the Phase III ARCTIC trial in 3rd-line, PDL1-low/negative NSCLC to be available in H1 2018. The timeline reflects the event-driven nature of the trial as the Company awaits greater maturity of OS data.

Ongoing key lung-cancer trials include:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status		
Monotherapy	Monotherapy							
ADJUVANT*	III	N/A	Stage Ib-IIIa NSCLC	Imfinzi vs placebo	FPCD¹ Q1 2015 First data anticipated 2020	Recruitment ongoing		
PACIFIC	III	N/A	Locally- advanced (Stage III), unresectable NSCLC	Imfinzi vs placebo	FPCD Q2 2014 LPCD <sup>2</sup> Q2 2016 Final OS data anticipated 2019	Recruitment completed  PFS primary endpoint met		
PEARL	III	1st line	NSCLC (Asia)	Imfinzi vs SoC chemotherapy	FPCD Q1 2017 First data anticipated 2020	Recruitment ongoing		
Combination t	therapy							
MYSTIC	III	1st line	NSCLC	Imfinzi, Imfinzi + treme vs SoC chemotherapy	FPCD Q3 2015 LPCD Q3 2016 Final OS data anticipated H1 2018	Recruitment completed  PFS primary endpoint not met		
NEPTUNE	III	1st line	NSCLC	Imfinzi + treme vs SoC chemotherapy	FPCD Q4 2015 LPCD Q2 2017	Recruitment completed		

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
					First data anticipated H2 2018	
POSEIDON	III	1st line	NSCLC	Imfinzi + SoC, Imfinzi + treme + SoC vs SoC chemotherapy	FPCD Q2 2017 First data anticipated 2019	Recruitment ongoing
ARCTIC	III	3rd line	PDL1- low/neg. NSCLC	Imfinzi, tremelimumab, Imfinzi + treme vs SoC chemotherapy	FPCD Q2 2015 LPCD Q3 2016 First data anticipated H1 2018	Recruitment completed
CASPIAN	III	1st line	Small-cell lung cancer (SCLC)	Imfinzi + SoC, Imfinzi + treme + SoC vs SoC chemotherapy	FPCD Q1 2017 First data anticipated 2020	Recruitment ongoing

\*Conducted by the National Cancer Institute of Canada

#### **Other Cancers**

In November 2017, *Imfinzi* received approval in Canada, under the Health Canada's accelerated-approval framework (Notice of Compliance with Conditions (NOC/c) policy), for the treatment of patients with locally-advanced or mUC who have disease progression during or following platinum-containing chemotherapy, or whose disease has progressed within 12 months of receiving platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery. Approval was granted in an 'all-comer' population based on both tumour response rate and duration of response. Data from Study 1108, which supported this approval, was shared at the recent 2017 ASCO annual meeting and showed a 17.0% objective response rate (ORR) by BICR in all-comers and a 26.3% ORR in patients with PDL1-positive tumours.

During the period, the Company amended its late-stage clinical development programme in 1st-line locally-advanced or metastatic urothelial carcinoma (bladder cancer). A refinement of the Phase III DANUBE trial meant that OS became the only primary endpoint, with the first data now anticipated in 2019. Patient enrolment was also increased from 1,005 to 1,200 patients, reflecting the inclusion of an expansion cohort in China.

The STRONG trial, a Phase IIIb, modular, five-year safety, open-label trial commenced dosing in the period and will evaluate the safety of a fixed-dose regimen equivalent to the current weight-based dose regimen of *Imfinzi* + tremelimumab combination therapy or *Imfinzi* monotherapy in patients with advanced solid tumours (via tumour-specific modules). The first tumour module dosed was metastatic urothelial carcinoma.

During the period, the Company launched a new Phase III trial to assess the safety and efficacy of *Imfinzi* monotherapy or *Imfinzi* plus tremelimumab combination therapy versus standard of care in patients with unresectable hepatocellular carcinoma (HCC, liver cancer). The HIMALAYA trial will include a fixed dose of *Imfinzi* (1,500mg, monthly) and tremelimumab (300mg).

<sup>&</sup>lt;sup>1</sup>First Patient Commenced Dosing

<sup>&</sup>lt;sup>2</sup>Last Patient Commenced Dosing

Ongoing key trials are listed below:

Name	Phase	Line of Treatment	Population	Design	Timelines	Status
DANUBE	III	1st line	Cisplatin chemotherapy- eligible/ ineligible bladder cancer	Imfinzi, Imfinzi + treme vs SoC chemotherapy	FPCD Q4 2015 LPCD Q1 2017 First data anticipated 2019	Recruitment completed
KESTREL	III	1st line	Head and neck squamous cell carcinoma (HNSCC, head and neck cancer)	Imfinzi, Imfinzi + treme vs SoC	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H1 2018	Recruitment completed
EAGLE	III	2nd line	HNSCC	Imfinzi, Imfinzi + treme vs SoC	FPCD Q4 2015 LPCD Q3 2017 First data anticipated H1 2018	Recruitment completed
HIMALAYA	III	1st line	HCC	Imfinzi, Imfinzi + treme vs sorafenib	First data anticipated 2019	Recruitment ongoing

On 7 September 2017, the Company announced that its partner, Celgene Corporation (Celgene) was informed by the US FDA that the agency had placed a partial clinical hold on five trials and a full clinical hold on one trial in the Celgene FUSION programme. The trials are testing *Imfinzi* in combination with immunomodulatory agents such as lenalidomide, with or without chemotherapy, in blood cancers such as multiple myeloma, chronic lymphocytic leukaemia and lymphoma.

# e) Calquence (acalabrutinib) (blood cancer)

On 31 October 2017, the Company announced that the US FDA had granted Accelerated Approval to *Calquence*, a kinase inhibitor indicated for the treatment of adult patients with MCL who have received at least one prior therapy. *Calquence* was approved under the FDA's Accelerated Approval Program, based on overall response rate, which allows for earlier approval of medicines that treat serious conditions and fill an unmet medical need based on a surrogate endpoint. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

The Accelerated Approval was based on results from the ACE-LY-004 trial, where *Calquence* demonstrated an 80% ORR, with a 40% complete response and 40% partial-response rate. Full results from the ACE-LY-004 clinical trial will be presented in December 2017 at the 59th American Society of Hematology annual meeting in Atlanta, US. The approval followed acceptance of the submission and the granting of Priority Review and Breakthrough Therapy Designation earlier in the period, based on the totality of clinical data from the *Calquence* development programme, including data from the Phase II ACE-LY-004 clinical trial.



# f) Moxetumomab pasudotox (leukaemia)

During the period, the Company maintained momentum in its efforts in blood cancers, with high-level results from a pivotal Phase III single-arm trial of moxetumomab pasudotox, an anti-CD22 recombinant immunotoxin, as treatment for adult patients with relapsed/refractory hairy cell leukaemia (HCL) who have had at least two prior lines of therapy. The clinical trial met its primary endpoint of durable complete response. HCL is an orphan disease with no cure and no established standard of care for patients in late-line therapy who relapse or refractory to prior therapies. AstraZeneca plans to submit the complete results from the Phase III trial for presentation at a forthcoming medical meeting.

#### **CVMD**

CV, renal and metabolic diseases are key areas of focus for AstraZeneca as the Company sets the challenge to better understand how its portfolio of medicines might be used to help address multiple risk factors or comorbidities across CVMD. Today, AstraZeneca is delivering life-changing results in the main CV-disease areas and their complications. AstraZeneca is investing in the science to demonstrate CV and mortality benefits by slowing the underlying progression of CV-related disease and protecting the organs of the CV system. Ultimately, AstraZeneca is looking to do more than just slow CV-related disease, but to modify or even halt the natural course of the disease itself and regenerate organs.

The net result is a strong, continued commitment to new CVMD treatment options that have the potential to deliver improved outcomes to hundreds of millions of patients across the globe.

# a) Brilique (CV disease)

During the period, the China FDA approved *Brilique* 60mg tablets for patients with a history of MI, following an MI event. The approval was based on data from the PEGASUS trial and expanded the use of *Brilique* in combination with aspirin, to reduce the rate of CV death, MI and stroke in patients with a history of MI and at least one additional high-risk factor for developing an atherothrombotic event.

During the 2017 European Society of Cardiology congress in Barcelona, AstraZeneca presented results from a new sub-analysis of data from the Phase III PEGASUS trial. The trial showed that treatment with *Brilique* 60mg twice daily reduced the risk in CV-caused death (versus placebo) by 29% in patients taking low-dose aspirin but still at high risk of an atherothrombotic event.

# b) Farxiga (diabetes)

24-week data from the DEPICT-1 trial was published in *The Lancet Diabetes and Endocrinology* and presented at the 2017 European Association for the Study of Diabetes (EASD) 53rd annual meeting in September 2017. The trial showed that *Farxiga*, when given as an oral adjunct to injectable insulin in patients with inadequately-controlled type-1 diabetes, demonstrated significant and clinically-relevant reductions from baseline in HbA1c, weight reductions and lowered total daily insulin dosing at 24 weeks compared to placebo at both the 5mg and 10mg dose. Furthermore, as assessed by continuous glucose monitoring, treatment with *Farxiga* at both doses reduced mean glucose and glucose fluctuations (assessed by mean amplitude of glycaemic excursions) and increased the percentage of glucose readings in the target range (70-180mg/dL). Specifically, patients treated with *Farxiga* 5mg and 10mg spent more than two hours and more than 2.5 hours longer in the target glucose range each day, respectively.

The overall adverse event profile was in line with the known clinical profile of *Farxiga*, with no imbalance in adverse events reported. The occurrence of hypoglycaemia overall, as well as severe hypoglycaemia, was not increased in the *Farxiga* treatment groups compared with placebo. Similarly, in this trial, *Farxiga* was not associated with an increase in the occurrence of definite diabetic ketoacidosis (DKA) compared with placebo. Four (1%) events occurred in the *Farxiga* 5mg group, five (2%) occurred in the *Farxiga* 10mg group and three (1%) occurred in the placebo group, respectively. Insulin pump failure and missed insulin doses were the most frequent risk factors for definite DKA in the placebo and *Farxiga* groups.

The DEPICT clinical programme for *Farxiga* is ongoing; final results are required to evaluate the next regulatory steps. *Farxiga* is not currently approved for the treatment of type-1 diabetes.



# c) Bydureon (type-2 diabetes)

AstraZeneca presented the full results from the EXSCEL (EXenatide Study of Cardiovascular Event Lowering) trial at the aforementioned EASD meeting. The trial demonstrated CV safety with *Bydureon* (exenatide extended release) in patients with type-2 diabetes across a range of CV outcomes.

