ASTRAZENECA PLC Form 6-K February 02, 2018

#### FORM 6-K

SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Report of Foreign Issuer

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

For the month of February 2018

Commission File Number: 001-11960

AstraZeneca PLC

1 Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 0AA United Kingdom

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

Form 20-F X Form 40-F \_\_\_\_

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

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

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

Yes \_\_ No X

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

#### AstraZeneca PLC

#### INDEX TO EXHIBITS

AstraZeneca PLC 2 February 2018 07:00

#### Full-Year 2017 Results

Encouraging progress made on commercial execution and cost discipline; Product Sales growth in the quarter. AstraZeneca positioned for Product Sales growth from FY 2018

**Financial Summary** 

	FY 201	7		Q4 2017		
	\$m	% change		\$m	% change	
	φIII	Actual	CER1	φIII	Actual	ICER
Total Revenue	22,465	(2)	(2)	5,777	3	2
Product Sales	20,152	(5)	(5)	5,487	4	3
Externalisation Revenue	2,313	37	38	290	(11)	(12)
Reported Operating Profit2	3,677	(25)	(28)	686	(73)	(71)
Core Operating Profit3	6,855	2	-	1,787	(12)	(11)
Reported Earnings Per Share (EPS)	\$2.37	(14)	(15)	\$1.03	(29)	(24)
Core EPS	\$4.28	(1)	(2)	\$1.30	7	13

#### **Financial Highlights**

Total Revenue declined by 2% in the year, in line with guidance. Externalisation Revenue increased by 37% (38% at CER) in the year to \$2,313m. Ongoing Externalisation Revenue4 of \$821m in the year represented 35% of total Externalisation Revenue (FY 2016: \$356m, 21%)

Cost discipline in the year continued:

- Reported R&D costs declined by 2% (1% at CER) to 5,757m; Core R&D costs declined by 4% (3% at CER) to 5,412m

- Reported SG&A costs increased by 9% (10% at CER) to \$10,233m; Core SG&A costs declined by 4% (3% at CER) to \$7,853m

Reported EPS of \$2.37 and Core EPS of \$4.28 for the year, including:

- A \$617m net benefit in Q4 2017 to Reported Profit After Tax, reflecting adjustments to deferred taxes in line with the recently reduced US federal income tax rate from 35% to 21%

- A \$321m benefit to Reported and Core Taxation in Q4 2017; the Reported Tax Rate in FY 2017 was (29)% and the Core Tax Rate in FY 2017 was 14%, driven by reductions in tax provisions

The Board reaffirms its commitment to the progressive dividend policy; a second interim dividend of \$1.90 per share has been declared, taking the full-year dividend per share to \$2.80 (unchanged)

FY 2018 guidance (CER): Product Sales - a low single-digit percentage increase; Core EPS - \$3.30 to \$3.50

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

"AstraZeneca's revenues improved over the course of the year, a sign of how our company is steadily turning a corner. Strong commercial execution helped us bring our science to more patients, making the most of our exciting pipeline. We made encouraging progress across the main therapy areas and delivered strong growth in China.

Alongside our CVMD medicines Brilinta and Farxiga reaching blockbuster status, we launched our first Respiratory biologic medicine, Fasenra and new cancer medicines, Imfinzi and Calquence. As well as bringing five new medicines to patients last year, we continued to find more potential uses for existing treatments, including Lynparza and Tagrisso.

We remain committed to our progressive dividend policy. Our strategy is working, propelled by a strong pipeline, good sales performance and continued cost discipline."

#### **Commercial Highlights**

Product Sales growth of 4% (3% at CER) in Q4 2017 to \$5,487m, which included favourable true-up adjustments relating to the first nine months of 2017; the great majority of these true-up adjustments concerned legacy medicines. The Growth Platforms gathered momentum in the year and represented 68% of Total Revenue. They grew by 5% (6% at CER) in the year and by 12% in the quarter:

Emerging Markets: Full-year growth of 6% (8% at CER), in line with long-term ambitions. China sales in the year grew by 12% (15% at CER) and in the quarter by 33% (30% at CER), supported by the launches of new medicines

Respiratory: Full-year sales declined by 1%; Q4 2017 sales up by 10% (8% at CER), reflecting improved performances by Symbicort and Pulmicort

New CVMD5: Full-year growth of 9%. Growth of 23% in the quarter (21% at CER), with strong performances from Farxiga and Brilinta, each becoming blockbusters by exceeding \$1bn in sales in the year

Japan: 1% full-year growth (4% at CER), underpinned by the growth of Tagrisso and Forxiga, partly mitigated by the impact of the entry of generic competition to Crestor in the second half of the year

New Oncology6: 98% full-year growth. Tagrisso reached \$955m to become AstraZeneca's largest-selling Oncology medicine. Imfinzi sales of \$18m in the quarter vs. \$19m in the full year

#### FY 2018 Guidance

All measures in this section are at CER. Company guidance is on Product Sales and Core EPS only.

Product Sales A low single-digit percentage increase Core EPS \$3.30 to \$3.50

The aforementioned growth in Product Sales is anticipated to be weighted towards the second half of the year. This reflects the remaining impact of generic competition, in particular Crestor in Europe and Japan.

Variations in performance between quarters can be expected to continue. The Company is unable to provide guidance and indications on a Reported basis because the Company cannot reliably forecast material elements of the Reported 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.

#### FY 2018 Currency Impact

Based only on average exchange rates in January 2018 and the Company's published currency sensitivities, there would be a low single-digit percentage favourable impact from currency movements on Product Sales and a minimal impact on Core EPS in the year. Further details on currency sensitivities are contained within the Operating and Financial Review.

FY 2018: Additional Commentary

Outside of guidance, the Company today provides additional indications for FY 2018 vs. the prior year:

The sum of Externalisation Revenue and Other Operating Income and Expense is anticipated to reduce vs. FY 2017. As part of its long-term growth strategy, the Company remains committed to focusing on appropriate cash-generating and value-accretive externalisation activities that reflect the ongoing productivity of the pipeline. It is also committed to the continued management of its portfolio disposals and to increasing the focus on the three main therapy areas over time

Core R&D costs in FY 2018 are anticipated to be in the range of a low single-digit percentage decline to stable. This expectation includes the favourable impact on development costs from the MSD collaboration (Merck & Co., Inc., Kenilworth, NJ, US (known as MSD outside the US and Canada))

The Company maintains its focus on reducing operational and infrastructure costs. Total Core SG&A costs, however, are expected to increase by a low to mid single-digit percentage in FY 2018, wholly reflecting targeted support for launches and potential launches, including Fasenra in severe, uncontrolled asthma and Imfinzi in locally-advanced, unresectable lung cancer. The Company also anticipates a reduction in restructuring costs in 2018 vs. the prior year

A Core Tax Rate of 16-20% (FY 2017: 14%)

Achieving Scientific Leadership

The table below highlights the development of the late-stage pipeline since the prior results announcement:

	Faslodex - breast cancer (combinations) (US, EU) Lynparza - ovarian cancer (JP)
Regulatory Approvals	Lynparza - breast cancer (US)
	Fasenra (benralizumab) - severe, uncontrolled asthma (US, EU, JP)
Regulatory Submissions and/or Acceptances	Tagrisso - lung cancer (1st line) (US - Priority Review, EU, JP)
Regulatory Submissions and/or Acceptances	ZS-9 - hyperkalaemia (US)
	Lynparza - ovarian cancer: Priority review (CN)
Major Dhasa III Data Daadauta and	roxadustat - anaemia: Priority review (CN)
Major Phase III Data Readouts and	PT010 - COPD1 (KRONOS trial) (most2 primary endpoints met)
Developments	tezepelumab - severe, uncontrolled asthma: First patient commenced
	dosing
	-

1Chronic Obstructive Pulmonary Disease.

2Eight of the nine primary endpoints in the KRONOS trial were met, including two non-inferiority endpoints to qualify PT009, one of the comparators.

#### Notes

1. Constant exchange rates. These are non-GAAP financial measures because they remove the effects of currency movements from Reported results.

2. Reported financial measures are our financial results presented in accordance with IFRS, the Generally Accepted Accounting Principles (GAAP) on the basis of which we prepare our financial results.

3. Core financial measures. These are non-GAAP financial 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.

4. Ongoing Externalisation Revenue is defined as Externalisation Revenue excluding Initial Externalisation Revenue (which is defined as Externalisation Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Externalisation Revenue comprises, among other items, royalties, milestones and profit sharing income. Ongoing Externalisation Revenue and Initial Externalisation Revenue are non-GAAP financial measures because they cannot be derived directly from the information included in the Group Financial Statements.

5. New Cardiovascular and Metabolic Diseases, incorporating Brilinta and Diabetes.

6. New Oncology, comprising Lynparza, Tagrisso, Iressa (US), Imfinzi and Calquence. All growth rates in this announcement 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 and are vs. the prior year, 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.

Lynparza - ovarian cancer (2nd line): Regulatory decision (EU) Lynparza - ovarian cancer (1st line): Data readout Lynparza - breast cancer: Regulatory submission (EU) Tagrisso - lung cancer: Regulatory decision (US)

Imfinzi - lung cancer (PACIFIC): Regulatory decision (US) Imfinzi +/- treme - lung cancer (ARCTIC) (3rd line): Data readout, regulatory submission Imfinzi +/- treme - lung cancer (MYSTIC) (1st line): Data readout (final overall-survival (OS)) Imfinzi +/- treme - head & neck cancer (KESTREL) (1st line): Data readout

H1 2018 Imfinzi +/- treme - head & neck cancer (KESTREL) (1st line): Data readout Imfinzi +/- treme - head & neck cancer (EAGLE) (2nd line): Data readout

selumetinib - thyroid cancer: Data readout

ZS-9 - hyperkalaemia: Regulatory decision (US, EU)

Bevespi - COPD: Regulatory submission (JP) Duaklir - COPD: Regulatory submission (US)

Lynparza - breast cancer: Regulatory decision (JP)

Lynparza - ovarian cancer (1st line): Regulatory submission

Lynparza - pancreatic cancer: Data readout

Tagrisso - lung cancer: Regulatory decision (EU, JP)

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

H2 2018 selumetinib - thyroid cancer: Regulatory submission

Farxiga - type-2 diabetes (DECLARE): Data readout Bydureon autoinjector - type-2 diabetes: Regulatory decision (EU) roxadustat - anaemia: Regulatory submission (US)

Bevespi - COPD: Regulatory decision (EU) Fasenra - COPD: Data readout PT010 - COPD: Regulatory submission

anifrolumab - lupus: Data readout

2019 Lynparza - pancreatic cancer: Regulatory submission Lynparza - ovarian cancer (3rd line): Data readout, regulatory submission

Imfinzi - lung cancer (PACIFIC): Data readout (final OS) Imfinzi +/- treme - lung cancer (POSEIDON): Data readout, regulatory submission Imfinzi +/- treme - small-cell lung cancer (CASPIAN): Data readout, regulatory submission Imfinzi +/- treme - bladder cancer (DANUBE): Data readout, regulatory submission Calquence - chronic lymphocytic leukaemia: Data readout Brilinta - coronary artery disease / type-2 diabetes: Data readout, regulatory submission Farxiga - type-2 diabetes (DECLARE): Regulatory submission Farxiga - heart failure: Data readout Fasenra - COPD: Regulatory submission anifrolumab - lupus: Regulatory submission lanabecestat - Alzheimer's disease: Data readout The term 'data readout' in this section refers to Phase III data readouts. **Conference** Call A live presentation and webcast for investors and analysts, hosted by management, will begin at 12:30pm UK time today. Details can be accessed via astrazeneca.com. **Reporting Calendar** The Company intends to publish its first-quarter financial results on 18 May 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 astrazeneca.com and follow us on Twitter @AstraZeneca.