Bydureon did not increase the incidence of major adverse CV events (MACE), a composite endpoint of CV death, non-fatal heart attack or non-fatal stroke, compared to placebo (HR 0.91; 95% confidence interval (CI): 0.83-1.00; p<0.001 for non-inferiority). There were also fewer CV events observed in the Bydureon arm of the trial (839 (11.4%) versus 905 (12.2%)), although the primary efficacy objective of a superior reduction in MACE did not meet statistical significance (p=0.061). Additionally, in a pre-specified secondary analysis, patients treated with exenatide had a 14% lower incidence of death from all causes (HR: 0.86; 95% CI: 0.77-0.97).

During the period, the US FDA approved the inclusion of data from the DURATION-8 clinical trial into the *Farxiga* and *Bydureon* labels. DURATION-8 evaluated the simultaneous combination of a GLP-1 receptor agonist with an SGLT2 inhibitor on a background of metformin therapy, in high baseline HbA1c patients with inadequate glycemic control. The results demonstrated that combining agents that work in different ways can significantly reduce HbA1c, as well as weight and systolic blood pressure.

In August 2017, the EMA approved the incorporation of DURATION-8 data into the *Bydureon* label. The label included updates to both the indication statement and the clinical-trial section. DURATION-8 data is now represented in both the *Bydureon* and *Forxiga* European summary of product characteristics.

In October 2017, the Company announced that the US FDA had approved *Bydureon BCise* (exenatide extended release) injectable suspension, a new formulation of *Bydureon* in an improved once-weekly, single-dose *BCise* device for adults with type-2 diabetes whose blood sugar remains uncontrolled on one or more oral medicines in addition to diet and exercise, to improve glycaemic control. AstraZeneca anticipates that *Bydureon BCise* will be available for patients in the US in the first quarter of 2018. A regulatory application for the new *BCise* device was also accepted by the EMA in the period.

Major ongoing outcomes trials for patients are highlighted in the following table:

Medicine	Trial	Mechanism	Population	Primary Endpoint	Timeline
Farxiga	DECLARE	SGLT2 inhibitor	~17,000¹ patients with type-2 diabetes	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	H2 2018 (final analysis)
Farxiga	DAPA-HF	SGLT2 inhibitor	~4,500 patients with heart failure (HF)	Time to first occurrence of CV death or hospitalisation for HF or an urgent HF visit	FPCD Q1 2017
Farxiga	DAPA-CKD	SGLT2 inhibitor	~4,000 patients with chronic kidney disease (CKD)	Time to first occurrence of ≥50% sustained decline in eGFR² or reaching ESRD³ or CV death or renal death	FPCD Q1 2017
Brilinta	THEMIS	P2Y12 receptor antagonist	~19,000 patients with type-2 diabetes and coronary artery disease without a history of MI or stroke	Composite of CV death, non-fatal MI and non-fatal stroke	2019
Epanova	STRENGTH	Omega-3 carboxylic acids	~13,000 patients with mixed dyslipidaemia	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	2019

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)

<sup>&</sup>lt;sup>2</sup>Estimated Glomerular Filtration Rate

<sup>&</sup>lt;sup>3</sup>End-Stage Renal Disease



#### d) ZS-9 (sodium zirconium cyclosilicate) (hyperkalaemia)

In April 2017, the EMA informed AstraZeneca that the Marketing Authorisation Application decision process for ZS-9 was put on hold until the agency had performed an inspection of the dedicated substance-manufacturing facility in Texas, US. This followed receipt of a second Complete Response Letter from the US FDA, as announced on 17 March 2017. During the period, the Company made further progress in addressing the manufacturing deficiencies identified by the FDA inspection and expects to be able to accommodate a new manufacturing inspection in due course.

#### e) Roxadustat (anaemia)

During the period, the Company and its partner FibroGen Inc. (Fibrogen) announced the regulatory submission of an NDA for roxadustat with the China FDA, concluding the rolling submission initiated in Q4 2016. The NDA was based on two Fibrogen-led Phase III trials, conducted in China, that met their primary efficacy endpoints in January 2017 respectively. If approved, roxadustat will be a first-in-class medicine, with China being the first approval country, ahead of other major markets.

#### 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 anticipated launches between 2017 and 2020. The capability in inhalation technology spans both pressurised, metered-dose inhalers 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 (COPD)

On 11 September 2017, the US FDA approved *Symbicort* for the reduction of exacerbations in patients with COPD. The approval was based on data that evaluated COPD exacerbations as the primary endpoint in two Phase IIIb trials (RISE and Study 003), supported by data from two legacy Phase IIIa trials (SUN and SHINE). The approval meant *Symbicort* was indicated to reduce exacerbations; the medicine is also used as a maintenance treatment for airflow obstruction in patients with COPD. The RISE data was published in *Respiratory Medicine*.

Following clinical data from the Phase III SYGMA trials, examining *Symbicort Turbuhaler* prescribed as an antiinflammatory reliever as needed in patients with mild asthma, the primary objectives in severe-asthma exacerbation rates and asthma control were met. A full evaluation of the SYGMA primary and secondary objectives is ongoing and the results will be presented at a forthcoming medical meeting.

#### b) Duaklir (COPD)

On 7 September 2017, AstraZeneca announced positive top-line results from the Phase III AMPLIFY trial for *Duaklir*, which met its primary endpoints and demonstrated a statistically-significant improvement in lung function in patients with moderate to very-severe stable COPD, compared to each individual component (either aclidinium bromide or formoterol). A full evaluation of the AMPLIFY data is ongoing and further results will be presented at a forthcoming medical meeting.



#### c) Bevespi (COPD)

On 25 September 2017, the Company announced positive top-line results of the Phase III PINNACLE 4 trial. The trial demonstrated a statistically-significant improvement in lung function as measured by trough forced expiratory volume in one second (FEV<sub>1</sub>), compared to its monotherapy components and placebo, all administered twice daily via pMDI to patients with moderate to very severe COPD. AstraZeneca will make regulatory submissions for *Bevespi Aerosphere* in Japan and China in 2018, based on data from PINNACLE 4, as well as previously-reported trials.

During the period, the first patient was randomised into AERISTO, a head-to-head trial that is assessing the efficacy and safety of *Bevespi Aerosphere* relative to the competing dual bronchodilator, a fixed-dose combination of umeclidinium and vilanterol, for patients with moderate to very severe COPD.

#### d) Benralizumab (severe, uncontrolled asthma)

On 11 September 2017, results from a sub-group analysis of the SIROCCO and CALIMA Phase III trials were presented at the aforementioned ERS Congress. The results confirmed benralizumab's efficacy and identified key predictive factors of those patients suffering from severe, uncontrolled asthma that would respond best to treatment with benralizumab. The results were published simultaneously in *The Lancet Respiratory Medicine*.

Benralizumab is under regulatory review in the US, EU, Japan and several other countries, with a US PDUFA date during the final quarter of 2017. Regulatory decisions are anticipated elsewhere during H1 2018.

#### e) Tralokinumab (severe, uncontrolled asthma)

On 1 November 2017, AstraZeneca announced the top-line results of the Phase III STRATOS 2 and TROPOS trials for tralokinumab, an anti-interleukin-13 human monoclonal antibody, in severe, uncontrolled asthma.

STRATOS 1 and 2 were Phase III multi-centre, randomised, double-blinded, parallel-group, placebo-controlled trials designed to evaluate the efficacy and safety of a regular, subcutaneous administration of tralokinumab for 52 weeks in adult and adolescent patients with severe, inadequately-controlled asthma, despite treatment with inhaled corticosteroids plus LABA.

In the STRATOS 2 trial, tralokinumab did not achieve a statistically-significant reduction in the annual asthma exacerbation rate, the primary endpoint, in patients with severe, uncontrolled asthma and elevated levels of a biomarker, Fractional exhaled Nitric Oxide, compared to placebo. In TROPOS, tralokinumab did not achieve a statistically-significant reduction in oral corticosteroid (OCS) use, the primary endpoint, when added to the standard of care, in patients dependent on OCS. Full data from STRATOS 1, STRATOS 2 and TROPOS will be presented at a forthcoming medical meeting.

#### f) Tezepelumab (asthma)

At the aforementioned ERS Congress, AstraZeneca and Amgen Inc. presented results from the PATHWAY Phase IIb trial of tezepelumab, a first-in-class treatment that blocks thymic stromal lymphopoietin (TSLP), an upstream driver of inflammation in asthma. The trial met its primary efficacy endpoint and the data demonstrated significant and clinically-meaningful annual asthma exacerbation-rate reductions of 61%, 71% and 66% in the tezepelumab arms receiving either 70mg or 210mg every four weeks or 280mg every two weeks, respectively, independent of baseline blood eosinophil count or other type-2 inflammatory biomarkers. Tezepelumab also demonstrated improvements in lung function at all doses and in asthma control at the two higher doses. The trial results were simultaneously published in the *New England Journal of Medicine*.

#### **OTHER**

#### a) Tezepelumab (atopic dermatitis)

During the period, the ALLEVIAD Phase IIa trial data showed that tezepelumab did not meet statistical significance on the primary endpoint (EASI 50) of the 12-week exploratory trial that evaluated tezepelumab in moderate to severe atopic dermatitis (AD) as add-on treatment to regular medium-to-high strength topical glucocorticosteroids. Numeric differences in favour of tezepelumab, however, were observed across a number of disease activity endpoints (EASI, IGA and SCORAD response) compared to placebo.

#### b) Anifrolumab (lupus)

During the period, the Company completed the enrolment of the second Phase III trial (TULIP 2) of anifrolumab



in patients with moderate-to-severe systemic lupus erythematosus (SLE, or lupus). Data readouts from both the TULIP 1 and TULIP 2 trials are expected in H2 2018, with anticipated regulatory submissions in 2019.

In addition, the Company also completed enrolment during the period of the Phase II SLE trial of a sub-cutaneous route of administration of anifrolumab.

#### c) Lanabecestat (Alzheimer's disease)

During the period, the Company and Lilly completed enrolment of the Phase II/III AMARANTH trial investigating the safety and efficacy of lanabecestat compared with placebo in the treatment of early Alzheimer's disease. A data readout from the lanabecestat clinical programme is anticipated in 2019.

#### **Development Pipeline 30 September 2017**

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#### 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.

Compound	Mechanism	Area Under	Date Commenced	Estimated Regulatory Acceptance Dat Submission Status			e Date /
<u> </u>		Investigation	Phase	US	EU	Japan	China
Oncology	1	T				T T	
Calquence <sup>#</sup> (acalabrutinib)	BTK inhibitor	B-cell malignancy	Q1 2015	Approved			
Calquence# (acalabrutinib)	BTK inhibitor	1st-line chronic lymphocytic leukaemia	Q3 2015	2020 (Orphan Drug Designation)	2020 (Orphan designation)		
Calquence# (acalabrutinib)	BTK inhibitor	relapsed/refract ory chronic lymphocytic leukaemia, high risk	Q4 2015	2020 (Orphan Drug Designation)	2020 (Orphan designation)		
Calquence <sup>#</sup> (acalabrutinib)	BTK inhibitor	1st-line mantle cell lymphoma	Q1 2017	2023			
savolitinib <sup>#</sup> SAVOIR	MET inhibitor	papillary renal cell carcinoma	Q3 2017	2020	2020		
selumetinib ASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	H2 2018 (Orphan Drug Designation)	H2 2018		
moxetumomab pasudotox <sup>#</sup> PLAIT	anti-CD22 recombinant immunotoxin	hairy cell leukaemia	Q2 2013	H1 2018 (Orphan Drug Designation)			
Imfinzi# + tremelimumab ARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	H1 2018	H1 2018	H1 2018	
<i>lmfinzi</i> # + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	H2 2018	H2 2018	H2 2018	
<i>lmfinzi</i> # + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019	2020
<i>lmfinz</i> # PACIFIC	PD-L1 mAb	locally-advanced (Stage III), NSCLC	Q2 2014	Accepted (Breakthrough Therapy Designation & Priority Review)	Accepted	Accepted	
Imfinzi# + tremelimumab + chemotherapy POSEIDON	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q2 2017	2019	2019	2019	2020
<i>lmfinzi</i> # + tremelimumab + SoC CASPIAN	PD-L1 mAb + CTLA-4 mAb + SoC	1st-line small cell lung cancer	Q1 2017	2020	2020	2020	
<i>lmfinzi</i> # + tremelimumab KESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	H2 2018	H2 2018	H2 2018	

Compound	Mechanism	Area Under	Date Commenced	Estimated Regulatory Acceptance D Submission Status			e Date /
		Investigation	Phase	US	EU	Japan	China
Imfinzi#+ tremelimumab EAGLE	PD-L1 mAb + CTLA-4 mAb	2nd-line HNSCC	Q4 2015	H2 2018	H2 2018	H2 2018	
Imfinzi# + tremelimumab DANUBE	PD-L1 mAb + CTLA-4 mAb	1st-line bladder cancer	Q4 2015	2019	2019	2019	
Lynparza#¶+ cediranib CONCERTO	PARP inhibitor + VEGF inhibitor	recurrent platinum- resistant ovarian cancer	Q1 2017	2019			
CVMD							
Epanova	omega-3 carboxylic acids	severe hypertriglycerid- aemia		Approved		2020	
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		-	Accepted <sup>1</sup>	2019	
roxadustat# OLYMPUS (US) ROCKIES (US)	hypoxia- inducible factor prolyl hydroxylase inhibitor	anaemia in CKD / end-stage renal disease	Q3 2014	H2 2018			Accepted <sup>2</sup>
Respiratory							
Bevespi Aerosphere (PT003)	LABA/LAMA	COPD		Launched	Accepted	H2 2018	H2 2018
benralizumab# CALIMA SIROCCO ZONDA BISE BORA GREGALE	IL-5R mAb	severe, uncontrolled asthma		Accepted	Accepted	Accepted	2021
benralizumab# TERRANOVA GALATHEA	IL-5R mAb	COPD	Q3 2014	H2 2018	H2 2018	2019	
PT010	LABA/LAMA/ ICS	COPD	Q3 2015	2019	2019	H2 2018	H2 2018
tralokinumab STRATOS 1,2 TROPOS MESOS	IL-13 mAb	severe, uncontrolled asthma	Q3 2014	-	-	-	
Other							
anifrolumab# TULIP	IFN-alphaR mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast Track)	2019	2019	
lanabecestat# AMARANTH + extension, DAYBREAK- ALZ	beta- secretase inhibitor	Alzheimer's disease	Q2 2016	2020 (Fast Track)	2020	2020	

- Registrational Phase II trial Collaboration CHMP positive opinion received Fibrogen completed rolling regulatory submission in China ¶ # 1 2

### Phases I and II

## NMEs and significant additional indications

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
Oncology				
Imfinzi#	PD-L1 mAb	solid tumours	<u>II</u>	Q3 2014
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	HCC	<u>II</u>	Q4 2016
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	<u>                                     </u>	Q2 2015
Imfinzi# + AZD5069	PD-L1 mAb + CXCR2 antagonist	pancreatic ductal adenocarcinoma	II	Q2 2017
Imfinzi# + AZD5069 or Imfinzi# + AZD9150#	PD-L1 mAb + CXCR2 antagonist or PD-L1 mAb + STAT3 inhibitor	HNSCC	II	Q3 2015
<i>Imfinzi</i> <sup>#</sup> + dabrafenib + trametinib	PD-L1 mAb + BRAF inhibitor + MEK inhibitor	melanoma	I	Q1 2014
Imfinzi# + AZD1775#	PD-L1 mAb + Wee1 inhibitor	solid tumours	1	Q4 2015
Imfinzi# + MEDI0680	PD-L1 mAb + PD-1 mAb	solid tumours	II	Q3 2016
Imfinzi# or Imfinzi# + (tremelimumab or AZD9150#)	PD-L1 mAb or PD-L1 mAb + (CTLA-4 mAb or STAT3 inhibitor)	diffuse large B-cell lymphoma	I	Q3 2016
Imfinzi# + Iressa	PD-L1 mAb + EGFR inhibitor	NSCLC	1	Q2 2014
Imfinzi# + MEDI0562#	PD-L1 mAb + humanised OX40 agonist	solid tumours	I	Q2 2016
Imfinzi#+ MEDI9197#	PD-L1 mAb + TLR 7/8 agonist	solid tumours	I	Q2 2017
<i>lmfinzi</i> <sup>#</sup> + MEDI9447	PD-L1 mAb + CD73 mAb	solid tumours	I	Q1 2016
<i>lmfinzi</i> <sup>#</sup> + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	I	Q1 2016
Imfinzi# + selumetinib	PD-L1 mAb + MEK inhibitor	solid tumours	I	Q4 2015
Imfinzi# + 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
Imfinzi# + azacitidine	PD-L1 mAb + azacitidine	myelodysplastic syndrome	I	Q2 2016
Imfinzi# + MEDI0457#	PD-L1 mAb + DNA HPV vaccine	HNSCC	I	Q3 2017
Lynparza# + AZD6738	PARP inhibitor + ATR inhibitor	gastric cancer	II	Q3 2016
Lynparza# + AZD1775#	PARP inhibitor + Wee1 inhibitor	solid tumours	I	Q3 2015
<i>Lynparza</i> <sup>#</sup> + <i>Imfinzi</i> MEDIOLA	PARP inhibitor + PD-L1 mAb	solid tumours	II	Q2 2016
Tagrisso + (selumetinib# or savolitinib#) TATTON	EGFR inhibitor + (MEK inhibitor or MET inhibitor)	advanced EGFRm NSCLC	II	Q2 2016
Tagrisso BLOOM	EGFR inhibitor	CNS metastases in advanced EGFRm NSCLC	II	Q4 2015
AZD1775# + chemotherapy	Wee1 inhibitor + chemotherapy	ovarian cancer	II	Q4 2012
AZD1775#	Wee1 inhibitor	solid tumours	II	Q1 2016
vistusertib	mTOR inhibitor	solid tumours	II	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	I	Q4 2015
AZD4635	A2aR inhibitor	solid tumours		Q2 2016
AZD4785	KRAS inhibitor	solid tumours	 I	Q2 2017
AZD6738	ATR inhibitor	solid tumours	I	Q4 2013
AZD8186	PI3k inhibitor	solid tumours	 I	Q2 2013

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
AZD9496	selective oestrogen receptor degrader	oestrogen receptor +ve breast cancer	I	Q4 2014
MEDI-565#	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0562#	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI0680	PD-1 mAb	solid tumours	I	Q4 2013
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3726#	PSMA antibody drug conjugate	prostate cancer	I	Q1 2017
MEDI4276	HER2 bi-specific antibody drug conjugate	solid tumours	I	Q4 2015
MEDI5083	immune activator	solid tumours	I	Q1 2017
MEDI7247	antibody drug conjugate	haematological malignancies	I	Q2 2017
MEDI9197#	TLR 7/8 agonist	solid tumours	ı	Q4 2015
MEDI9447	CD73 mAb	solid tumours	I	Q3 2015
CVMD				
CVMD	LIDAT1 inhibitor	СКД	11	Q2 2017
verinurad MEDI0382	URAT1 inhibitor GLP-1 /	type-2 diabetes / obesity	II II	Q2 2017 Q3 2016
	glucagon dual agonist	,,		
MEDI6012	LCAT	CV disease	II ·	Q4 2015
AZD4831	myeloperoxidase	HF with a preserved ejection fraction	I	Q3 2016
AZD5718	FLAP	coronary artery disease	I	Q1 2016
AZD8601#	VEGF-A	CV disease	I	Q1 2017
MEDI5884#	cholesterol modulation	CV disease	I	Q1 2017
Respiratory				
abediterol#	LABA	asthma / COPD	II	Q4 2007
tezepelumab#	TSLP mAb	asthma / atopic dermatitis	II	Q2 2014
AZD1419#	inhaled TLR9 agonist	asthma	II	Q4 2016
AZD7594	inhaled SGRM	asthma / COPD	II	Q3 2015
AZD8871#	MABA	COPD	ll	Q1 2017
PT010	LABA/LAMA/ICS	asthma	ll .	Q2 2014
AZD5634	inhaled ENaC	cystic fibrosis	<u> </u>	Q1 2016
AZD7594 + abediterol#	inhaled SGRM + LABA	asthma / COPD	!	Q4 2016
AZD7986# AZD9567	DPP1 oral SGRM	COPD rheumatoid arthritis /	I	Q4 2014 Q4 2015
		respiratory	_	
AZD9898#	LTC4S	asthma	<u> </u>	Q2 2017
MEDI3506	IL-33 mAb	COPD	<u> </u>	Q2 2017
Other	LEN LL D AL	II I w		04.0045
anifrolumab#	IFN-alphaR mAb	lupus nephritis	II 	Q4 2015
anifrolumab#	IFN-alphaR mAb	systemic lupus erythematosus (subcutaneous)	II II	Q1 2017
inebilizumab#	CD19 mAb	neuromyelitis optica	 (Orphan drug US, EU)	Q1 2015
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	US, EU)	Q1 2010
MEDI3902	Psl/PcrV bispecific mAb	prevention of nosocomial  Pseudomonas aeruginosa pneumonia	II (Fast Track, US)	Q2 2016
MEDI4893	mAb binding to S. aureus toxin	prevention of nosocomial Staphylococcus aureus pneumonia	II (Fast Track, US)	Q4 2014
MEDI5872#	B7RP1 mAb	primary Sjögren's syndrome	II	Q3 2015
MEDI8852	influenza A mAb	influenza A treatment	I  (Fast Track, US)	Q4 2015