Media Relations		
Esra Erkal-Paler	UK/Global	+44 203 749 5638
Gonzalo Viña	UK/Global	+44 203 749 5916
Rob Skelding	UK/Global	+44 203 749 5821
Karen Birmingham	UK/Global	+44 203 749 5634
Matt Kent	UK/Global	+44 203 749 5906
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677
Investor Relations		
Thomas Kudsk Larsen		+44 203 749 5712
Thomas Kudsk Larsen Craig Marks	Finance; Fixed Income; M&A	
Craig Marks	Finance; Fixed Income; M&A	+44 7881 615 764
Craig Marks Henry Wheeler	Finance; Fixed Income; M&A Oncology	+44 7881 615 764 +44 203 749 5797
Craig Marks Henry Wheeler Mitchell Chan	Finance; Fixed Income; M&A Oncology Oncology; Other	+44 7881 615 764 +44 203 749 5797 +1 240 477 3771

Operating and Financial Review

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 twelve and three-month

periods to 31 December 2017 (the year (FY 2017), or the quarter (Q4 2017), respectively) compared to the twelve and three-month periods to 31 December 2016 (FY 2016 and Q4 2016, respectively). All commentary in the Operating and Financial Review relates to the full year, unless stated otherwise.

Core financial measures, EBITDA, Net Debt, Initial Externalisation Revenue and Ongoing Externalisation Revenue 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 readers 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, which includes charges that relate to the impact of global restructuring programmes on capitalised IT assets

Other specified items, principally comprising acquisition-related costs, which include fair value adjustments and the imputed finance charge relating to contingent consideration on business combinations, legal settlements and foreign-exchange gains and losses on certain non-structural intra-group loans\*

Details on the nature of Core financial measures are provided on page 64 of the Annual Report 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.

\*This element has been added to the definition of Core financial measures during 2017. There were no such gains and losses in the income statement in prior periods.

EBITDA is defined as Reported Profit Before Tax after adding back Net Finance Expense, results from 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.

Ongoing Externalisation Revenue is defined as Externalisation Revenue excluding Initial Externalisation Revenue (which is defined as Externalisation Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Externalisation Revenue comprises, among other items, royalties, milestones and profit sharing income.

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

	FY 2017			Q4 2017		
	\$m	% cha	nge	\$m	% change ActualCER	
	φIII	Actual	CER	φIII		
Total Revenue	22,465	(2)	(2)	5,777	3	2
Product Sales	20,152	(5)	(5)	5,487	4	3
Externalisation Revenue	2,313	37	38	290	(11)	(12)

#### Product Sales

Growth in Product Sales was reached in the final quarter of the year after a number of years of decline. Quarterly growth rates in FY 2017 Product Sales are shown below:

Actual CER Q1 2017 (13) (12) Q2 2017 (10) (8) Q3 2017 (3) (2) Q4 2017 4 3

The growth in the fourth quarter included the favourable impact from true-up adjustments in the US relating to the first nine months of 2017, resulting from improved data insight and methodology in the estimation of payer rebates, product returns and discounts; AstraZeneca does not anticipate a similar magnitude of adjustments in future periods. Over the full year, Product Sales declined by 5% from \$21,319m to \$20,152m, a difference of \$1,167m; Crestor sales declined by \$1,036m and Seroquel XR sales declined by \$403m. Both medicines lost exclusivity in the US in the second half of 2016.

Emerging Markets sales grew by 6% (8% at CER) to \$6,149m, in line with an unchanged average-growth ambition of a mid to high single-digit percentage. In the quarter, Emerging Markets sales grew by 10% (9% at CER) to \$1,630m. China sales increased by 12% (15% at CER) to \$2,955m in the year and, in the quarter, by 33% (30% at CER) to \$813m. These results reflected strong performances across all three main therapy areas, including the impact of the launches of new medicines.

US sales declined by 16% to \$6,169m and were, alongside the effects of the Crestor and Seroquel XR losses of exclusivity, impacted by the adverse sales performance of Symbicort, which declined by 12% to \$1,099m. US sales, however, grew by 9% to \$1,770m in the quarter as the effects of the Crestor and Seroquel XR losses of exclusivity dissipated. Sales in the quarter also benefitted from favourable true-up adjustments in the US relating to the first nine months of 2017.

Product Sales in Europe declined by 6% (7% at CER) to \$4,753m in the year, partly driven by pricing pressures on Symbicort and the initial impact from generic competition to Crestor.

The Growth Platforms grew by 5% (6% at CER) to \$15,231m, representing 68% of Total Revenue and, in the quarter, by 12% to \$4,180m:

	FY 2017			Q4 20	2017		
	\$m	% change		\$m	% chan	ge	
	ψIII	Actual	CER	φΠ	Actual	CER	
<b>Emerging Markets</b>	6,149	6	8	1,630	10	9	
Respiratory	4,706	(1)	(1)	1,334	10	8	
New CVMD	3,567	9	9	1,024	23	21	
Japan	2,208	1	4	563	(5)	2	
New Oncology	1,313	98	98	437	102	100	

Total\* 15,231 5 6 4,180 12 12

\*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, revenue arising from externalisation agreements is reported as Externalisation Revenue in the Company's financial statements. A breakdown of Initial Externalisation Revenue in the year is shown below:

Medicine	Partner	Region	\$m
Lynparza	MSD	Global	997
Zoladex	TerSera Therapeutics LLC (TerSera)	US and Canada	250
MEDI8897	Sanofi Pasteur, Inc. (Sanofi Pasteur)	Global	127
Tudorza/Duaklir	Circassia Pharmaceuticals plc (Circassia)	US	64
MEDI1341	Takeda Pharmaceutical Company Limited	Global	50
Other			4

Total

1,492

A breakdown of Ongoing Externalisation Revenue in the year is shown below:					
Medicine	Partner	Region	\$m		
Lynparza	MSD - option payment	Global	250		
Anaesthetics	Aspen Global, Inc. (Aspen)1 - milestone revenue	Global (excl.US)	150		
Siliq	Valeant Pharmaceuticals International, Inc. (Valeant) - milestone revenue	US	130		
Lanabecestat	Eli Lilly and Company - milestone revenue	Global	50		
Crestor AG2	Daiichi Sankyo Company, Ltd (Daiichi Sankyo) - milestone revenue	Japan	45		
Bydureon Other	3SBio Inc. (3SBio) - milestone revenue	China	25 171		
Total			821		

for the E-th • • . 1. . 1 A 1 1 1

1Following the sale of the remaining rights to the anaesthetics portfolio to Aspen in Q4 2017, any future income relating to these medicines will be recorded as Other Operating Income and Expense.

2Authorised Generic.

Ongoing Externalisation Revenue of \$821m represented 35% of total Externalisation Revenue (FY 2016: \$356m, 21%). The Company anticipates that Ongoing Externalisation Revenue will grow as a proportion of Externalisation Revenue over time. .....

	FY 2017				Q4	2017		
	\$m	% of total1	% cha Actua	nge ICER	\$m	% of total	% cha Actua	
Royalties	108	5	(9)	(6)	8	3	(82)	(72)
Milestones/Other2	713	31	n/m	n/m	282	97	n/m	n/m
Ongoing Externalisation Revenue	821	35	n/m	n/m	290	100	n/m	n/m
Initial Externalisation Revenue	1,492	265	12	12	-	-	n/m	n/m
Total Externalisation Revenue	2,313	3100	37	38	290	100	(11)	(12)

1Due to rounding, the sum of individual medicine percentages may not agree to totals. 2May include, inter alia, option and profit sharing income.

A number of AstraZeneca medicines were externalised or disposed of in FY 2017, thus adversely impacting the Product Sales performance:

Completion Medicine		Dagion	FY 2017*FY 2016 Difference Adverse Impact on FY 2017 Product Sales					
		Region	\$m	\$m	\$m			
March	Zoladex	US and Canada	23	66	(43)			
June	Seloken	Europe	52	90	(38)			
June	Zomig	Global (excl. Japan	)58	78	(20)			
October	Anaesthetic	cs Global	292	472	(180)			

r	Гotal	425 7	06 (281	) 1%
		-	-	under manufacturing and supply agreements.
Exan	ples of transactions th	nat include Ongoing Ex	xternalisation	n Revenue are shown below:
Completion	Medicine	Partner	Region	Externalisation Revenue
				Initial \$1.0bn revenue
				Up to \$0.75bn for certain licence options,
July 2017	Lynparza	MSD	Global	including \$0.25bn paid in Q4 2017
				Up to \$6.15bn in regulatory and sales
				milestones
				Initial €120m revenue
March 2017	MEDI8897	Sanofi Pasteur	Global	Up to €495m in sales and development-related
				milestones
			US and	Initial \$250m revenue
March 2017	Zoladex	TerSera	Canada	Up to \$70m in sales-related milestones
			Callada	Mid-teen percentage royalties on sales
				Initial \$175m revenue
October	Toprol-XL	Aralez	US	Up to \$48m milestone and sales-related
2016	TOPIOI-AL	Pharmaceuticals Inc.	05	revenue
				Mid-teen percentage royalties on sales
				Initial \$115m revenue
	tralokinumab - atopic	LEO Pharma A/S		Up to \$1bn in commercially-related
August 2016	dermatitis	(LEO Pharma)	Global	milestones
	definition	(LLO I harma)		Up to mid-teen tiered percentage royalties on
				sales
			Global,	Initial \$100m revenue
October	Siliq	Valeant	later	Pre-launch milestone of \$130m
2015	omq	, alount	amended to	<b>J 1</b>
			US	Profit sharing
March 2015	Movantik	Daiichi Sankyo	US	Initial \$200m revenue
			- ~	Up to \$625m in sales-related revenue

#### Product Sales

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

		FY 201	7	~ .		Q4 2017		~ .	
Therapy Area	Medicine	\$m % of total*		% change		\$m % of total		% change	
				Actual	CER			Actual	CER
	Tagrisso	955	5	126	126	304	6	107	105
	Iressa	528	3	3	3	130	2	10	8
	Lynparza	297	1	36	35	100	2	61	58
	Imfinzi	19	-	n/m	n/m	18	-	n/m	n/m
	Calquence	3	-	n/m	n/m	3	-	n/m	n/m

	Legacy:								
	Faslodex	941	5	13	13	238	4	7	5
	Zoladex	735	4	(10)	(9)	187	3	(20)	(21)
	Casodex	215	1	(13)	(11)	54	1	(10)	(8)
	Arimidex	217	1	(6)	(4)	57	1	-	(2)
	Others	114	-	10	13	29	1	-	3
	Total Oncology	4,024	20	19	19	1,120	20	20	19
	Brilinta	1,079	5	29	29	299	5	27	24
	Farxiga	1,074	5	29	28	332	6	39	37
	Onglyza	611	3	(15)	(16)	180	3	21	19
	Bydureon	574	3	(1)	(1)	147	3	4	2
	Byetta	176	1	(31)	(30)	48	1	(13)	(13)
CVMD	Symlin	48	-	20	20	13	-	-	-
CVMD	Qtern	5	-	n/m	n/m	5	-	n/m	n/m
	Legacy:								
	Crestor	2,365	12	(30)	(30)	594	11	(6)	(7)
	Seloken/Toprol-XL	695	3	(6)	(4)	168	3	(6)	(7)
	Atacand	300	1	(5)	(3)	73	1	(10)	(10)
	Others	339	2	(15)	(13)	80	1	(8)	(10)
	Total CVMD	7,266	36	(10)	(10)	1,939	35	7	6
	Symbicort	2,803	14	(6)	(6)	752	14	2	-
	Pulmicort	1,176	6	11	12	371	7	29	26
	Daliresp/Daxas	198	1	29	28	53	1	29	27
Respiratory	Tudorza/Eklira	150	1	(12)	(12)	42	1	17	11
	Duaklir	79	-	25	25	23	-	21	16
	Bevespi	16	-	n/m	n/m	8	-	n/m	n/m

	Others	284	1	(10)	(9)	85	2	1	(2)
Total Respiratory Nexium Synagis Losec/Prilosec Seroquel XR	Total Respiratory	4,706	23	(1)	(1)	1,334	24	10	8
		1,952 687	10 3	(4) 1	(3) 1	427 234	8 4	(13) (23)	(12) (23)
	271	1	(2)	(1)	69	1	17	14	
	Seroquel XR	332	2	(55)	(55)	108	2	(8)	(9)
Other	Movantik/Moventig	122	1	34	34	30	1	15	15
	FluMist/Fluenz	78	-	(25)	(28)	58	1	(13)	(18)
	Others	714	4	(38)	(38)	168	3	(32)	(33)
	Total Other	4,156	21	(18)	(17)	1,094	20	(16)	(17)
	Total Product Sales	20,152	100	(5)	(5)	5,487	100	4	3

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

Product Sales Summary

#### ONCOLOGY

0

Product Sales of \$4,024m; an increase of 19%. Oncology Product Sales represented 20% of total Product Sales, up from 16% in FY 2016.