Compound	Mechanism	Area Under Investigation	Phase	Date Commenced Phase
MEDI8897#	RSV mAb-YTE	passive RSV prophylaxis	 (Fast Track, US)	Q1 2015
AZD0284	RORg	psoriasis / respiratory	I	Q4 2016
MEDI0700#	BAFF/B7RP1 bispecific mAb	systemic lupus erythematosus	I	Q1 2016
MEDI1814 <sup>#</sup>	amyloid beta mAb	Alzheimer's disease	I	Q2 2014
MEDI4920	anti-CD40L-Tn3 fusion protein	primary Sjögren's syndrome	I	Q2 2014
MEDI7352	NGF/TNF bi-specific mAb	osteoarthritis pain	I	Q1 2016
MEDI7734	ILT7 mAb	myositis	I	Q3 2016
MEDI9314	IL-4R mAb	atopic dermatitis	Ī	Q1 2016

<sup>#</sup> Collaboration

# **Significant Lifecycle Management**

Compound	Mechanism	Area Under	Date Commenced	Estimated Regulatory Acceptan Submission Status			ce Date /
·		Investigation	Phase	US	EU	Japan	China
Oncology							
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer		Approved	Approved	Approved	H2 2017
Imfinzi <sup>#</sup> PEARL (China)	PD-L1 mAb	1st-line NSCLC	Q1 2017				2020
<i>Lynparza</i> # OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2014	Accepted (Priority Review)	H1 2018	Accepted (Orphan drug designation, Priority Review)	H2 2018
<i>Lynparza</i> <sup>#</sup> SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2013	Approved (Priority Review)	Accepted	Accepted (Orphan drug designation)	H1 2018
<i>Lynparza</i> # SOLO-1	PARP inhibitor	1st-line BRCAm ovarian cancer	Q3 2013	H2 2018	H2 2018	H2 2018	2019
<i>Lynparza</i> # SOLO-3	PARP inhibitor	gBRCA PSR ovarian cancer	Q1 2015	H2 2018			
<i>Lynparza</i> # POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2019	2019		
<i>Lynparza</i> # PROfound	PARP inhibitor	prostate cancer	Q1 2017	2020 (Breakthrough Therapy Designation)	2020	2020	2020
<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 (Breakthrough Therapy designation)	H2 2017	H2 2017	2018
<i>Tagrisso</i> ADAURA	EGFR inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
CVMD	•						
Brilinta <sup>1</sup> THEMIS	P2Y12 receptor antagonist	CV outcomes trial in patients with type-2 diabetes and coronary artery disease without a previous history of MI or stroke	Q1 2014	2019	2019	2019	2020

Compound	Mechanism	Area Under	Date Commenced	Estimated	Regulatory Submissio		ce Date /
·		Investigation	Phase	US	EU	Japan	China
Brilinta <sup>1</sup> HESTIA	P2Y12 receptor antagonist	prevention of vaso- occlusive crises in paediatric patients with sickle cell disease	Q1 2014	2021	2021	·	
Kombiglyze XR/Komboglyze <sup>2</sup>	DPP-4 inhibitor / metformin FDC	type-2 diabetes		Launched	Launched		Launched
Farxiga <sup>3</sup> DECLARE- TIMI 58	SGLT2 inhibitor	CV outcomes trial in patients with type-2 diabetes	Q2 2013	2019	2019		
Farxiga <sup>3</sup>	SGLT2 inhibitor	type-1 diabetes	Q4 2014	H2 2018	H1 2018	H2 2018	
Farxiga <sup>3</sup>	SGLT2 inhibitor	worsening HF or CV death in patients with chronic HF	Q1 2017	2020	2020	2020	2020
Farxiga <sup>3</sup>	SGLT2 inhibitor	renal outcomes and CV mortality in patients with CKD	Q1 2017	2021	2021	N/A	2021
Xigduo XR/ Xigduo⁴	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		2020
Qtern	DPP-4 inhibitor / SGLT2 inhibitor FDC	type-2 diabetes		Approved	Launched		
Bydureon BCise (autoinjector)	GLP-1 receptor agonist	type-2 diabetes	Q1 2013	Approved	Accepted		
Bydureon EXSCEL	GLP-1 receptor agonist	type-2 diabetes outcomes trial	Q2 2010	H2 2017	H2 2017		H2 2018
saxagliptin/ dapagliflozin/ metformin	DPP-4 inhibitor / SGLT2 inhibitor	type-2 diabetes	Q2 2017	H1 2018	H1 2018		
Epanova STRENGTH	omega-3 carboxylic acids	CV outcomes trial in statin-treated patients at high CV risk, with persistent hypertriglyceridae- mia 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
Duaklir Genuair#	LAMA/LABA	COPD		H1 2018	Launched		2019
Other							
Nexium	proton-pump inhibitor	stress ulcer prophylaxis					Accepted
Nexium	proton-pump inhibitor	paediatrics		Launched	Launched	Accepted	
linaclotide# # Collaboration	GC-C receptor peptide agonist	irritable bowel syndrome with constipation (IBS-C)					Accepted

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 1 2 3 4

Terminations (discontinued projects: 1 July 2017 to 30 September 2017)

NME / Line Extension	Compound	Reason for Discontinuation	Area Under Investigation	
NME	MEDI8111	strategic	trauma / bleeding	

Completed Projects/Divestitures (1 July 2017 to 30 September 2017)

Compound	Mechanism	Area Under	Completed/	Estimated Regulatory Subm		ubmission A	Acceptance
Compound	Wechanism	Investigation	Divested	US	EU	Japan	China
AZD9150	STAT3 inhibitor	haematological malignancies	Completed	-	-	-	-

<sup>#</sup> Collaboration

# **Condensed Consolidated Statement of Comprehensive Income**

For the <b>nine months</b> ended 30 September	2017 \$m	2016 \$m
Product sales	14,665	16,059
Externalisation revenue	2,023	1,358
Total revenue	16,688	17,417
Cost of sales	(3,093)	(2,966)
Gross profit	13,595	14,451
Distribution costs	(225)	(243)
Research and development expense	(4,206)	(4,347)
Selling, general and administrative costs	(7,155)	(8,027)
Other operating income and expense	982	535
Operating profit	2,991	2,369
Finance income	71	44
Finance expense	(1,199)	(1,022)
Share of after tax losses in associates and joint ventures	(43)	(22)
Profit before tax	1,820	1,369
Taxation	(213)	220
Profit for the period	1,607	1,589
Other comprehensive income/(loss)		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(146)	(1,127)
Tax on items that will not be reclassified to profit or loss	23	256
	(123)	(871)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	531	(690)
Foreign exchange arising on designating borrowings in net investment hedges	622	(194)
Fair value movements on cash flow hedges	226	(26)
Fair value movements on cash flow hedges transferred to profit or loss	(281)	41
Fair value movements on derivatives designated in net investment hedges	(39)	(96)
Amortisation of loss on cash flow hedge	1	1
Net available for sale (losses)/gains taken to equity	(36)	126
Tax on items that may be reclassified subsequently to profit or loss	(125)	63
	899	(775)
Other comprehensive income/(loss) for the period, net of tax	776	(1,646)
Total comprehensive income/(loss) for the period	2,383	(57)
Profit attributable to:		
Owners of the Parent	1,700	1,657
Non-controlling interests	(93)	(68)
Non-controlling interests	1,607	1,589
		1,000
Total comprehensive income/(loss) attributable to:		
Owners of the Parent	2,476	12
Non-controlling interests	(93)	(69)
	2,383	(57)
Basic earnings per \$0.25 Ordinary Share	\$1.34	\$1.31
Diluted earnings per \$0.25 Ordinary Share	\$1.34	\$1.31
Weighted average number of Ordinary Shares in issue (millions)	1,266	1,265
Diluted weighted average number of Ordinary Shares in issue (millions)	1,266	1,266

# **Condensed Consolidated Statement of Comprehensive Income**

For the <b>quarter</b> ended 30 September	2017 \$m	2016 \$m
Product sales	4,882	5,025
Externalisation revenue	1,350	674
Total revenue	6,232	5,699
Cost of sales	(1,249)	(900)
Gross profit	4,983	4,799
Distribution costs	(76)	(76)
Research and development expense	(1,404)	(1,402)
Selling, general and administrative costs	(2,497)	(2,403)
Other operating income and expense	143	110
Operating profit	1,149	1,028
Finance income	32	13
Finance expense	(418)	(355)
Share of after tax losses in associates and joint ventures	(17)	(10)
Profit before tax	746	676
Taxation	(97)	319
Profit for the period	649	995
Other comprehensive income/(loss)		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	125	(285)
Tax on items that will not be reclassified to profit or loss	(48)	21
	77	(264)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	154	(167)
Foreign exchange arising on designating borrowings in net investment hedges	239	(127)
Fair value movements on cash flow hedges	99	` 77 <sup>°</sup>
Fair value movements on cash flow hedges transferred to profit or loss	(81)	(19)
Fair value movements on derivatives designated in net investment hedges	(4)	(17)
Net available for sale gains taken to equity	58	162 <sup>°</sup>
Tax on items that may be reclassified subsequently to profit or loss	(55)	(12)
	410	(103)
Other comprehensive income/(loss) for the period, net of tax	487	(367)
Total comprehensive income for the period	1,136	628
Total completionate modific for the period	1,100	
Profit attributable to:		
Owners of the Parent	686	1,014
Non-controlling interests	(37)	(19)
	649	995
Total comprehensive income attributable to		
Total comprehensive income attributable to:  Owners of the Parent	1 170	640
	1,173	648
Non-controlling interests	(37)	(20)
	1,136	628
Basic earnings per \$0.25 Ordinary Share	\$0.54	\$0.80
Diluted earnings per \$0.25 Ordinary Share	\$0.54	\$0.80
Weighted average number of Ordinary Shares in issue (millions)	1,266	1,265
Diluted weighted average number of Ordinary Shares in issue (millions)	1,267	1,266
	.,20,	.,200

## **Condensed Consolidated Statement of Financial Position**

	At 30 Sep 2017 \$m	At 31 Dec 2016 \$m	Restated* At 30 Sep 2016 \$m
ASSETS			•
Non-current assets			
Property, plant and equipment	7,329	6,848	6,690
Goodwill	11,841	11,658	11,756
Intangible assets	27,124	27,586	28,507
Derivative financial instruments	440	343	278
Investments in associates and joint ventures	78	99	95
Other investments	1,004	727	715
Other receivables	953	901	681
Deferred tax assets	2,184	1,102	1,584
Current assets	50,953	49,264	50,306
Inventories	3,162	2,334	2 420
Assets held for sale	3,102	2,334	2,420
	4.540	4 572	332
Trade and other receivables	4,540 4 175	4,573	5,449
Other investments Derivative financial instruments	1,175	884 27	909 26
Income tax receivable	- 721	426	640
Cash and cash equivalents	4,036	5,018	3,090
Casil and casil equivalents	13,634	13,262	12,866
Total assets	64,587	62,526	63,172
100000			00,172
LIABILITIES			
Current liabilities			
Interest-bearing loans and borrowings	(941)	(2,307)	(2,939)
Trade and other payables	(10,832)	(10,486)	(9,961)
Derivative financial instruments	(10)	(18)	(12)
Provisions	(1,167)	(1,065)	(936)
Income tax payable	(1,513)	(1,380)	(1,534)
AL ALL LUIG	(14,463)	(15,256)	(15,382)
Non-current liabilities	(40.044)	(4.4.504)	(4.4.7.4.4)
Interest-bearing loans and borrowings Derivative financial instruments	(16,911)	(14,501)	(14,744)
	(3)	(117)	(25)
Deferred tax liabilities	(5,079)	(3,956)	(4,001)
Retirement benefit obligations	(2,490)	(2,186)	(2,870)
Provisions Other payables	(387)	(353)	(396)
Other payables	(9,807)	(9,488)	(10,842)
Total liabilities	(34,677)	(30,601)	(32,878)
Net assets	(49,140) 15,447	(45,857) 16,669	(48,260) 14,912
Net assets	15,447	10,009	14,912
EQUITY			
Capital and reserves attributable to equity holders of the			
Company			
Share capital	316	316	316
Share premium account	4,381	4,351	4,344
Other reserves	2,027	2,047	2,031
Retained earnings	7,001	8,140	6,381
	13,725	14,854	13,072
Non-controlling interests	1,722	1,815	1,840
Total equity	15,447	16,669	14,912

<sup>\*30</sup> September comparatives have been restated to reflect an adjustment to the acquisition-accounting for Acerta Pharma (as detailed in Note 4 of the Full Year and Fourth Quarter 2016 Results Announcement).

# **Condensed Consolidated Statement of Cash Flows**

For the <b>nine months</b> ended 30 September	2017 \$m	2016 \$m
Cash flows from operating activities		
Profit before tax	1,820	1,369
Finance income and expense	1,128	978
Share of after tax losses in associates and joint ventures	43	22
Depreciation, amortisation and impairment	1,929	1,767
Increase in working capital and short-term provisions	(228)	(472)
Gains on disposal of intangible assets	(735)	(198)
Fair value movements on contingent consideration arising from business combinations	(62)	132
Non-cash and other movements	(322)	(479)
Cash generated from operations	3,573	3,119
Interest paid	(519)	(489)
Tax paid	(473)	(445)
Net cash inflow from operating activities	2,581	2,185
Cash flows from investing activities		
Movement in short-term investments and fixed deposits	(288)	(165)
Purchase of property, plant and equipment	(849)	(912)
Disposal of property, plant and equipment	57	47
Purchase of intangible assets	(220)	(761)
Disposal of intangible assets	894	117
Purchase of non-current asset investments	(91)	(210)
Disposal of non-current asset investments	14	-
Payments to joint ventures	(11)	(19)
Upfront payments on business combinations	-	(2,564)
Payment of contingent consideration from business combinations	(310)	(197)
Interest received	118	105
Payments made by subsidiaries to non-controlling interests	-	(13)
Net cash outflow from investing activities	(686)	(4,572)
Net cash inflow/(outflow) before financing activities	1,895	(2,387)
Cash flows from financing activities		
Proceeds from issue of share capital	30	40
Issue of loans	1,988	2,483
Repayment of loans	(1,750)	-
Dividends paid	(3,519)	(3,561)
Hedge contracts relating to dividend payments	(20)	18
Repayment of obligations under finance leases	(14)	(12)
Movement in short-term borrowings	361	12
Net cash outflow from financing activities	(2,924)	(1,020)
Net decrease in cash and cash equivalents in the period	(1,029)	(3,407
Cash and cash equivalents at the beginning of the period	4,924	6,051
Exchange rate effects	(71)	43
Cash and cash equivalents at the end of the period	3,824	2,687
Cash and cash equivalents consists of:		,
Cash and cash equivalents	4,036	3,090
Overdrafts	(212)	(403)
	3,824	2,687

What science can do

**Condensed Consolidated Statement of Changes in Equity** 

	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings	Total	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2016	316	4,304	2,036	11,834	18,490	19	18,509
Profit for the period	-	-	-	1,657	1,657	(68)	1,589
Other comprehensive income	-	-	-	(1,645)	(1,645)	(1)	(1,646)
Transfer to other reserves	-	-	(5)	5	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,540)	(3,540)	-	(3,540)
Dividends 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
Issue of Ordinary Shares	-	40	-	-	40	-	40
Share-based payments				(105)	(105)		(105)
Net movement	-	40	(5)	(5,453)	(5,418)	1,821	(3,597)
At 30 Sep 2016	316	4,344	2,031	6,381	13,072	1,840	14,912
	Share capital \$m	Share premium account \$m	Other reserves* \$m	Retained earnings \$m	Total \$m	Non- controlling interests \$m	Total equity \$m
At 1 Jan 2017	316	4,351	2,047	8,140	14,854	1,815	16,669
Profit for the period	-	-	-	1,700	1,700	(93)	1,607
Other comprehensive income	-	-	-	776	776	-	776
Transfer to other reserves	-	-	(20)	20	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,543)	(3,543)	-	(3,543)
Issue of Ordinary Shares	-	30	-	-	30	-	30
Share-based payments				(92)	(92)		(92)
Net movement		30	(20)	(1,139)	(1,129)	(93)	(1,222)
At 30 Sep 2017	316	4,381	2,027	7,001	13,725	1,722	15,447

<sup>\*</sup> Other reserves include the capital redemption reserve and the merger reserve.

What science can do

### Notes to the Interim Financial Statements

#### 1 BASIS OF PREPARATION AND ACCOUNTING POLICIES

These unaudited condensed consolidated interim financial statements (interim financial statements) for the nine months ended 30 September 2017 have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the European Union (EU) and as issued by the International Accounting Standards Board (IASB).

The annual financial statements of the Group are prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the EU and as issued by the IASB. The interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2016. There have been no significant new or revised accounting standards applied in the nine months ended 30 September 2017.

We have revised the balance sheet presentation of deferred tax with effect from 1 January 2017 with no impact upon net deferred tax, balance sheet net assets, the cash flow statement or the income statement. This presentation change has resulted in us showing gross, rather than net, deferred tax assets and deferred tax liabilities of a group entity. This change has been made as that entity has transactions that are subject to tax by two different taxation authorities and has the effect of separately disclosing the deferred tax effects for each country. The comparative balance sheet has not been revised for this presentational change. If the 31 December 2016 and 30 September 2016 balances were presented in a comparable way the deferred tax assets would have been \$2,093m and \$2,234m, respectively. The deferred tax liabilities would have been \$4,947m and \$4,701m, respectively.

As disclosed in our 2016 Annual Report on Page 181, the Group has entered into a number of financial derivative transactions with commercial banks. The Group has agreements with some bank counterparties whereby the parties agree to post cash collateral, for the benefit of the other, equivalent to the market valuation of the derivative positions above a predetermined threshold. We have revised the balance sheet presentation of these collateral balances with effect from 1 January 2017, so that the cash collateral is included in cash and cash equivalents, with an offsetting liability presented in current interest-bearing loans and borrowings. This revision has no impact on our balance sheet net assets, or the income statement. The comparative balance sheet has not been revised for this presentational change. If the 31 December 2016 and 30 September 2016 balances were presented in a comparable way the cash and cash equivalents balance would have been \$5,260m and \$3,345m, respectively. Current interest-bearing loans and borrowings would have been \$2,549m and \$3,194m, respectively.

#### Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2016 and interim financial statements for the six months ended 30 June 2017.

### Going concern

The Group has considerable financial resources available. As at 30 September 2017 the Group has \$6.1bn in financial resources (cash balances of \$4bn and undrawn committed bank facilities of \$3bn which are available until April 2022, with only \$0.9bn 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, the going concern basis has been adopted in these interim financial statements.

#### Financial information

This results announcement does not constitute statutory accounts of the Group within the meaning of sections 434(3) and 435(3) of the Companies Act 2006. The Group's accounts for 2016 were published in the Annual Report 2016, which has been delivered to the registrar of companies. The report of the auditors, KPMG LLP, was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.



#### **2 RESTRUCTURING COSTS**

Profit before tax for the nine months ended 30 September 2017 is stated after charging restructuring costs of \$645m (\$250m for the YTD ended 30 September 2016). These have been charged to profit as follows:

	YTD 2017 \$m	YTD 2016 \$m	Q3 2017 \$m	Q3 2016 \$m
Cost of sales	128	87	47	59
Research and development expense	177	146	35	39
Selling, general and administrative costs	265	504	68	176
Other operating income and expense	75	(24)	(1)	(24)
Total	645	713	149	250

#### 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.

The Group monitors net debt as part of its capital management policy as described in Note 26 of the Annual Report and Form 20-F Information 2016.

	At 1 Jan 2017 \$m	Cash Flow \$m	Non-cash & Other \$m	Exchange Movements \$m	At 30 Sep 2017 \$m
Loans due after one year	(14,495)	(1,988)	(7)	(420)	(16,910)
Finance leases due after one year	(6)	-	5	-	(1)
Total long-term debt	(14,501)	(1,988)	(2)	(420)	(16,911)
Current instalments of loans	(1,769)	1,750	19	-	-
Current instalments of finance leases	(87)	14	63	(1)	(11)
Total current debt	(1,856)	1,764	82	(1)	(11)
Other investments - current	884	288	-	3	1,175
Other investments - non- current	14	66	-	-	80
Net derivative financial instruments	235	20	172	-	427
Cash and cash equivalents	5,018	(913)	-	(69)	4,036
Overdrafts	(94)	(116)	-	(2)	(212)
Short-term borrowings	(357)	(361)	-	-	(718)
	5,700	(1,016)	172	(68)	4,788
Net debt	(10,657)	(1,240)	252	(489)	(12,134)

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



#### **4 FINANCIAL INSTRUMENTS**

As detailed in the Group's most recent annual financial statements, our principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, and interest-bearing loans and borrowings. The accounting policies for financial instruments, including fair value measurement, can be found on pages 144 and 145 of the Company's Annual Report and Form 20-F Information 2016. There have been no significant new or revised accounting standards applied in the nine months ended 30 September 2017 and there have been no changes of significance to the categorisation or fair value hierarchy classification of our financial instruments. During the year, we revised the balance sheet presentation of cash collateral balances held with commercial bank counterparties, effective from 1 January 2017 (see Note 1).