#### Lung Cancer

#### Tagrisso

Product Sales of \$955m; an increase of 126%. In the year, the medicine became AstraZeneca's largest-selling Oncology medicine and, by the end of 2017, the medicine had received regulatory approval in more than 60 countries. Global growth partly reflected higher testing rates, led by Japan and the US.

Sales in the US were \$405m and grew by 59%, with a steady increase in epidermal growth factor receptor (EGFR) T790M-mutation testing rates. In September 2017, US National Comprehensive Cancer Network (NCCN) clinical-practice guidelines were updated to include the use of Tagrisso as a 1st-line treatment of patients with metastatic EGFR-mutated non-small cell lung cancer (NSCLC). The use of Tagrisso in this indication is not yet approved by the US FDA.

Within Emerging Markets, Tagrisso sales were \$135m in the year (FY 2016: \$10m). In Europe, sales of \$187m represented growth of 146% (142% at CER) and were driven by a continued uptake, positive reimbursement decisions and further growth in testing rates. Tagrisso was reimbursed in 15 European countries at the end of the year and was under reimbursement review in additional European countries, with positive decisions anticipated in 2018. Testing rates in Japan continued to exceed 90%, with full-year sales of \$219m (FY 2016: \$82m) reflecting a high penetration rate in the currently-approved 2nd-line EGFR T790M-mutation setting.

#### Iressa

Product Sales of \$528m; an increase of 3%.

Emerging Markets sales increased by 8% to \$251m. China Product Sales increased by 24% (28% at CER) to \$144m, reflecting an improvement in patient access following the conclusion of the national negotiation process in 2016; Iressa was subsequently included on the National Reimbursement Drug List (NRDL). Other Emerging Markets sales, however, were adversely impacted by competition from branded and generic medicines, most notably in the Republic of Korea.

Sales in the US increased by 70% to \$39m and declined in Europe by 7% (8% at CER) to \$112m. Given the significant future potential of Tagrisso, the Company continues to prioritise commercial support for Tagrisso in established markets over Iressa.

## Other Cancers

Lynparza

Product Sales of \$297m; an increase of 36% (35% at CER). By the end of 2017, the medicine had received regulatory approval in 57 countries, with reviews underway in a number of additional markets.

US sales grew by 11% in the year to \$141m. First-half sales were adversely impacted by the introduction of competing poly ADP ribose polymerase (PARP)-inhibitor medicines. A much-improved performance in the second half, however, reflected the launch of Lynparza tablets for patients regardless of BRCA-mutation status, for the treatment of 2nd-line ovarian cancer. This was illustrated by sequential quarterly US sales from Q3 2017 to Q4 2017, where sales grew by 46%, from \$37m to \$54m. By the end of November 2017, Lynparza was the leading PARP inhibitor in the US, measured by total prescription volumes.

Sales in Europe increased by 60% (58% at CER) to \$130m, reflecting high BRCA-testing rates and a number of successful launches, most recently in Finland and the Republic of Ireland.

On 27 July 2017, AstraZeneca and MSD announced a global strategic oncology collaboration to co-develop Lynparza and the potential medicine selumetinib for multiple cancer types as monotherapies and in combinations. The integration of development and commercial activities is progressing well. Imfinzi

Product Sales of \$19m (\$18m in Q4 2017); launched in the US in May 2017. By the end of 2017, Imfinzi had also received regulatory approvals in Canada, Brazil and Israel.

Imfinzi was approved under the US FDA's Accelerated-Approval pathway and launched on the same day as a fast-to-market, limited commercial opportunity, indicated for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer).

The Company is actively preparing for the potential launch of Imfinzi in locally-advanced, unresectable NSCLC in H1 2018, reflecting the US FDA regulatory submission acceptance and the award of Priority Review status in the quarter. Calquence

Product Sales of \$3m. Approved and launched in the US on 31 October 2017, Calquence delivered a promising performance in the number of new-patient starts in previously-treated mantle cell lymphoma (MCL). The medicine was included within NCCN MCL guidelines on 15 November 2017.

Legacy: Faslodex

Product Sales of \$941m; an increase of 13%.

Emerging Markets sales grew by 20% (18% at CER) to \$115m. In 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 29% in the year (14% at CER) to \$18m.

US sales increased by 12% to \$492m, 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 12% (11% at CER) to \$256m but increased by only 5% (down by 3% at CER) to \$62m in the quarter, reflecting the impact of generic entrants in certain markets. In June 2017, a label extension based upon the FALCON trial in the 1st-line setting was approved in Japan, where sales grew by 14% (17% at CER) in the year to \$72m.

Legacy: Zoladex

Product Sales of \$735m; a decline of 10% (9% at CER).

Emerging Markets sales declined by 1% to \$353m in the year. Sales in Europe declined by 10% (8% at CER) to \$141m, reflecting the impact of generic competition, mainly in Central and Eastern Europe. In Established Rest Of

World (ROW, comprising Japan, Canada, Australia and New Zealand), sales fell by 16% (15% at CER) to \$226m, driven by increased competition. On 31 March 2017, the Company completed an agreement with TerSera for the sale of the commercial rights to Zoladex in the US and Canada.

CVMD

Product Sales of \$7,266m; a decline of 10%. CVMD Product Sales represented 36% of total Product Sales, down from 38% in FY 2016.

Within the New CVMD Growth Platform, comprising Brilinta and Diabetes and excluding medicines such as Crestor, sales grew by 9% to \$3,567m. Strong performances were delivered by Farxiga and Brilinta, each becoming blockbusters by exceeding \$1bn in sales in the year.

## Brilinta

Product Sales of \$1,079m; an increase of 29%.

Emerging Markets sales of Brilinta in the year grew by 19% (21% at CER) to \$224m. Growth in Emerging Markets was reflected in a continued outperformance of growth in the oral anti-platelet market. Encouraging sales performances were delivered in many markets.

US sales of Brilinta, at \$509m, represented an increase of 46% for the full year, including growth of 47% in the quarter. The performance was driven primarily by an increase in the average duration of therapy and strong growth in the number of patients sent home from hospital with Brilinta. Furthermore, Brilinta achieved a record total-prescription market share of 7.2% at the end of the year; days-of-therapy volume market-share data was particularly encouraging. The performance reflected the growth in demand that was partly supported 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 is the standard of care in the treatment of ST-segment elevation myocardial infarction (STEMI) and remained the branded oral anti-platelet market leader in the US in the period. Sales of Brilique in Europe increased by 14% (13% at CER) to \$295m, reflecting indication leadership across a number of markets and bolstered by the inclusion in high-risk, post myocardial infarction (HR PMI) guidelines from the European Society of Cardiology in 2017. Volume share reached 6.5% at the end of the year, with improvements delivered across the major markets; Brilique continued to outperform the oral anti-platelet market in the year. Brilique gained further reimbursement in key markets in its HR PMI indication with the 60mg dose.

#### Farxiga

Product Sales of \$1,074m; an increase of 29% (28% at CER), consolidating its global leadership position within the sodium-glucose co-transporter 2 (SGLT2) inhibitor class.

Emerging Markets sales increased by 74% (73% at CER) to \$232m, reflecting ongoing launches and improved levels of patient access. In March 2017, Forxiga became the first SGLT2-inhibitor medicine to be approved in China. US sales in the year increased by 7% to \$489m. The first-half performance, with a sales decline of 1% to \$206m, was adversely impacted by the Company's level of participation in affordability programmes. Significant changes to the Company's approach to these programmes, however, saw a much-improved performance in the second half, illustrated by Q4 2017 sales growth of 15% to \$150m. SGLT2-class growth was supported by growing evidence around cardiovascular (CV) benefits, including data from the CVD-REAL study that was published in March 2017. Sales in Europe increased by 29% (28% at CER) to \$242m as the medicine continued to gain market share in the innovative oral class; it also retained leadership in the SGLT2 class, which had the strongest class growth amongst innovative oral diabetes medicines in the year. In Japan, where Ono Pharmaceutical Co., Ltd is a partner and records in-market sales, sales to the partner amounted to \$53m, representing a growth of 89% (93% at CER).

## Onglyza

Product Sales of \$611m in the year, a decline of 15% (16% at CER). Onglyza sales, however, grew by 21% in Q4 2017 (19% at CER) to \$180m. The performance in the latter period partly reflected favourable true-up adjustments relating to the first nine months of 2017 in the US, as well as an encouraging performance in Emerging Markets. Given the significant future potential of Farxiga, the Company continues to prioritise its commercial support over Onglyza.

The full-year performance reflected adverse pressures on the dipeptidyl peptidase-4 (DPP-4) class and an acceleration of ongoing Diabetes market dynamics, where patients are moving to medicines and classes of medicines with documented CV benefits.

Sales in Emerging Markets declined by 8% (10% at CER) to \$130m. Onglyza, however, entered the NRDL in China in the year, underpinning Q4 2017 Emerging Markets sales growth of 16% (13% at CER) in the quarter to \$37m. Sales in Europe in the year declined by 21% to \$104m, reflecting the broader dynamic of shift away from the DPP-4 class. In Japan, in-market sales are recorded by Kyowa Hakko Kirin Co., Ltd, to whom sales totalled \$13m.

## Bydureon

Product Sales of \$574m; a decline of 1%, driven by pricing pressures. Favourable sales volumes were a result of continued growth in the glucagon-like peptide-1 (GLP-1) class at the expense of insulin.

Sales of Bydureon in Emerging Markets were \$9m. In 2016, AstraZeneca entered a strategic collaboration with 3SBio for the rights to commercialise Bydureon in China as the Company focused on its oral Diabetes strategy.

Sales in the US declined by 1% to \$458m, reflecting the level of competition and resulting price pressures. US sales in the quarter grew by 1% to \$115m, partly reflecting market growth and the impact of the aforementioned true-up sales adjustments. In the third quarter of the year, the Company successfully launched the injectable suspension autoinjector, known as Bydureon BCise in the US. The new autoinjector is a new formulation of Bydureon injectable suspension in an improved once-weekly, single-dose autoinjector device. It is designed for patient convenience in a pre-filled device with a pre-attached, hidden needle.

Bydureon sales in Europe declined by 12% (11% at CER) in the year to \$88m, resulting from the impact of increased levels of competition.

## Legacy: Crestor

Product Sales of \$2,365m; a decline of 30%.

Sales in China grew by 20% (23% at CER) to \$373m. In the US, sales declined by 70% to \$373m, driven by the market entry in July 2016 of multiple Crestor generic medicines. In the quarter, US sales increased by 34% to \$127m, benefitting from true-up adjustments. In Europe, sales declined by 23% to \$666m; in Q4 2017, Europe sales of Crestor declined by 27% (32% at CER) to \$152m, reflecting the impact of generic medicines in certain markets, such as France and Spain. This impact on Europe sales is anticipated to continue in FY 2018.

In Japan, where Shionogi Co. Ltd is a partner, Crestor maintained its position as the leading statin, despite sales declining by 6% (4% at CER) to \$489m. This decline reflected the recent entry of multiple Crestor competitors in the market in the latter stages of the year.