Financial instruments measured at fair value include \$1,175m of other investments, \$2,007m of loans, and \$427m of derivatives as at 30 September 2017. The total fair value of interest-bearing loans and borrowings at 30 September 2017 which have a carrying value of \$17,852m in the Condensed Consolidated Statement of Financial Position, was \$17,242m. 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	Total
	2017 \$m	2017 \$m	2017 \$m	2016 \$m
At 1 January	4,240	1,217	5,457	6,411
Settlements	(235)	(75)	(310)	(197)
Revaluations	(71)	9	(62)	132
Discount unwind	234	71	305	372
Foreign exchange	-	-	-	2
At 30 September	4,168	1,222	5,390	6,720

What science can do

### 5 LEGAL PROCEEDINGS AND CONTINGENT LIABILITIES

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2016, the interim financial statements for the three months ended 31 March 2017 and the interim financial statements for the three months ended 30 June 2017 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

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

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

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

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

Matters disclosed in respect of the third quarter of 2017 and to 9 November 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 relating to patents listed in the FDA Orange Book with reference to *Faslodex* after AstraZeneca received notice of Abbreviated New Drug Applications (ANDA) seeking FDA approval to market generic versions of *Faslodex* prior to the expiration of AstraZeneca's patents. As previously disclosed, AstraZeneca has resolved the lawsuits with several of the ANDA filers. In October 2017, AstraZeneca resolved the lawsuit with an eighth ANDA filer.

In October 2017, AstraZeneca received a Paragraph IV notice regarding a New Drug Application submitted pursuant to 21 U.S.C. § 355(b)(2) by Fresenius Kabi USA LLC relating to the same FDA Orange Book-listed patents.

As previously disclosed, in February 2017, AstraZeneca was served with three petitions for *inter partes* review by the Patent Trial and Appeal Board (PTAB) of the US Patent and Trademark Office relating to FDA Orange Book-listed patents with reference to *Faslodex*. In September 2017, the PTAB denied institution of all three petitions, and no appeals have been made to date.

#### *Imfinzi* (durvalumab)

US patent proceedings

In July 2017, Bristol-Myers Squibb, E.R. Squibb & Sons L.L.C., Ono Pharmaceutical Co. and Tasuku Honjo filed a patent infringement action in the US District Court in Delaware relating to AstraZeneca's commercialisation of *Imfinzi* in the US. AstraZeneca filed an answer to the complaint in October 2017 alleging, *inter alia*, that the asserted patent is invalid and not infringed. The litigation is ongoing.

#### Calquence (acalabrutinib)

US patent proceedings

In November 2017, Pharmacyclics LLC filed a complaint in the US District Court for the District of Delaware against Acerta Pharma BV, Acerta Pharma LLC, and AstraZeneca Pharmaceuticals LP (collectively, AstraZeneca) alleging that AstraZeneca's *Calquence* infringes certain claims of US Patent Nos. 9,079,908; 9,139,591; and 9,556,182. AstraZeneca will respond to the complaint in due course.

#### Brilinta (ticagrelor)

Patent proceedings outside the US

In Canada, in June 2017, Teva Canada Limited challenged the patents listed on the Canadian Patent Register with reference to *Brilinta*. In September 2017, Apotex Inc. did the same. AstraZeneca has commenced applications to respond to the challenges.



In China, in October 2017, the Chinese Patent Office issued a decision invalidating one of AstraZeneca's Chinese substance patents relating to *Brilinta*. The patent, Chinese Patent No. ZL99815926.3, is due to expire in December 2019. AstraZeneca will appeal the decision.

#### Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

US patent proceedings

As previously disclosed, in 2016, the US Patent and Trademark Office (USPTO) instituted an *inter partes* review brought by several generic entities challenging the validity of US Patent No. RE44,186 (the '186 Patent), which is listed in the FDA Orange Book with reference to *Onglyza* and *Kombiglyze* XR. In August 2017, the USPTO decided in AstraZeneca's favour and upheld the challenged claims of the '186 Patent. In October 2017, the USPTO's decision was appealed.

#### 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 Court) found that Apotex had infringed AstraZeneca's *Losec* formulation patent (Canadian Patent No. 1,292,693). This finding was upheld on appeal. In July 2017, after a reference to account for Apotex' profits earned as a result of the infringement, the Court issued its decision describing how the quantification of monies owed to AstraZeneca should proceed. Apotex has appealed.

#### **Product liability litigation**

#### Onglyza (saxagliptin) and Kombiglyze (saxagliptin and metformin)

As previously disclosed, AstraZeneca is defending claims in the US brought by plaintiffs alleging heart failure, cardiac failure and/or death from treatment with *Onglyza* and/or *Kombiglyze*. In October 2017, counsel for a group of such plaintiffs filed a motion with the Judicial Panel on Multidistrict Litigation seeking the transfer of any currently pending federal court cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation proceeding.

#### Nexium (esomeprazole magnesium) and Losec/Prilosec (omeprazole)

As previously disclosed, in the US, AstraZeneca is defending various lawsuits involving multiple plaintiffs claiming that they have been diagnosed with kidney injuries following treatment with proton pump inhibitors (PPIs), including *Nexium* and *Prilosec* and, in May 2017, counsel for a group of such plaintiffs filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking the transfer of any currently pending federal court cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation (MDL) proceeding. In August 2017, the JPML granted the motion and consolidated the pending federal court cases in an MDL proceeding in federal court in New Jersey for pre-trial purposes.

In Canada, in July and August 2017, AstraZeneca was served with three putative class action lawsuits. Two of the lawsuits, pending in Ontario and Saskatchewan, seek authorisation to represent individuals resident in Canada who allegedly suffered kidney injuries from the use of proton pump inhibitors, including *Nexium* and *Losec*, and the third, pending in Quebec, seeks authorisation to represent such individuals resident in Quebec.

#### **Commercial litigation**

#### Anti-Terrorism Act Civil Lawsuit

In the US, in October 2017, AstraZeneca and certain other pharmaceutical and/or medical device companies were named as defendants in a complaint filed in federal court in the District of Columbia by US nationals (or their estates, survivors, or heirs) who were killed or wounded in Iraq between 2005 and 2009. The plaintiffs allege that the defendants violated the US Anti-Terrorism Act and various state laws by selling pharmaceuticals and medical supplies to the Iraqi Ministry of Health.

#### Government investigations/proceedings

#### Seroquel IR (quetiapine fumarate) and Seroquel XR (quetiapine fumarate)

Texas Attorney General litigation

As previously disclosed, in the US, in October 2014, following a previously disclosed investigation by the State of Texas (the State) into AstraZeneca's sales and marketing activities involving *Seroquel*, the Texas Attorney General's Office intervened in a State whistleblower action pending in Travis County Court, Texas (the County Court). The lawsuit alleges that AstraZeneca engaged in inappropriate promotion of *Seroquel* and made improper payments intended to influence the formulary status of *Seroquel*. The relief that the State seeks to recover from AstraZeneca includes trebled civil remedies, penalties, interest, and attorneys' fees pursuant to the Texas Medicaid Fraud Prevention Act) and damages pursuant to Texas common law. In June 2017, the Court entered an order denying all of the State's motions for summary judgment except for the State's motion on the defence of waiver, and denying AstraZeneca's motion for summary judgment.

The trial, which was scheduled for October 2017, has been postponed until after the Texas Supreme Court resolves the appeals in unrelated cases called *Nazari v. State* and *In re Xerox Corp.* A provision has been taken with regard to claims brought by the State and other related lawsuits.

#### Nexium (esomeprazole magnesium)

Federal Trade Commission inquiry
As previously disclosed, in the US, in 2008, AstraZeneca received a Civil Investigative Demand from the US Federal Trade Commission (FTC) in 2008 seeking information regarding the *Nexium* patent litigation settlement with Ranbaxy Laboratories Ltd. This investigation was officially closed by the FTC in October 2017.



6 PRODUCT ANALYSIS – YTD 2017
The table below provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth.

Oncology Tagrisso Iressa Lynparza Imfinzi Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	7TD 2017 \$m  651 398 197 1  703 548 161 160 85 2,904	Actual %  136 1 26 n/m  16 (6) (14) (9) 13	138 2 26 n/m 16 (5)	YTD 2017 \$m 85 200 11 -	Actual % n/m 7 n/m	n/m 8 n/m	YTD 2017 \$m 277 27	<b>Actual</b> % 54 69	YTD 2017 \$m 124 80	Actual % 153 (12)	157	YTD 2017 \$m	Actual %	CER %
Tagrisso Iressa Lynparza Imfinzi Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	651 398 197 1 703 548 161 160 85	136 1 26 n/m 16 (6) (14) (9)	138 2 26 n/m	85 200 11	n/m 7 n/m	n/m 8	277 27	54	124	153	157	165	n/m	n/m
Tagrisso Iressa Lynparza Imfinzi Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	398 197 1 703 548 161 160 85	1 26 n/m 16 (6) (14)	2 26 n/m	200 11 -	7 n/m	8	27							n/m
Iressa Lynparza Lynparza Imfinzi Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	398 197 1 703 548 161 160 85	1 26 n/m 16 (6) (14)	2 26 n/m	200 11 -	7 n/m	8	27							n/m
Lynparza Imfinzi Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	197 1 703 548 161 160 85	26 n/m 16 (6) (14) (9)	26 n/m	11 -	n/m			69	80	(12)	(40)	04		
Imfinzi Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	703 548 161 160 85	n/m 16 (6) (14) (9)	n/m 16	-		n/m					(12)	91	(10)	(9)
Legacy: Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	703 548 161 160 85	16 (6) (14) (9)	16	-	-		87	(9)	94	68	70	5	n/m	n/m
Faslodex Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	548 161 160 85	(6) (14) (9)		00		-	1	n/m	-	-	-	-	-	-
Zoladex Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	548 161 160 85	(6) (14) (9)		00										
Casodex Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	161 160 85	(14) (9)	(5)		26	23	368	15	194	15	16	53	10	13
Arimidex Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	160 85	(9)		260	9	10	16	(41)	104	(11)	(8)	168	(16)	(15)
Others Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	85		(12)	78	(5)	(1)	1	(50)	17	(11)	(11)	65	(23)	(21)
Total Oncology  CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:		13	(6)	85	2	6	5	(58)	26	(4)	(4)	44	(17)	(15)
CVMD Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:	2,904		16	21	5	10	-	-	4	-	-	60	18	20
Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:		18	19	828	20	22	782	20	643	21	23	651	12	14
Brilinta Farxiga Onglyza Bydureon Byetta Symlin Legacy:														
Farxiga Onglyza Bydureon Byetta Symlin Legacy:	780	29	31	175	29	32	355	46	213	11	13	37	16	13
Onglyza Bydureon Byetta Symlin Legacy:	742	24	24	160	74	72	339	4	171	26	27	72	76	76
Bydureon Byetta Symlin Legacy:	431	(25)	(25)	93	(15)	(16)	217	(29)	78	(24)	(23)	43	(22)	(22)
Byetta Symlin Legacy:	427	(2)	(2)	5	25	25	343	(2)	65	(13)	(12)	14	75	75
Symlin Legacy:	128	(36)	(35)	9	(53)	(53)	81	(36)	26	(30)	(27)	12	(25)	(25)
Legacy:	35	30	30	-	-	-	35	30		-	(=: )		(20)	-
	00	00	00					- 00						
Crestor	1,771	(36)	(35)	577	7	10	246	(78)	514	(22)	(21)	434	(2)	(1)
Seloken/Toprol-XL	527	(6)	(4)	437	9	12	34	(58)	48	(28)	(27)	8	(20)	(20)
Atacand	227	(3)	(1)	135	15	19	17	(39)	63	(15)	(15)	12	(20)	(20)
Others	259	(16)	(14)	157	(14)	(9)	2	n/m	69	(22)	(22)	31	(18)	(18)
Total CVMD	5,327	(16)	(14)	1,748	9	12	1,669	(36)	1,247	(13)	(12)	663	(10)	1
B														
Respiratory		(0)	(0)		_	_		(4=)	=00	(4.0)				_
Symbicort	2,051	(9)	(8)	322	7	8	811	(15)	590	(13)	(11)	328	6	5
Pulmicort	805	4	7	571	14	19	107	(22)	66	(10)	(10)	61	-	2
Daliresp/Daxas	145	28	28	4	n/m	n/m	124	23	16	60	60	1	-	-
Tudorza/Eklira	108	(19)	(18)	-	n/m	n/m	47	(23)	55	(15)	(14)	6	(14)	(14)
Duaklir	56	27	30	-	n/m	n/m	-	-	54	23	25	2	100	100
Bevespi	8	n/m	n/m	-	-	-	8	n/m	-	-	-	-	-	-
Others	199	(13)	(12)	68	(38)	(35)	1	(86)	98	21	22	32	(3)	(3) <b>4</b>
Total Respiratory	3,372	(5)	(3)	965	6	9	1,098	(13)	879	(8)	(6)	430	4	4
Other														
Nexium	1,525	(1)	-	516	(5)	(2)	442	6	176	(7)	(7)	391	1	2
Synagis	453	21	21	-	`-	`-	182	6	271	33	33	-	-	-
Losec/Prilosec	202	(7)	(5)	104	(1)	3	9	29	57	(10)	(10)	32	(24)	(24)
Seroquel XR	224	(64)	(64)	47	(11)	(11)	103	(77)	61	(42)	(42)	13	(7)	(7)
Movantik/Moventig	92	42	42	-	n/m	n/m	91	42	1	n/m	n/m	-	-	-
FluMist/Fluenz	20	(46)	(46)	-	n/m	n/m	-	(100)	18	(14)	(14)	2	-	-
Others	546	(40)	(39)	311	(22)	(23)	23	(77)						
Total Other	540	(-+0)		311	(22)	(23)	∠3	(//)	107	(56)	(51)	105	(39)	(42)
TOTAL PRODUCT SALES	3,062	(19)	(18)	978	(22) <b>(11)</b>	(23) <b>(10)</b>	850	(30)	107 <b>691</b>	(56) <b>(16)</b>	(51) <b>(15)</b>	105 <b>543</b>	(39) <b>(12)</b>	(42) <b>(12)</b>



### 7 PRODUCT ANALYSIS - Q3 2017

The table below provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth.

		World		Eme	rging Markets		US	S		Europe			blished ROW	
	Q3 2017 \$m	Actual %	CER %	Q3 2017 \$m	Actual %	CER %	Q3 2017 \$m	Actual %	Q3 2017 \$m	Actual %	CER %	Q3 2017 \$m	Actual %	CER %
Oncology	Ψιιι	70	/0	Ψ	70	70	Ψ	70	Ψ	70	70	ΨΠ	70	
Tagrisso	248	86	89	45	n/m	n/m	97	26	48	100	96	58	107	121
Iressa	137	10	10	71	34	32	10	67	26	(13)	(13)	30	(17)	(11)
Lynparza	81	40	36	6	n/m	n/m	37	9	36	50	54	2	n/m	n/m
Imfinzi	-	-	-	-	-	-	-	-	-	-	-		-	-
Legacy:														
Faslodex	241	16	16	34	48	52	127	15	61	9	4	19	6	11
Zoladex	185	(7)	(6)	92	8	7	2	(75)	37	-	-	54	(22)	(17)
Casodex	51	(18)	(16)	22	(21)	(21)	1	n/m	6	-	-	22	(21)	(17)
Arimidex	54	(4)	(2)	28	4	4	2	- 11/111	9	-	-	15	(17)	(11)
Others	29	7	15	8	14	29	-	-	1	-	-	20	5	
Total Oncology	1,026	18	19	306	35	34	276	16	224	20	18	<b>220</b>	2	11
	1,026	10	19	306	33	34	2/6	10	224	20	10	220	2	0
CVMD	004	07	00	<b>5</b> 4	00	0.4	4.40	07	70	40	40	40		(0)
Brilinta	284	37	36	54	20	24	140	67	78	16	12	12	-	(8)
Farxiga	285	30	29	60	54	56	133	13	66	40	34	26	63	63
Onglyza	127	(25)	(25)	30	-	(3)	58	(37)	26	(10)	(10)	13	(28)	(28)
Bydureon	128	(12)	(12)	-	n/m	n/m	100	(13)	23	(8)	(8)	5	67	67
Byetta	39	(36)	(36)	4	(20)	(20)	23	(39)	8	(33)	(33)	4	(33)	(33)
Symlin	10	(9)	(9)	-	-	-	10	(9)	-	-	-	-	-	-
Legacy:														
Crestor	580	(16)	(14)	188	1	3	93	(25)	152	(31)	(32)	147	(8)	(2)
Seloken/Toprol-XL	160	(14)	(12)	148	15	16	4	(86)	6	(74)	(74)	2	(60)	(60)
Atacand	80	10	11	50	39	44	5	(29)	21	(16)	(20)	4	(20)	(20)
Others	80	(6)	(5)	47	-	2	2	n/m	20	(20)	(20)	11	(15)	(15)
Total CVMD	1,773	(4)	(4)	581	12	14	568	(8)	400	(15)	(18)	224	(5)	(2)
Respiratory														
Symbicort	668	(4)	(4)	109	17	17	257	(7)	191	(10)	(12)	111	(3)	(1)
Pulmicort	242	8	`9 <sup>°</sup>	175	15	16	29	(9)	18	`(5)	(11)	20	(3) (5)	`-
Daliresp/Daxas	53	26	26	1	n/m	n/m	45	29	7	17	17		n/m	n/m
Tudorza/Eklira	37	(21)	(21)	-	-	-	18	(10)	17	(29)	(29)	2	(33)	(33)
Duaklir	21	50	43	-	n/m	n/m	-	-	20	25	19	1	n/m	n/m
Bevespi	4	n/m	n/m	_	-		4	n/m			-	-	-	-
Others	67	(22)	(22)	21	(45)	(45)	(1)	n/m	37	19	19	10	(41)	(41)
Total Respiratory	1,092	(2)	(2)	306	9	10	352	(3)	290	(6)	(8)	144	(8)	(6)
Other														
Nexium	469	(9)	(7)	172	(2)	_	103	(17)	56	(11)	(16)	138	(9)	(4)
Synagis	153	47	47	112	(2)	_	15	88	138	44	44	100	(9)	(4)
Losec/Prilosec	66	(8)	(8)	34	3	6	1	(50)	19	(14)	(18)	12	(20)	(20)
Seroquel XR	62	(67)	(68)	15	(17)	(22)	26	(81)	18	(40)	(40)	3	(25)	(25)
Movantik/Moventig	30	20	20	-	n/m	n/m	29	21	10	n/m	n/m	-	(23)	(23)
FluMist/Fluenz	20	(23)	(23)	-	n/m	n/m	- 29	(100)	18	(14)	(14)	2	-	-
Others	191	(30)	(23)	101			16		24			50	11	11)
	991				(28)	(23)		(32)		(65)	(69)			
Total Other	991	(18)	(17)	322	(13)	(10)	190	(41)	274	(8)	(10)	205	(6)	(2)
TOTAL PRODUCT SALES	4,882	(3)	(2)	1,515	9	10	1,386	(10)	1,188	(6)	(8)	793	(4)	_



### **8 QUARTERLY PRODUCT SALES – 2017**

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth.

	Q1 2017	Actual	CER	Q2 2017	Actual	CER	Q3 2017	Actual	CER
0	\$m	%	%_	\$m	%	%_	\$m	%	%
Oncology	474	40	40	000	00	0.4	0.40	7	_
Tagrisso	171	16	19	232	36	34	248	•	5
Iressa	124	5	8	137	10	9	137	-	(1)
Lynparza	57	(8)	(6)	59	. 4	2	81	37	33
Imfinzi	-	-	-	1	n/m	n/m	-	-	-
Legacy:			<i>(</i> =)					(-)	(=)
Faslodex	214	(4)	(3)	248	16	15	241	(3)	(5)
Zoladex	185	(21)	(12)	178	(4)	(5)	185	4	2
Casodex	56	(7)	(2)	54	(4)	(3)	51	(6)	(9)
Arimidex	52	(9)	(7)	54	4	4	54	-	(2)
Others	26	(10)	(3)	30	15	7	29	(3)	(3)
Total Oncology	885	(5)	-	993	12	11	1,026	3	(9) (2) (3) <b>1</b>
CVMD									
Brilinta	224	(5) (13)	(4)	272	21	20	284	4	3
Farxiga	207	(13)	(13)	250	21	20	285	14	11
Onglyza	154	3	3	150	(3)	(3)	127	(15)	(17)
Bydureon	153	8	8	146	(5)	(5)	128	(12)	(14)
Byetta	46	(16)	(16)	43	(7)	(7)	39	(9)	(9)
Symlin	14	-	-	11	(21)	(21)	10	(9)	(9) (9)
Legacy:					(= · )	(= · )		(-)	(-)
Crestor	631	-	3	560	(11)	(12)	580	4	2
Seloken/Toprol-XL	186	4	6	181	(3)	(4)	160	(12)	(14)
Atacand	75	(7)	(6)	72	(4)	(5)	80	11	8
Others	89	3	12	90	1	(3)	80	(11)	(12)
Total CVMD	1,779	(2)	-	1,775	-	(1)	1,773	-	(12) <b>(2)</b>
Respiratory									
	677	(0)	(7)	700	4	0	000	(5)	(7)
Symbicort		(9)	(7)	706	4	3	668	(5) 7	(7)
Pulmicort	337	17	19	226	(33)	(33)	242		5
Daliresp/Daxas	44	7	10	48	9	9	53	10	8
Tudorza/Eklira	37	3	6	34	(8)	(8)	37	9	6
Duaklir	19	-	-	16	(16)	(15)	21	31	18
Bevespi	1	(67)	(50)	3	n/m	n/m	4	33	33
Others	66	(20)	(19)	66	-	(4) <b>(8)</b>	67	2	4
Total Respiratory	1,181	(2)	(1)	1,099	(7)	(8)	1,092	(1)	(3)
Other									
Nexium	461	(6)	(4)	595	29	28	469	(21)	(22)
Synagis	230	(24)	(24)	70	(70)	(70)	153	n/m	n/m
Losec/Prilosec	68	15	18	68	-	(3)	66	(3)	(6)
Seroquel XR	67	(43)	(42)	95	42	38	62	(35)	(36)
Movantik/Moventig	30	15	Ì15	32	7	7	30	(6)	(6)
FluMist/Fluenz	-	n/m	n/m	-	-	-	20	n/m	n/m
Others	142	(42)	(41)	213	50	51	191	(10)	(11)
Total Other	998	(24)	(22)	1,073	8	7	991	(8)	(9)
TOTAL PRODUCT SALES	4.042	(9)	(6)	4.040			4 000	(4)	(0)
TOTAL PRODUCT SALES	4,843	(8)	(6)	4,940	2	1	4,882	(1)	(3)



### 9 QUARTERLY PRODUCT SALES - 2016

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth.