## RESPIRATORY

Product Sales of \$4,706m; a decline of 1%. Respiratory Product Sales represented 23% of total Product Sales, from 22% in FY 2016.

#### Symbicort

Product Sales of \$2,803m; a decline of 6%. In Q4 2017, sales increased by 2% (stable at CER) to \$752m, partly reflecting the aforementioned favourable true-up adjustments relating to the first nine months of 2017 in the US. 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 9% (10% at CER) to \$439m, partly reflecting growth in China of 13% (17% at CER) to \$177m and in Latin America (ex-Brazil), where sales grew by 24% (30% at CER) to \$46m.

In contrast, US sales declined by 12% to \$1,099m, in line with expectations of continued challenging market 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. Symbicort sales in the US in the quarter grew by 1% to \$288m, driven by market growth, the impact of the aforementioned true-up sales adjustments and increased demand in government and non-retail channels.

In Europe, sales declined by 10% to \$819m, reflecting the level of competition from other branded and Symbicort-analogue medicines. Symbicort, however, continued to retain its class-leadership position and stabilise its

volume market share in the LABA/ICS class.

In Japan, where Astellas Pharma Co. Ltd assists as a promotional partner, sales declined by 3% (stable at CER) to \$205m.

## Pulmicort

Product Sales of \$1,176m; an increase of 11% (12% at CER).

Emerging Markets sales increased by 20% (23% at CER) to \$840m, reflecting strong underlying volume growth, with sales in China, Middle East and North Africa proving particularly encouraging. Emerging Markets represented 71% of global sales and, in the quarter, sales increased by 37% (34% at CER), reflecting a significant level of seasonal demand. Usage in China progressed further, with an increasing prevalence of acute COPD and paediatric asthma accompanied by continued investment by the Company in new hospital nebulisation centres by around 2,000 to 15,000.

Sales in the US and Europe declined by 10% to \$156m and by 7% (8% at CER) to \$92m, respectively.

## Daliresp/Daxas

Product Sales of \$198m; an increase of 29% (28% at CER).

US sales, representing 84% of global sales, increased by 25% to \$167m, driven by increased adoption of the medicine which is the only oral, selective, long-acting inhibitor of the enzyme phosphodiesterase-4, an inflammatory agent in COPD. Sales in Europe increased by 73% to \$26m.

## Tudorza/Eklira

Product Sales of \$150m; a decline of 12%.

Sales in the US declined by 14% to \$66m, reflecting lower levels of use of inhaled monotherapy medicines for COPD and the Company's commercial focus on the launch of Bevespi. 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 and, in the quarter, sales increased by 19% to \$19m. AstraZeneca books Product Sales of Tudorza in the US.

Sales in Europe declined by 12% (11% at CER) to \$73m, impacted by the decline of the overall LAMA monotherapy class.

#### Duaklir

Product Sales of \$79m; an increase of 25%.

Duaklir, the Company's first inhaled dual bronchodilator, is now available for patients in over 25 countries, with almost all sales emanating from Europe. The growth in sales in the year was favourably impacted by the performances in Germany and the UK, as well as the recent launch in Italy. The LAMA/LABA class continued to grow strongly, albeit below expectations. 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 \$16m; launched in early 2017. Q4 2017 sales of \$8m.

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

#### OTHER

Product Sales of \$4,156m; a decline of 18% (17% at CER). Other Product Sales represented 21% of total Product Sales, down from 24% in FY 2016.

#### Nexium

Product Sales of \$1,952m; a decline of 4% (3% at CER).

Emerging Markets sales declined by 1% (up 2% at CER) to \$684m. Sales in the US declined by 10% to \$499m in the year and by 58% in the quarter to \$57m, reflecting a true-up adjustment. Sales in Europe declined by 1% (3% at CER) in the year to \$248m. In Japan, where Daiichi Sankyo is a partner, sales increased by 1% (4% at CER) to \$439m.

#### Synagis

Product Sales of \$687m; an increase of 1%.

US sales decreased by 2% to \$317m, constrained by the guidelines from the American Academy of Pediatrics Committee on Infectious Diseases, which restricted 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 5% to \$370m.

#### Seroquel XR

Product Sales of \$332m; a decline of 55%.

Sales of Seroquel XR in the US, where several competitors launched generic Seroquel XR medicines from November 2016, declined by 66% to \$175m. Sales of Seroquel XR in Europe declined by 42% to \$78m, also reflecting the impact of generic-medicine competition.

#### FluMist/Fluenz

#### Product Sales of \$78m; a decline of 25% (28% at CER).

No US sales of FluMist were recorded in the quarter due to the continued absence of a recommendation for use by the US Advisory Committee on Immunization Practices (ACIP) during the 2017-2018 influenza season. FluMist continues to be recommended for use outside the US. Sales in Europe increased by 17% (12% at CER) to \$76m, driven primarily by higher usage rates in the UK, which reflected the favourable impact of the UK National Immunisation Programme.

	FY 2017			Q4 2017				
	\$m	% of total1	% chan Actual	•	\$m	% of total	% chan Actual	•
Emerging Markets2	6,149	31	6	8	1,630	30	10	9
China	2,955	15	12	15	813	15	33	30
Ex. China	3,194	16	1	2	817	15	(7)	(6)
US	6,169	31	(16)	(16)	1,770	32	9	9
Europe	4,753	24	(6)	(7)	1,293	24	(3)	(9)
Established ROW Japan Canada Other Established ROW	3,081 2,208 484 389	15 11 2 2	- 1 (3) (6)	1 4 (5) (9)	794 563 131 100	14 10 2 2	(4) (5) 4 (7)	- 2 (2) (8)
Total	20,152	100	(5)	(5)	5,487	100	4	3

**Regional Product Sales** 

1Due to rounding, the sum of individual medicine percentages may not agree to totals.

2Emerging Markets comprises all remaining Rest of World markets, including Brazil, China, India, Mexico, Russia and Turkey.

## **Emerging Markets**

Product Sales of \$6,149m; an increase of 6% (8% at CER).

China sales grew by 12% (15% at CER) to \$2,955m, representing 48% of total Emerging Markets sales. Onglyza and Iressa were included on the NRDL in China in the year, as were Brilinta, Faslodex and Seroquel XR; the benefits of this inclusion are anticipated to favourably impact Product Sales after FY 2017. 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. In the quarter, China sales grew strongly by 33% (30% at CER), reflecting strong performances from newly-launched medicines. Tagrisso was launched in China in April 2017. Emerging Markets sales excluding China, however, declined by 7% (6% at CER) in Q4 2017, primarily driven by challenging conditions in Russia and Latin America, as well as the adverse impact of medicines externalised or disposed of in FY 2017. Sales in Latin America (ex-Brazil) declined by 12% (10% at CER) to \$453m. Brazil sales increased by 4% (but declined by 5% at CER) to \$361m. Russia sales declined by 1% (14% at CER) to \$231m. Sales of Symbicort grew by 9% (10% at CER) to \$439m, reflecting higher prescription demand, with notable performances in Latin America and China.

## US

Product Sales of \$6,169m; a decline of 16%. Q4 2017 sales in the US grew by 9% to \$1,770m, partly reflecting favourable true-up adjustments relating to the first nine months of 2017.

The decline in sales in the year 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 12% to \$1,099m.

The New Oncology Growth Platform in the US grew by 50% to \$607m, primarily driven by encouraging Tagrisso sales growth of 59% to \$405m in the year (FY 2016: \$254m). Brilinta sales grew by 46% in the US to \$509m. The New CVMD Growth Platform increased sales by 5% in the US to \$1,942m, reflecting strong performances from Farxiga and Brilinta.

## Europe

#### Product Sales of \$4,753m; a decline of 6% (7% at CER).

The New Oncology Growth Platform in Europe grew by 102% (99% at CER) to \$317m, partly driven by Tagrisso sales of \$187m. Lynparza sales of \$130m represented growth of 60% (58% at CER). Forxiga sales growth of 29% (28% at CER) to \$242m was accompanied by Brilique growth of 14% (13% at CER) to \$295m. These performances were more than offset by declines in other areas, however, including a 10% decline in Symbicort sales to \$819m. Symbicort maintained its position, however, as the number one ICS/LABA medicine, despite competition from branded and analogue medicines. Crestor sales declined by 23% to \$666m, reflecting the entry of generic medicines in certain markets in the year.

#### Established ROW

#### Product Sales of \$3,081m; stable (up 1% at CER).

Japan sales increased by 1% (4% at CER) to \$2,208m. EGFR T790M-mutation testing rates in Japan continued to exceed 90% through the year, with full-year Tagrisso sales of \$219m (FY 2016: \$82m) reflecting a high penetration rate in the currently-approved 2nd-line setting. Faslodex sales in Japan were favourably impacted by a new label in the year; Faslodex sales in Japan increased by 14% (17% at CER) to \$72m.

The first generic competitor to Crestor was launched in Japan in Q3 2017 and further generic competition entered the market in the final quarter. Full-year Crestor sales in Japan declined by 6% (4% at CER) to \$489m; in the quarter, they declined by 26% (21% at CER) to \$95m. Nexium sales in Japan increased by 1% (4% at CER) in the year to \$439m and sales of Forxiga increased by 89% (93% at CER) in the year to \$53m.

#### **Financial Performance**

	Reported FY 2017	1 FY 2016	Actua	1CER
	\$m	\$m	% cha	inge
Total Revenue	22.465	23,002		(2)
Product Sales	20,152		(5)	(5)
Externalisation Revenue	2,313	1,683	37	38
Cost of Sales	(4,318)	(4,126)	5	7
λ.	,	,		
Gross Profit	18,147	18,876	(4)	(4)
Gross Margin*	79.6%	80.8%	-1	-1
Distribution Expense	(310)	(326)	(5)	(3)
% Total Revenue	1.4%	1.4%	-	-
R&D Expense	(5,757)		(2)	(1)
% Total Revenue	25.6%	,	-	-
SG&A Expense	(10,233)	(9,413)	9	10
% Total Revenue	45.5%	40.9%	-5	-5
Other Operating Income and Expense	1,830	1,655	11	11
% Total Revenue	8.1%	7.2%	+1	+1
Operating Profit	3,677	4,902	(25)	(28)
% Total Revenue	16.4%	21.3%	-5	-6
Net Finance Expense	(1,395)	(1,317)	6	(4)
Joint Ventures and Associates	(55)	(33)	66	66
Profit Before Tax	2,227	3,552	(37)	(38)
Taxation	641	(146)		
Tax Rate	(29)%	4%		
Profit After Tax	2,868	3,406	(16)	(16)
Earnings Per Share	\$2.37	\$2.77	(14)	(15)

\*Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales.

FY 2017 Cost of Sales included \$198m of costs relating to externalisation activities, which is excluded from the calculation of Gross Margin (FY 2016: \$32m). Movements in Gross Margin are expressed in percentage points.

	Reported Q4 2017 Q4 2016 Actual CER				
	\$m	\$m	% cha	ange	
Total Revenue	5,777	5,585	3	2	
Product Sales	5,487	5,260	4	3	
Externalisation Revenue	290	325	(11)	(12)	
Cost of Sales	(1,225)	(1,160)	6	2	

١				
Gross Profit	4,552	4,425	3	2
Gross Margin*	77.6%	77.9%	-	-
Distribution Expense	(85)	(83)	3	-
% Total Revenue	1.5%	1.5%	-	-
R&D Expense	(1,551)	(1,543)	-	(2)
% Total Revenue	26.8%	27.6%	+1	+1
SG&A Expense	(3,078)	(1,386)	n/m	n/m
% Total Revenue	53.3%	24.8%	-28	-28
Other Operating Income and Expense	848	1,120	(24)	(25)
% Total Revenue	14.7%	20.1%	-5	-5
Operating Profit	686	2,533	(73)	(71)
% Total Revenue	11.9%	45.4%	-33	-32
Net Finance Expense	(267)	(339)	(21)	(27)
Joint Ventures and Associates	(12)	(11)	19	19
Profit Before Tax	407	2,183	(81)	(78)
Taxation	854	(366)		
Tax Rate	(210)%	17%		
Profit After Tax	1,261	1,817	(31)	(25)
	¢1 02	¢1 4C	$\langle 0 0 \rangle$	( <b>0 1</b> )

Earnings Per Share \$1.03 \$1.46 (29) (24)

\*Gross Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales.

Q4 2017 Cost of Sales included \$2m of income relating to externalisation activities (Q4 2016: \$nil), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

Reconciliation of Reported Profit Before Tax to EBITDA

	FY 2017			Q4 20		
	\$m	% cha	nge	\$m	% cha Actual	nge
	φIII	Actua	CER	φIII	Actual	ICER
Reported Profit Before Tax	2,227	(37)	(38)	407	(81)	(78)
Net Finance Expense	1,395	6	(4)	267	(21)	(27)
Joint Ventures and Associates	55	66	66	12	19	19
Depreciation, Amortisation and Impairment	3,036	29	29	1,107	88	81

EBITDA\*

6,713(8) (10) 1,793(43) (42)

\*EBITDA is a non-GAAP financial measure. See the Operating and Financial Review for a definition of EBITDA.

Reconciliation of Reported to Core Financial Measures

FY 2017	Reported	dRestructurin	Intangible Asset g Amortisation & Impairments	Diabetes Alliance	Other	l Core2	Core Actua	lCER
	\$m	\$m	\$m	\$m	\$m	\$m	% cha	ange
Gross Profit	18,147	181	149	-	-	18,477	(3)	(3)
Gross Margin3	79.6%	-	-	-	-	81.2%	-1	-1
Distribution Expense	(310)	-	-	-	-	(310)	(5)	(3)
R&D Expense	(5,757)	201	144	-	-	(5,412)	)(4)	(3)
SG&A Expense	(10,233)	347	1,469	641	(77)	(7,853)	)(4)	(3)

Other Operating Income and Expense	<sup>1</sup> 1,830	78	45	-	-	1,953 14	14
Operating Profit % Total Revenue	3,677 16.4%	807 -	1,807 -	641 -	(77) -	6,855 2 30.5% +1	- +1
Net Finance Expense	(1,395)	-	-	313	432	(650) (2)	(4)
Taxation	641	(169)	(453)	(198)	(681)	(860) 31	23
Earnings Per Share	\$2.37	\$0.50	\$1.07	\$0.60	\$(0.26	5)\$4.28 (1)	(2)

10ther adjustments include fair value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4), provision charges related to certain legal matters (see Note 5), foreign-exchange gains and losses relating to the classification of certain non-structural intra-group loans and a one-off adjustment of \$617m reflecting adjustments to deferred taxes in line with the recently reduced US federal income tax rate.

2Each of the measures in the Core column in the above table are non-GAAP financial measures. See the Operating and Financial Review for related definitions.

3Gross Margin, as a percentage of Product Sales, reflects gross profit derived from Product Sales, divided by Product Sales. FY 2017 Cost of Sales included \$198m of costs relating to externalisation activities (FY 2016: \$32m), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

Q4 2017	Reporte	dRestructurin	Intangible Asset gAmortisation & Impairments	Diabetes Alliance	Other	Core2	Core Actua	lCER
	\$m	\$m	\$m	\$m	\$m	\$m	% cha	inge
Gross Profit	4,552	53	46	-	-	4,651	3	3
Gross Margin3	77.6%	-	-	-	-	79.4%	-	+1
Distribution Expense	(85)	-	-	-	-	(85)	3	-
R&D Expense	(1,551)	24	71	-	-	(1,456)	)(2)	(4)
SG&A Expense	(3,078)	82	696	406	(281)	(2,175)	)6	5
Other Operating Income and Expense	<sup>1</sup> 848	3	1	-	-	852	(25)	(26)
Operating Profit % Total Revenue	686 11.9%	162 -	814 -	406 -	(281)	1,787 30.9%	· /	(11) -5
Net Finance Expense	(267)	-	-	79	64	(124)	(28)	(31)
Taxation	854	(34)	(213)	(54)	(595)	(42)	(87)	(100)
Earnings Per Share	\$1.03	\$0.10	\$0.48	\$0.34	\$(0.65	)\$1.30	7	13

10ther adjustments include fair value adjustments relating to contingent consideration on business combinations (see Note 4), discount unwind on acquisition-related liabilities (see Note 4), provision charges related to certain legal matters (see Note 5), foreign-exchange gains and losses relating to the classification of certain non-structural intra-group loans and a one-off adjustment of \$617m reflecting adjustments to deferred taxes in line with the recently reduced US federal income tax rate.

2Each of the measures in the Core column in the above table are non-GAAP financial measures. See the Operating and Financial Review for related definitions.

3Gross Margin, as a percentage of Product Sales, reflects gross profit derived from Product Sales, divided by Product Sales. Q4 2017 Cost of Sales included \$2m of income relating to externalisation activities (Q4 2016: \$nil), which is excluded from the calculation of Gross Margin. Movements in Gross Margin are expressed in percentage points.

Profit and Loss Commentary for the Year

#### Gross Profit

Reported Gross Profit declined by 4% to \$18,147m; Core Gross Profit declined by 3% to \$18,477m, one percentage point more than the Total Revenue decline. Externalisation Revenue of \$2,313m included \$1,247m received as part of the Lynparza and selumetinib collaboration with MSD. This was outweighed by the adverse impact of product mix, the ramp-up of manufacturing capacity for new medicines and the inclusion of the profit-share on the aforementioned collaboration.

The calculation of Reported and Core Gross Margin excludes the impact of Externalisation Revenue, thereby reflecting the underlying performance of Product Sales. The Reported Gross Margin declined by one percentage point to 79.6%. The Core Gross Margin declined by one percentage point to 81.2%. The declines were primarily driven by the effect of losses of exclusivity on higher-margin Crestor and Seroquel XR, as well as the factors mentioned above. In the quarter, the Reported Gross Margin was stable at 77.6%; the Core Gross Margin was stable (increased by one percentage point at CER) to 79.4%.

## Operating Expenses: R&D

Reported R&D costs declined by 2% (1% at CER) to \$5,757m, with the Company continuing to focus on resource prioritisation and cost discipline. Core R&D costs declined by 4% (3% at CER) to \$5,412m. The movement vs. the prior year was in line with commitments made in February 2017.

#### Operating Expenses: SG&A

Reported SG&A costs increased by 9% (10% at CER) to \$10,233m in the year and by 122% (119% at CER) to \$3,078m in the quarter. This reflected the impact of fair-value adjustments to contingent consideration on business combinations in the comparative period and, to a lesser extent, impairment charges recorded in the quarter. Core SG&A costs declined by 4% (3% at CER) to \$7,853m. This was in line with commitments made in February 2017 and despite strategic investment in new launches.

Core SG&A costs in the quarter increased by 6% (5% at CER) to \$2,175m. This reflected the aforementioned increased investment, including in medical-affairs capability and capacity in order to support the launches and early-stage commercialisation phases of specialty-care medicines such as Tagrisso, Imfinzi, Lynparza and Fasenra. SG&A general infrastructure costs declined in the quarter as the Company maintained its focus on cost discipline. The Company booked a one-time gain of \$92m in the quarter following adjustments to its retirement benefit plans in the US.

In the year, the Company continued to consolidate its operations that support the business. It is committed to driving simplification and standardisation through targeted centralisation of back and middle office activities that are currently performed in various enabling units, including Finance, Compliance, HR, Procurement and IT. As a result, underlying operational-infrastructure costs were consistently reduced, in line with prior trends. The recently-launched Global Business Services organisation provides integration of governance, locations and business practices to 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 11% in the year to \$1,830m and included:

\$555m resulting from the sale of remaining rights to the anaesthetics portfolio to Aspen

\$301m resulting from the sale of rights to Seloken in Europe to Recordati S.p.A (Recordati)

\$175m of milestone receipts in relation to the disposal of Zavicefta to Pfizer Inc.

\$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 Other gains on disposal of intangible assets

Core Other Operating Income and Expense increased by 14% to \$1,953m, 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 declined by 25% (28% at CER) in the year to \$3,677m. In the quarter, Reported Operating Profit declined by 73% (71% at CER) to \$686m, driven by higher Other Operating Income and Expense in Q4 2016. The Reported Operating Profit margin declined by five percentage points (six percentage points at CER) to 16% of Total Revenue. Core Operating Profit increased by 2% (stable at CER) to \$6,855m. The Core Operating Profit margin increased by one percentage point to 31% of Total Revenue.

## Brexit Planning

Following the UK referendum outcome of a decision for the UK to leave the European Union (EU) in June 2016, the progress of current negotiations between the UK Government and the EU will likely determine the future terms of the UK's relationship with the EU, as well as to what extent the UK will be able to continue to benefit from the EU's single market and its regulatory frameworks.

In response to this, the Company has taken the decision to implement certain actions to mitigate the potential risk of disruption to the supply of medicines including but not limited to duplication of release testing and procedures for products based in the EU27 and the UK, transfer of regulatory licenses, customs and duties set up for introduction or amendment of existing tariffs or processes and associated IT systems upgrades. The costs associated with this and certain other actions directly related to Brexit will be charged as restructuring with the majority of such costs expected to be cash costs. However, until the Brexit negotiation process is completed, it is difficult to anticipate the overall potential impact on AstraZeneca's operations and hence the final expected costs to be incurred.

## Net Finance Expense

Reported Net Finance Expense increased by 6% in the year to \$1,395m, primarily reflecting a foreign-exchange impact relating to the classification of certain non-structural intra-group loans. Reported Net Finance Expense declined by 4% at CER, reflecting reduced levels of discount unwind on acquisition-related liabilities resulting from the diabetes alliance with Bristol-Myers Squibb Company (BMS). Excluding the discount unwind on acquisition-related liabilities and the adverse foreign-exchange impact, the Core Net Finance Expense declined by 2% (4% at CER) to \$650m.

#### Profit Before Tax

Reported Profit Before Tax declined by 37% (38% at CER) to \$2,227m, reflecting the lower Reported Gross Margin and an increase in Reported SG&A costs. EBITDA declined by 8% (10% at CER) to \$6,713m. Taxation

The Reported Tax Rate of (29)% in the year benefitted from a favourable net adjustment of \$617m to deferred taxes, reflecting the recently reduced US federal income tax rate and non-taxable remeasurements of acquisition-related liabilities. Additionally, there was a \$321m benefit in the final quarter to the Reported and Core Tax Rates, reflecting:

reductions in tax provisions and provision to return adjustments, reflecting:

- the expiry of statute of limitations

- favourable progress of discussions with tax authorities

the recognition of previously unrecognised tax losses

the favourable impact of UK Patent box profits

The Core Tax Rate for the year was 14%. Excluding these benefits, both the Reported and Core Tax Rates would have been 22%. The net cash tax paid for the year was \$454m, representing 20% of Reported Profit Before Tax. The Reported and Core Tax Rates for the comparative period were 4% and 11% 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 period from 2004-2016. Excluding this effect, the Reported and Core Tax Rates for the comparative period were 17% and 18% respectively. The cash tax paid for the comparative period was \$412m, which was 12% of Reported Profit Before Tax. Earnings Per Share (EPS)

Reported EPS of \$2.37 represented a decline of 14% (15% at CER) in the year. The performance was driven by a decline in Total Revenue and increased SG&A costs, partly offset by the aforementioned net tax benefit, continued progress on R&D cost control and an increase in Other Operating Income and Expense. Core EPS declined by 1% (2% at CER) to \$4.28.