	Q1 2016	Actual	CER	Q2 2016	Actual	CER	Q3 2016	Actual	CER	Q4 2016	Actual	CER
	\$m	%	%	\$m	%	%	\$m	%	%_	\$m	%	%
Oncology												
Tagrisso	51	183	200	92	80	82	133	45	44	147	11	11
Iressa	135	5	5	135	-	(2)	125	(7)	(8)	118	(6)	(4)
Lynparza	44	22	22	54	23	23	58	7	7	62	7	9
Imfinzi	-	-	-	-	-	-	-	-	-	-	-	-
Legacy:												
Faslodex	190	3	3	211	11	9	207	(2)	(2)	222	7	9
Zoladex	178	(10)	(8)	204	15	8	199	(2)	(2)	235	18	11
Casodex	62	(2) (5)	(6)	63	2	-	62	(2)	(5)	60	(3)	(2)
Arimidex	57	(5)	(5)	62	9	7	56	(10)	(13)	57	2	5
Others	21	(22)	(22)	27	29	12	27	-	4	29	7	-
Total Oncology	738	3	3	848	15	12	867	2	2	930	7	7
CVMD												
Brilinta	181	4	5	214	18	16	208	(3)	(2)	236	13	15
Farxiga	165	9	10	211	28	26	220	4	4	239	9	9
Onglyza	211	10	12	191	(9)	(11)	169	(12)	(11)	149	(12)	(11)
Bydureon	135	(13)	(16)	156	16	14	145	(7)	(6)	142	(2)	(1)
Byetta	62	(14)	(14)	76	23	21	61	(20)	(19)	55	(10)	(10)
Symlin	5	(64)	(64)	10	n/m	n/m	11	10	10	14	27	27
Legacy:	•	()	()		14.11							
Crestor	1,156	(13)	(13)	926	(20)	(21)	688	(26)	(26)	631	(8)	(7)
Seloken/Toprol-XL	185	16	11	189	2	-	185	(2)	(2)	178	(4)	(2)
Atacand	71	(17)	(15)	89	25	22	74	(17)	(19)	81	9	14
Others	121	(9)	(16)	106	(12)	(11)	84	(21)	(19)	86	2	
Total CVMD	2,292	(9) <b>(7)</b>	(7)	2,168	(5)	(7)	1,845	(15)	(15)	1,811	(2)	(1)
	,	. ,	. ,	,	` ,	,	•	,	` ,	•	` ,	. ,
Respiratory												
Symbicort	749	(13)	(12)	803	7	6	697	(13)	(13)	740	6	8
Pulmicort	310	13	14	239	(23)	(23)	224	(6)	(6)	288	29	31
Daliresp/Daxas	31	(3)	(3)	40	29	29	42	5	5	41	(2)	(2)
Tudorza/Eklira	39	(17)	(17)	48	23	21	47	(2)	-	36	(23)	(23)
Duaklir	13	8	8	17	31	31	14	(18)	(18)	19	36	43
Bevespi	-	-	-	-	-	-	-	-	`-	3	n/m	n/m
Others	65	-	(3)	79	22	18	86	9	12	83		1
Total Respiratory	1,207	(6)	(6)	1,226	2	1	1,110	(9)	(9)	1,210	(3) <b>9</b>	10
Other												
Nexium	463	(18)	(18)	562	21	20	516	(8)	(9)	491	(5)	(4)
Synagis	244	(11)	(11)	27	(89)	(89)	104	n/m	n/m	302	n/m	n/m
Losec/Prilosec	75	(3)	(4)	70	(7)	(9)	72	3	4	59	(18)	(17)
Seroquel XR	202	(16)	(16)	225	11	11	190	(16)	(16)	118	(38)	(37)
Movantik/Moventig	17	13	13	23	35	35	25	9	9	26	4	4
FluMist/Fluenz	5	(97)	(97)	6	20	20	26	n/m	n/m	67	n/m	n/m
Others	322	(15)	(7)	314	(2)	(4)	270	(14)	(16)	246	(9)	(8)
Total Other	1,328	(24)	(22)	1,227	(8)	(9)	1,203	(2)	(3)	1,309	9	10
TOTAL PRODUCT SALES	5,565	(10)	(10)	5,469	(2)	(3)	5,025	(8)	(8)	5,260	5	6



### 10 QUARTERLY PRODUCT SALES - 2015

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth.

	Q1 2015	Actual	CER	Q2 2015	Actual	CER	Q3 2015	Actual	CER	Q4 2015	Actual	CER
	Q1 2015 \$m	Actual %	%	Q2 2015 \$m	Actual %	CER %	Q3 2015 \$m	Actuai %	CER %	Q4 2015 \$m	Actual %	CER %
Oncology	Ψιιι	70	70	ΨΠ	70	70_	Ψιιι	70	70	Ψιιι	70	/0
Tagrisso	-	-	-	-	-	-	-	-	-	18	n/m	n/m
Iressa	144	(4)	-	129	(10)	(8)	141	9	10	129	(9)	(7)
Lynparza	9	n/m	n/m	21	133	133	28	33	33	36	29	29
Imfinzi	-	-	-	-	-	-	-	-	-	-	-	-
Legacy:												
Faslodex	161	(12)	(6)	172	7	8	186	8	8	185	(1)	1
Zoladex	194	(15)	(9)	215	11	11	209	(3)	-	198	(5)	(2)
Casodex	70	(5)	1	69	(1)	- ''	65	(6)	(4)	63	(3)	(1)
Arimidex	62	(9)	(5)	64	3	7	64	(0)	-	60	(6)	(5)
Others	34	(13)	(10)	37	9	9	35	(5)	-	27	(23)	(16)
Total Oncology	674	(13) (9)	(10) (4)	707	5	6	<b>728</b>	3	5	716	(23) (2)	(16)
Total Olicology	0/4	(3)	(+)	701	J	•	720	J	•	710	(2)	
CVMD	404	(0)		444	40	40	470	40	40	474		
Brilinta	131	(2)	3	144	10	13	170	18	19	174	2	4
Farxiga	76	(19)	(18)	129	70	75	135	5	5	152	13	14
Onglyza	183	(9)	(5)	208	14	15	203	(2)	(2)	192	(5)	(5)
Bydureon	123	-	8	140	14	11	162	16	13	155	(4)	(1)
Byetta	90	30	35	82	(9)	(9)	72	(12)	(12)	72	-	1
Symlin	16	60	60	13	(19)	(19)	5	(62)	(62)	14	n/m	n/m
Legacy:												
Crestor	1,167	(16)	(13)	1,310	12	14	1,218	(7)	(7)	1,322	9	9
Seloken/Toprol-XL	194	11	22	184	(5)	(4)	172	(7)	(3)	160	(7)	-
Atacand	95	(19)	(11)	99	4	9	78	(21)	(19)	86	10	13
Others	155	(7)	7	143	(8)	(7)	132	(8)	(7)	133	1	4
Total CVMD	2,230	(10)	(6)	2,452	10	12	2,347	(4)	(4)	2,460	5	7
Respiratory												
Symbicort	845	(14)	(9)	842	_	2	848	1	1	859	1	3
Pulmicort	286	6	11	232	(19)	(17)	222	(4)	(6)	274	23	26
Daliresp/Daxas	7	n/m	n/m	32	n/m	n/m	33	3	3	32	(3)	(3)
Tudorza/Eklira	30	n/m	n/m	55	83	90	58	5	5	47	(19)	(19)
Duaklir	2	n/m	n/m	5	n/m	n/m	8	60	60	12	50	50
Bevespi	-	-	-	-	- 1////	-	-	-	-	-	-	-
Others	73	(4)	12	59	(19)	(20)	61	3	3	65	7	11
Total Respiratory	1,243	(7)	(2)	1,225	(1)	1	1,230	-	-	1,289	5	6
Other												
	044	(00)	(00)	0.47			0.44	(4)	(0)	504	(40)	(40)
Nexium	644	(23)	(20)	647	- (00)	3	641	(1)	(2)	564	(12)	(10)
Synagis	204	(50)	(50)	66	(68)	(68)	117	77	77	275	135	135
Losec/Prilosec	96	(13)	(8)	85	(11)	(9)	82	(4)	(5)	77	(6)	(2)
Seroquel XR	262	(15)	(13)	264	1	4	258	(2)	(2)	241	(7)	(6)
Movantik/Moventig	3	n/m	n/m	1	(67)	(67)	10	n/m	n/m	15	50	50
FluMist/Fluenz	7	(95)	(94)	14	n/m	n/m	76	n/m	n/m	191	n/m	n/m
Others	385	12	16	375	(3)	1	361	(4)	2	379	5	2
Total Other	1,601	(25)	(24)	1,452	(9)	(7)	1,545	6	8	1,742	13	13
TOTAL PRODUCT SALES	5,748	(14)	(10)	5,836	2	3	5,850	_	1	6,207	6	7
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#### **Shareholder Information**

Announcement of full year and final quarter 2017 results 2 February 2018
Announcement of first quarter 2018 results 18 May 2018
Annual General Meeting 18 May 2018

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 2017, payable on 19 March 2018, will be 16 February 2018. The ex-dividend date will be 15 February 2018.

The record date for the first interim dividend for 2018, payable on 10 September 2018, will be 10 August 2018. The ex-dividend date will be 09 August 2018.

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#### **Cautionary Statements Regarding Forward-Looking Statements**

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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; effects of patent litigation in respect of IP rights; 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 that R&D will not yield new products that achieve commercial success; the risk of delay to new product launches; the risk that new products do not perform as we expect; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the risks from pressures resulting from generic competition; the impact of competition, price controls and price reductions; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the difficulties of obtaining and maintaining regulatory approvals for products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk of failure of critical processes affecting business continuity; economic, regulatory and political pressures to limit or reduce the cost of our products; failure to achieve strategic priorities or to meet targets or expectations; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; the risk of substantial product liability claims; 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 impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; taxation risks; exchange rate fluctuations; 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 impact of failing to attract and retain key personnel and to successfully engage with our employees; the risk of misuse of social medial platforms and new technology; and the risk of failure of information technology and cybercrime. Nothing in this presentation / webcast should be construed as a profit forecast.