Dividend Per Share and Dividend Commitment

The Board has declared a second interim dividend of \$1.90 per share (133.6 pence, 14.97 SEK) bringing the dividend per share for the full year to \$2.80 (202.5 pence, 22.37 SEK). The Board reaffirms its commitment to the Company's progressive dividend policy.

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

Cash Flow and Balance Sheet Cash Flow

	FY 2017 FY 2016 Difference		
	\$m	\$m	\$m
Reported operating profit	3,677	4,902	(1,225)
Depreciation, amortisation and impairment	3,036	2,357	679
(Increase)/decrease in working capital and short-term provisions	(50)	926	(976)
(Gains)/losses on disposal of intangible assets	(1,518)	(1,301)	(217)
Fair value movement on contingent consideration arising from business combinations	109	(1,158)	1,267
Non-cash and other movements	(524)	(492)	(32)
Interest paid	(698)	(677)	(21)
Tax paid	(454)	(412)	(42)
Net cash inflow from operating activities	3,578	4,145	(567)

The Company generated a net cash inflow from operating activities of \$3,578m in the year, compared with \$4,145m in FY 2016. 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.

Net cash outflows from investing activities were \$2,328m in the year compared with \$3,969m in FY 2016. In the final quarter, \$1.5bn was paid to shareholders of Acerta Pharma B.V. (Acerta Pharma), a contractual obligation triggered by the first regulatory approval for Calquence. 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 BMS share of the global Diabetes alliance amounted to \$284m in the year, which included a \$100m milestone payment in respect of Qtern and royalty payments.

Net cash outflows from financing activities were \$2,936m in the year compared to \$1,324m in FY 2016, as the Company repaid a loan falling due.

**Capital Expenditure** 

Capital expenditure amounted to \$1,326m in the year, 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 31 Dec 20	17 At 31 Dec 2016
	\$m	\$m
Cash and cash equivalents	3,324	5,018
Other investments	1,300	898

Net derivatives	504	235
Cash, short-term investments and derivatives	5,128	6,151
Overdrafts and short-term borrowings	(845)	(451)
Finance leases	(5)	(93)
Current instalments of loans	(1,397)	(1,769)
Loans due after one year	(15,560)	(14,495)
Interest-bearing loans and borrowings (gross debt)	(17,807)	(16,808)
Net Debt	(12,679)	(10,657)

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		Impact Of 5%	Strengthening in
		Rates vs.	USD		Exchange Rat	te vs. USD (\$m)1
Currency	Primary Relevance	FY 2017	YTD 20182	% change	Product Sales	Core Operating Profit
EUR	Product Sales	0.89	0.82	+8	+160	+93
JPY	Product Sales	112.18	111.07	+1	+117	+82
CNY	Product Sales	6.75	6.43	+5	+146	+75
SEK	Costs	8.54	8.06	+6	+5	-44
GBP	Costs	0.78	0.73	+7	+23	-46
Other3					+193	+97
	1Based on 2017 re	sults at 2	017 actual ex	change rat	es	

1Based on 2017 results at 2017 actual exchange rates. 2Based on average daily spot rates between 1 January and 31 January 2018.

30ther important currencies include AUD, BRL, CAD, KRW and RUB.

#### Foreign-Exchange Hedging

The Group's transactional currency exposures on working-capital balances, which typically extend for up to three months, are hedged where practicable using forward foreign-exchange contracts against the individual Group Companies' reporting currency. In addition, the Group's external dividend payments, paid principally in pounds sterling and Swedish krona, are fully hedged from announcement to payment date. Foreign-exchange gains and losses on forward contracts for transactional hedging are taken to profit.

Corporate and Business Development Update

On 20 December 2017, it was announced by ANI Pharmaceuticals, Inc. that it had acquired the rights to market Atacand, Arimidex and Casodex from AstraZeneca for \$47m in cash upfront, recorded as Other Operating Income and Expense in the Company's financial statements in the quarter. AstraZeneca will receive future royalties and sales-based milestones.

Research and Development Update

comprehensive table comprising AstraZeneca's pipeline of medicines in human trials can be found later in this document. Highlights of developments in the Company's late-stage pipeline since the prior results announcement are shown below:

**Regulatory Approvals** 

Regulatory Submissions and/or Acceptances

Major Phase III Data Readouts and Developments

New Molecular Entities(NMEs) in Phase III Trials or Under Regulatory Review and Major Lifecycle Medicines

-Faslodex - breast cancer (combinations) (US, EU) Lynparza - ovarian cancer (JP) -7 - Lynparza - breast cancer (US) - Fasenra - severe, uncontrolled asthma (US, EU, JP) Tagrisso - lung cancer (1st line) (US -Priority Review, EU, JP) 4 ZS-9 - hyperkalaemia (US) Lynparza - ovarian cancer: Priority review (CN) roxadustat - anaemia: Priority review (CN) -\_ PT010 - COPD (KRONOS trial): Most 4 primary endpoints met1 tezepelumab - severe, uncontrolled asthma: First patient commenced dosing Oncology Lynparza - multiple cancers2 -Tagrisso - lung cancer2 Imfinzi - multiple cancers2 -Calquence - blood cancers Imfinzi + treme - multiple cancers moxetumomab pasudotox - leukaemia selumetinib - thyroid cancer savolitinib - kidney cancer \_ **CVMD** ZS-9 (sodium zirconium cyclosilicate) -15 hyperkalaemia2 roxadustat - anaemia2 -Respiratory Fasenra - COPD PT010 - COPD, asthma

- tezepelumab - severe, uncontrolled asthma

#### Other

132

- anifrolumab lupus
- lanabecestat Alzheimer's disease

Projects in Clinical Pipeline

1Eight of the nine primary endpoints in the KRONOS trial were met, including two non-inferiority endpoints to qualify PT009, one of the comparators

2Under Regulatory Review. The table shown above as at today.

#### 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 the treatment of lung, ovarian, breast and blood cancers, as one of AstraZeneca's Growth Platforms.

During the period, the Company presented Lynparza data at the San Antonio Breast Cancer annual symposium; highlights included data from the MEDIOLA combination trial (Lynparza + Imfinzi) and the Asian-cohort data from the OlympiAD Lynparza metastatic breast-cancer trial. The Company also presented data from the new and emerging haematology portfolio at the American Society of Hematology (ASH) annual meeting; highlights included Calquence data in several cancer types, including MCL and chronic lymphocytic leukaemia (CLL). a) Faslodex (breast cancer)

On 13 November 2017, the Company announced that the European Medicines Agency (EMA) had approved a new indication for Faslodex in Europe in combination with a CDK4/6 inhibitor, palbociclib, for the treatment of hormone receptor-positive (HR+), human epidermal growth factor receptor 2 negative (HER2-), locally-advanced or metastatic breast cancer in patients who have received prior endocrine therapy.

On 14 November 2017, the Company announced that the US FDA had approved a new indication for Faslodex, expanding the indication to include use with abemaciclib, a CDK4/6 inhibitor, for the treatment of HR+, HER2advanced or metastatic breast cancer in patients with disease progression after endocrine therapy. b) Lynparza (multiple cancers)

On 12 January 2018, the Company announced that the US FDA had approved Lynparza for use in patients with deleterious or suspected deleterious germline BRCA (gBRCA)-mutated HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. The approval was based on data from the randomised, open-label, Phase III OlympiAD trial, which investigated Lynparza vs. physician's choice of chemotherapy (capecitabine, eribulin or vinorelbine). In the trial, Lynparza significantly prolonged progression-free survival (PFS) compared with chemotherapy and reduced the risk of disease progression or death by 42% (Hazard Ratio (HR) 0.58; median PFS of 7.0 vs 4.2 months).

On 19 January 2018, AstraZeneca and MSD announced that the Japanese Ministry of Health, Labour and Welfare had approved Lynparza tablets (300mg twice daily) for use in patients as a maintenance therapy for platinum-sensitive relapsed ovarian cancer, regardless of their BRCA mutation status, who are in response to their last platinum-based chemotherapy. Lynparza was the first PARP inhibitor to be approved in Japan. During the period, the Company also received priority review status for Lynparza in platinum-sensitive relapsed ovarian cancer from the China FDA. During the period, the Company presented an analysis of the comparison in endpoints from the Phase III trials of Lynparza and niraparib in patients with platinum-sensitive, relapsed germline BRCA (gBRCA)-mutated ovarian cancer at the International Society for PharmacoEconomics and Outcomes Research European Congress. Lynparza and niraparib are PARP inhibitors.

A key summary of the efficacy and tolerability measures are detailed in the table below, which includes an investigator-assessed 14.8 months of median PFS (mPFS) for niraparib in gBRCA patients: Efficacy - platinum-sensitive, relapsed gBRCA-mutated ovarian cancer

PARP inhibitor	Trial	HR and mPFS (Independent Review Committee)	HR and mPFS (Investigator Assessed)	HR (median time to first subsequent therapy or death)
Lynparza 300mg	SOLO-2 (Lynparza vs.	0.25	0.30	0.28
tablets, bid1	placebo)	30.2m vs. 5.5m	19.1m vs. 5.5m	27.9m vs. 7.1m
niraparib 300mg	NOVA	0.27	0.27	0.31
capsules, qd2	(niraparib vs. placebo)	21.0m vs. 5.5m	14.8m vs. 5.5m	21.0m vs. 8.4m
1bid = twi	ce daily.			

2qd = once daily. Hettle, et al., ISPOR 20th Annual European Congress, November 2017

Safety - platinum-sensitive, relapsed gBRCA-mutated ovarian cancer

PARP inhibitor	Trial	Grade 3-4 adverse event % (PARP inhibitor vs. placebo)	Treatment interruption % (PARP inhibitor vs. placebo)	Dose reduction % (PARP inhibitor vs. placebo)	Drug discontinuation % (PARP inhibitor vs. placebo)
Lynparza 300mg tablets, bid	SOLO-2 (Lynparza vs. placebo)	36.9 vs. 18.2	45.1 vs. 18.2	25.1 vs. 3.0	10.8 vs. 2.0
niraparib 300mg capsules, qd	NOVA (niraparib vs. placebo)	74.1 vs. 22.9	68.9 vs. 5.0	66.5 vs. 15.5	14.7 vs. 2.2

Hettle, et al., ISPOR 20th Annual European Congress, November 2017

The Company also presented an update on an Asian cohort from the Phase III OlympiAD trial of Lynparza in HER2-negative, gBRCA-mutated metastatic breast-cancer patients. Data from the 87 Asian patients demonstrated that PFS was prolonged in patients receiving Lynparza compared with those treated with physician's choice treatment (median value of 5.7 months vs. 4.2 months, HR 0.53). The findings demonstrated that Lynparza is generally well tolerated in Asian patients and provides a clinically-meaningful PFS benefit compared with physician's choice treatment. Efficacy and safety profiles were generally consistent with those seen in the global population.

Updated data from the gBRCAm HER2-negative metastatic breast-cancer cohort of the MEDIOLA Phase II basket trial of Lynparza and Imfinzi were also presented: 20 patients (80%) had disease control (comprising complete response, partial response and stable disease) at 12 weeks (primary efficacy endpoint) and 12 patients (48%) at 28 weeks (secondary endpoint). The combination was well tolerated and the 12-week disease control rate (80%) exceeded the pre-specified target. The data supported the hypothesis that the addition of Imfinzi may enhance the efficacy of Lynparza monotherapy. Ongoing key Lynparza combination trials include:

Name	Phas	Entreatment	Population	Design	Timelines	Status
				Lynparza maintenance +	FPCD2 Q2 2015	
PAOLA1	III	1st line	Ovarian cancer	bevacizumab vs. bevacizumab maintenance	First data anticipated 2022	Recruitment ongoing
			gBRCA-mutated ovarian cancer 2nd line			
						Recruitment ongoing
MEDIOLA	A I/II	Advanced	gBRCA-mutated HER2-negative breast cancer (1st to 3rd line) Small cell lung cancer (SCLC)	Lynparza + Imfinzi	FPCD Q2 2016	Initial data from lung and breast cancer cohorts presented in 2017
VIOLETT	EII	Advanced	(2nd line) Gastric cancer (2nd line) Triple-negative breast cancer:	Lynparza + ATR (AZD6738)	FPCD Q4 2017	Recruitment ongoing

-HRRm3 (BRCA)

			-HRRm (Non-BRCA) -Non-HRRm	Lynparza + Wee1 (AZD1775)		
				Lynparza	FPCD	
Study 8	Π	Advanced	Metastatic castration resistant prostate cancer	Lynparza + abiraterone vs. abiraterone	Q3 2014 LPCD4 Q3 2015	Recruitment complete
	11Co	onducted by t	he ARCAGY/Groupe d'Inv	estigateurs National	des Etudes des	Cancers Ovariens et du
sein	3Hoi	mologous Re	nmenced Dosing combination Repair mutate nmenced Dosing	d		

#### c) Tagrisso (lung cancer)

On 18 December 2017, the Company announced that the US FDA had accepted a supplemental New Drug Application (sNDA) for the use of Tagrisso in the 1st-line treatment of patients with metastatic NSCLC whose tumours have EGFR mutations (exon 19 deletions or exon 21 (L858R) substitution mutations). The application was based on data from the Phase III FLAURA trial, which showed that Tagrisso significantly improves PFS compared to current 1st-line EGFR tyrosine kinase inhibitors, erlotinib or gefitinib, in previously-untreated patients with locally-advanced or metastatic EGFR-mutated NSCLC. The US FDA granted Tagrisso Priority Review status in 2017 and previously granted Breakthrough Therapy Designation in the 1st-line treatment of patients with metastatic EGFR-mutated NSCLC.

On 28 November 2017, the Company announced that the EMA had accepted a variation to the Marketing Authorisation Application for Tagrisso. The application was in line with the aforementioned US application. On 27 November 2017, the Company announced the submission of a sNDA to Japan's Pharmaceuticals and Medical Devices Agency for the use of Tagrisso for the 1st-line treatment of patients with inoperable or recurrent EGFR-mutated NSCLC.

#### 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

In November 2017, the Company presented further data at the European Society For Medical Oncology meeting in Singapore in respect of the PACIFIC Phase III trial, including clinical activity, patient-reported outcomes and safety data regarding sequential treatment with Imfinzi in patients with locally-advanced, unresectable NSCLC, who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy. The analysis demonstrated a PFS improvement across all pre-specified subgroups and the incidence of new lesions, including new brain metastases, was lower with Imfinzi vs. placebo.

During the period, the Brazil Health Regulatory Agency granted Imfinzi an expedited review, based on the PACIFIC trial data, as a sequential treatment in patients with locally-advanced, unresectable NSCLC, who had not progressed following standard platinum-based chemotherapy concurrent with radiation therapy. The Republic of Korea Ministry of Food and Drug Safety also accepted the marketing authorisation application of Imfinzi, based on the aforementioned PACIFIC trial data.

Ongoing key lung cancer late-stage trials include:

Name	Phase Line of Treatment	Population	Design	Timelines	Status
------	-------------------------	------------	--------	-----------	--------

Monotherapy						
ADJUVANT	I III	N/A	Stage Ib-IIIa NSCLC	Imfinzi vs placebo	FPCD Q1 2015 First data anticipated 2020 FPCD	Recruitment ongoing
PACIFIC	ш	N/A	Locally-advanced, unresectable NSCLC	Imfinzi vs placebo	Q2 2014 LPCD Q2 2016 OS2 data anticipated 2019	Recruitment completed PFS primary endpoint met
PEARL	III	1st line	NSCLC (Asia)	Imfinzi vs SoC3 chemotherapy	FPCD Q1 2017 First data anticipated 2020	Recruitment ongoing
Combination	therapy	у	Locally-advanced,	Imfinzi + epacadostat vs	First data	Recruitment
PACIFIC-3	III	N/A	unresectable NSCLC	Imfinzi	anticipated 2021	
MYSTIC	III	1st line	NSCLC	Imfinzi, Imfinzi + treme v	FPCD Q3 2015 LPCD Q3 2016	Recruitment completed
				SoC chemotherapy	Final OS data anticipated H1 2018 FPCD Q4 2015	PFS primary endpoint not met
NEPTUNE	III	1st line	NSCLC	Imfinzi + treme vs SoC chemotherapy	LPCD Q2 2017	Recruitment completed
					First data anticipated H2 2018 FPCD	
POSEIDON	III	1st line	NSCLC	Imfinzi + SoC, Imfinzi + treme + SoC vs SoC	Q2 2017	Recruitment ongoing
				chemotherapy	First data anticipated 2019	ongoing
ARCTIC	III	3rd line	PDL1- low/neg. NSCLC	Imfinzi, tremelimumab, Imfinzi + treme vs SoC chemotherapy	FPCD Q2 2015	Recruitment completed
					LPCD Q3 2016	

CASPIAN	III	1st line	Small-cell lung cancer	Imfinzi + SoC, Imfinzi + treme + SoC vs SoC chemotherapy	First data anticipated H1 2018 FPCD Q1 2017 First data	Recruitment ongoing
				enemotierapy	anticipated 2019	
100	nducte	ed by the Nati	ional Cancer Institute of (	Tanada		

1Conducted by the National Cancer Institute of Canada 2Overall survival 3Standard of care

#### Other Cancers

During the period, the Brazil Health Regulatory Agency granted approval to Imfinzi for the treatment of patients with locally-advanced or metastatic bladder cancer who have suffered disease progression during or following platinum-containing chemotherapy or who have suffered disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. The regulatory decision was the fastest-ever immuno-oncology approval in Brazil. Imfinzi's approval, based on Phase Ib/II clinical-trial data, was received only 10 months after submission, reflecting the importance of a new treatment option for patients and compelling clinical data. Ongoing key trials are listed below:

Name	Phas	Line of Treatment	Population	Design	Timelines	Status
					FPCD Q4 2015	
DANUBE	III	1st line	Cisplatin chemotherapy- eligible/ ineligible bladder cancer	Imfinzi, Imfinzi + treme vs SoC chemotherapy	LPCD Q1 2017	Recruitment completed
					First data anticipated 2019 FPCD Q4 2015	
KESTREL	III	1st line	Head and neck squamous cell carcinoma (HNSCC, head and neck cancer)	Imfinzi, Imfinzi + treme vs SoC	LPCD Q1 2017	Recruitment completed
					First data anticipated H1 2018 FPCD Q4 2015	
EAGLE	III	2nd line	HNSCC	Imfinzi, Imfinzi + treme vs SoC	LPCD Q3 2017	Recruitment completed
	A 111	1 of line			First data anticipated H1 2018	
HIMALAY	AIII	1st line			FPCD	

hepatocellular carcinoma (HCC, liver cancer)

Imfinzi, Imfinzi + treme Q4 2017 (two dosing regimens) vs sorafenib

Recruitment ongoing

First data anticipated 2020

During the period, it was confirmed that the FUSION programme, conducted by Celgene Corporation (Celgene), will not enrol further patients in the clinical trials in multiple myeloma (MM) (MM-001, MM-002, MM-003, and MM-005). This update followed an announcement in September 2017 that Celgene had been informed that the US FDA had placed a partial clinical hold on five trials and a full clinical hold on one trial in the programme. The trials were testing Imfinzi in combination with immunomodulatory agents such as lenalidomide, with or without chemotherapy, in blood cancers such as MM, CLL and lymphoma. Two ongoing Company trials of Imfinzi in myelodysplastic syndrome (MDS) and diffuse large B-cell lymphoma (DLBCL) will continue as planned. The MDS-001 trial, that has separate cohorts for newly-diagnosed acute myeloid leukaemia and MDS patients, has completed enrolment and will continue as planned. The DLBCL-001 trial will continue to enrol, with all patients receiving Imfinzi + R-CHOP, a chemotherapy treatment using rituximab.

e) Calquence (blood cancer)

Following the US FDA accelerated approval of Calquence on 31 October 2017, AstraZeneca presented data from MCL and CLL clinical trials at the aforementioned ASH meeting. Results were presented in MCL from the open-label, single-arm Phase II ACE-LY-004 clinical trial, which served as the basis for the approval. The data demonstrated an objective response rate of 81%, with a complete response rate of 40%.

Efficacy measure	Patients (percent response)
Objective response rate	81%
(Complete response + partial response)	
Complete response	40%
Partial response	41%
Stable disease	9%
Progressive disease	8%
Not evaluable	2%

The data shown in the table above are as per the 2014 Lugano classification response criteria for non-Hodgkin lymphoma; high concordance was observed between investigator-assessed and independent review committee-assessed overall response and complete response rates, respectively.

In CLL, data from the Phase Ib/II ACE-CL-003 clinical trial and updated results from the Phase I/II ACE-CL-001 clinical trial that are testing Calquence in combination and alone for the treatment of CLL in multiple treatment settings were also presented. In the ACE-CL-003 trial, the combination of Calquence and obinutuzumab demonstrated an objective response rate (the primary endpoint) of 95% for the 19 patients in the treatment-naïve cohort and 92% in the 26 patients with relapsed or refractory CLL. Additionally, the complete response rate was 16% for treatment-naïve patients and 8% for previously-treated patients. Longer-term safety follow-up of the Calquence monotherapy ACE-CL-001 trial was also presented where safety (primary endpoint) and efficacy (secondary endpoint) data of the full-trial cohort of 134 patients with relapsed or refractory CLL was shown, with a median time on trial and follow-up of 24.5 months.

#### **CVMD**

CV and metabolic diseases (CVMD) 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 co-morbidities 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, by modifying or even halting 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) Brilinta (CV disease)

In the period, the Company announced the initiation of a new Brilinta outcomes trial, THALES; the decision to initiate another stroke trial followed the encouraging trend data seen in the prior SOCRATES trial. The THALES trial will evaluate the safety and efficacy of 30-day treatment with Brilinta vs. placebo, both in addition to aspirin, for reducing stroke and death in patients who have already suffered an acute ischaemic stroke or high-risk transient ischaemic attack in the preceding 24 hours. During the period, the first patient was dosed in the THALES trial. b) Farxiga (diabetes)

During the period, top-line results from the ongoing DEPICT clinical programme, exploring the use of Farxiga in type-1 diabetes, became available in-house. These results from the DEPICT-1 52-week and DEPICT-2 24-week trial data demonstrated significant and clinically-relevant reductions from baseline in HbA1c, weight reductions and lowered total daily insulin dosing, compared to placebo at both the 5mg and 10mg dose. The safety profile of Farxiga in the DEPICT-1 52 week and DEPICT-2 24 week trials was similar to the known safety profile of Farxiga in patients with type-2 diabetes, with the exception of a higher proportion of diabetic ketoacidosis (DKA) events in Farxiga-treated patients vs. placebo within these type-1 diabetes trials. Further analysis of the data is required, along with the 52 week results of the DEPICT-2 trial.

During the period, the Company also received top-line results for DERIVE, a trial designed to evaluate the glycemic efficacy and renal safety of Farxiga in patients with type-2 diabetes and moderate renal impairment who have inadequate glycaemic control. The top-line results showed that, in patients with type-2 diabetes and chronic kidney disease (CKD) stage 3A, treatment with Farxiga for 24 weeks resulted in clinically-relevant and

statistically-significant improvements in glycemic control. Farxiga was well tolerated, with no imbalances in adverse events (AEs) or serious adverse events or no new safety signals in the overall safety summary. Specifically, there were no AEs of hypoglycaemia, DKA or fractures reported in the trial. As these were the initial data, additional sensitivity analyses and safety evaluations are being conducted.

c) Bydureon (type-2 diabetes)

In the period, the EMA approved the use of Bydureon with basal insulin based on the results of the DURATION-7 clinical trial. The decision followed a positive recommendation in October 2017 from the Committee for Medicinal Products for Human Use (CHMP). The DURATION-7 trial assessed the efficacy and safety of Bydureon vs. placebo when added to titrated basal insulin with or without metformin in patients with uncontrolled type-2 diabetes over 28 weeks.

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

During the period, the US FDA accepted the Class II regulatory resubmission for ZS-9 following the progress the Company has made in addressing the deficiencies identified during previous inspections of the dedicated manufacturing facility in Texas.

During the period, the CHMP reiterated its previous positive opinion and recommended the granting of a marketing authorisation for ZS-9 in the EU, for the treatment of hyperkalaemia. A positive opinion was provided in February 2017; the opinion was, however, suspended following concerns relating to the aforementioned manufacturing deficiencies. On the basis of recent inspection findings, the Committee reiterated its original opinion in January 2018.

#### e) Roxadustat (anaemia)

During the period, the Company and its partner FibroGen Inc. (Fibrogen) announced that roxadustat was granted priority review by the China FDA. The Company anticipates a regulatory decision in H2 2018 based on the data from two Fibrogen-led Phase III trials, conducted in China, that met their primary efficacy endpoints in January 2017. If approved, roxadustat will be a first-in-class medicine, with China being the first approval country, ahead of other major markets.

Major Ongoing Cardiovascular Outcomes Trials

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

MedicineTrial	Mechanism	Population	Primary Endpoint	Timeline
Farxiga DECLARE	SGLT2 inhibitor	c.17,0001 patients with type-2 diabetes	Time to first occurrence of CV death, non-fatal myocardial infarction (MI) or non-fatal stroke	Data anticipated H2 2018 (final analysis)
Farxiga DAPA-HF	SGLT2 inhibitor	c.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 Data anticipated 2019
Farxiga DAPA-CKI	SGLT2 inhibitor	c.4,000 patients with 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	c.19,000 patients with type-2 diabetes and coronary artery disease without a history of MI or stroke	h Composite of CV death, non-fatal MI and non-fatal stroke	Data anticipated 2019
Epanova STRENGT	acids		<sup>h</sup> Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	2019

11ncludes c.10,000 patients who have had no prior index event and c.7,000 patients who have suffered an index event.

2Estimated Glomerular Filtration Rate.

3End-Stage Renal Disease.

#### RESPIRATORY

AstraZeneca's Respiratory focus 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; of these, Bevespi and Fasenra are already benefitting patients. 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 Delivery Technology, a focus of AstraZeneca's future-platform development for respiratory-disease combination therapies. a) Symbicort (asthma)

During the period, the US FDA approved updates to the Symbicort labelling, including removal of the boxed warning for Symbicort and other ICS/LABA medicines for serious asthma-related outcomes. The update followed a 2011 post-marketing requirement from the US FDA, which required all manufacturers of LABA medicines to further evaluate their safety when used in combination with ICS for the treatment of asthma. The agency analysed four clinical trials involving over 42,000 patients and the results did not show a significant increase in the risk of serious asthma-related events (hospitalisation, intubations and death) with an ICS/LABA fixed-dose combination, compared with ICS alone.

b) Tudorza (COPD)

On 4 December 2017, AstraZeneca announced positive top-line results of the Phase IV ASCENT trial for Tudorza, a long-acting muscarinic antagonist (LAMA), in patients with moderate to very severe COPD, with a history of CV disease and/or significant CV risk factors.

The US FDA required data from the ASCENT trial as a post-marketing requirement to evaluate major adverse CV events for up to three years with aclidinium bromide, the active ingredient in Tudorza. The trial included more than 3,600 patients from Canada and the US and demonstrated a reduction in exacerbations and CV safety. A full analysis of the data is ongoing and results will be presented at a forthcoming medical meeting. AstraZeneca intends to submit an sNDA for an expanded Tudorza label.

c) Fasenra (benralizumab) (severe, uncontrolled asthma)

On 15 November 2017, the Company announced that the US FDA had approved Fasenra as a new medicine for patients with severe asthma aged 12 years and older and with an eosinophilic phenotype.

On 10 January 2018, the EMA approved Fasenra as an add-on maintenance treatment in adult patients with severe, inadequately-controlled eosinophilic asthma, despite high-dose inhaled corticosteroids plus LABA. The approvals were based on results from the WINDWARD programme, including the pivotal Phase III exacerbation trials SIROCCO and CALIMA, plus the Phase III oral corticosteroid (OCS)-sparing trial, ZONDA. Regulatory decisions are anticipated in several other jurisdictions in H1 2018.

On 19 January 2018, the Company announced that the Japanese Ministry of Health, Labour and Welfare had approved Fasenra as an add-on treatment for bronchial asthma in patients who continue to experience asthma exacerbations, despite treatment with high-dose inhaled corticosteroid and other asthma controller(s).

During the period, the Phase III GRECO trial met its primary endpoint, showing that patients and caregivers could self-administer Fasenra with an autoinjector. GRECO was a multicentre, open-label trial designed to assess the functionality and reliability of a single use autoinjector of Fasenra, administered subcutaneously in an at-home setting with monitoring of the autoinjector performance after use. The device performed as expected during the clinical trial. d) Tralokinumab (asthma)

During the period, AstraZeneca decided to discontinue the development of tralokinumab, an investigational anti-IL-13 human immunoglobulin-G4 monoclonal antibody, in severe, uncontrolled asthma. The decision followed the publication of results of the Phase III programme, in which the primary endpoint of a significant reduction in the annual asthma exacerbation rate was not met in the two pivotal trials, STRATOS 1 and STRATOS 2. In an OCS-sparing trial, TROPOS, tralokinumab did not achieve a statistically-significant reduction in OCS use when added to the standard of care, in patients dependent on OCS.

e) PT010 (COPD)

On 26 January 2018, AstraZeneca announced the top-line results of the pivotal Phase III KRONOS trial for PT010, a potential triple-combination therapy (budesonide/glycopyrronium/formoterol fumarate) for the treatment of moderate to very severe COPD. In the trial, PT010 significantly improved lung function compared to PT009

(budesonide/formoterol fumarate), Bevespi (glycopyrronium/formoterol fumarate) and Symbicort Turbuhaler (budesonide/formoterol fumarate). AstraZeneca anticipates presentation of the results at a forthcoming medical meeting and intends to make the first regulatory submission for PT010 in H2 2018.

During the period, the Phase III TELOS trial read out, which compared two doses of PT009 (budesonide/formoterol fumarate) to its individual components, PT005 (formoterol fumarate) and PT008 (budesonide), and to Symbicort. The trial assessed lung function in patients with moderate to very severe COPD to qualify PT009 as an active comparator in the PT010 clinical-trial programme.

PT009, PT005 and PT008 were all delivered using Aerosphere Delivery Technology. All primary endpoints were met, with the exception of the lung-function primary endpoint that compared low-dose PT009 to PT005. A full evaluation of the TELOS trial results is ongoing, and the Company intends to present the results at a forthcoming medical meeting.

f) Tezepelumab (asthma)

In November 2017, the Company and its partner Amgen Inc. initiated the Phase III PATHFINDER programme for tezepelumab. During the period, the first patient was enrolled in the first Phase III trial, NAVIGATOR. The decision to proceed with the programme was based on the results from the Phase IIb PATHWAY trial in patients with severe, uncontrolled asthma. Results from the trial were published in the New England Journal of Medicine and presented at the European Respiratory Society International Congress in September 2017.

Development Pipeline 31 December 2017

#### 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 Investigation	Date Commenced	Estimated Re /Submission	Status	cceptance
Oncology		Investigation	Phase	US	EU	Japan
Calquence# (acalabrutinib)	BTK inhibitor	B-cell malignancy	Q1 2015	Launched		
savolitinib# SAVOIR	MET inhibitor	papillary renal cell carcinoma	Q3 2017	2020	2020	
selumetinibASTRA	MEK inhibitor	differentiated thyroid cancer	Q3 2013	H2 2018 (Orphan Drug Designation) H1 2018	H2 2018	
moxetumomab pasudotox# PLAIT	recombinantimmunotoxin	hairy cell leukaemia	Q2 2013	(Orphan Drug Designation)		
Imfinzi# + tremelimumabARCTIC	PD-L1 mAb + CTLA-4 mAb	3rd-line NSCLC	Q2 2015	H1 2018	H1 2018	H1 2018
Imfinzi# + tremelimumab MYSTIC	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q3 2015	H2 2018	H2 2018	H2 2018
Imfinzi# + tremelimumab NEPTUNE	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q4 2015	2019	2019	2019
Imfinzi# + tremelimumab + chemotherapy POSEIDON	PD-L1 mAb + CTLA-4 mAb	1st-line NSCLC	Q2 2017	2019	2019	2019
Imfinzi# + tremelimumab + SoC CASPIAN	PD-L1 mAb + CTLA-4 mAb + SoC	1st-line SCLC	Q1 2017	2019	2019	2019
Imfinzi# + tremelimumabKESTREL	PD-L1 mAb + CTLA-4 mAb	1st-line HNSCC	Q4 2015	H2 2018	H2 2018	H2 2018
Imfinzi# + tremelimumabEAGLE	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
Imfinzi# + tremelimumab HIMALAYA	PD-L1 mAb + CTLA-4 mAb	1st-line hepatocellular carcinoma	Q4 2017	2021	2021	2021
Lynparza#¶+ cediranib CONCERTO	PARP inhibitor + VEGF inhibitor	recurrent platinum-resistant ovarian cancer	Q1 2017	2019		
CVMD						

CVMD

Epanova	omega-3 carboxylic acids	severe hypertriglycerid-aemia	L	Approv	ved		2020
ZS-9 (sodium zirconium cyclosilicate)	potassium binder	hyperkalaemia		-		Accepted1	2019
roxadustat# OLYMPUS (US) ROCKIES (US)	hypoxia-inducible factor prolyl hydroxylase inhibitor	anaemia in CKD / end-stage renal disease	Q3 2014	H2 201	8		
Respiratory							
Bevespi (PT003) Fasenra# (benralizumab#)	LABA/LAMA	COPD		Launch	ied	Accepted	H2 2018
CALIMA SIROCCO ZONDA BISE BORA	IL-5R mAb	severe, uncontrolled asthma		Launch	ied	Approved	Approve
GREGALE PT010	LABA/LAMA/ ICS	COPD	Q3 2015	2019		2019	H2 2018
tezepelumab NAVIGATOR SOURCE Other	TSLP mAb	severe, uncontrolled asthma	Q1 2018	2021		2021	2021
anifrolumab# TULIP	Type I IFN receptor mAb	systemic lupus erythematosus	Q3 2015	2019 (Fast T	rack)	2019	2019
lanabecestat# AMARANTH + extension, DAYBREAK-ALZ	beta-secretase inhibitor	Alzheimer's disease	Q2 2016	2020 (Fast T	rack)	2020	2020
<ul> <li># Collaboration</li> <li>¶ Registrational Pl</li> <li>1 CHMP positive</li> <li>2 Fibrogen complete</li> </ul>		nission in China					
Phases I and II NMEs and significant	additional indications						
Compound M	Mechanism	Area Under Invest	igation	Phase	Date Com Phase	menced	
Oncology Imfinzi# P Imfinzi# + tremelimumab P	PD-L1 mAb PD-L1 mAb + CTLA-4 mA	solid tumours b gastric cancer		II II	Q3 2 Q2 2	014	

Compound	Mechanism	Area Under Investigation	Phase	Commenced Phase
Oncology				
Imfinzi#	PD-L1 mAb	solid tumours	II	Q3 2014
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	gastric cancer	II	Q2 2015
Imfinzi# + tremelimumab	PD-L1 mAb + CTLA-4 mAb	biliary tract, osophageal	II	Q4 2013
Imfinzi# + tremelimumab + chemo	PD-L1 mAb + CTLA-4 mAb	1st-line pancreatic ductal adenocarcinoma, osophageal and SCLC	Ι	Q2 2016
Imfinzi# + AZD5069	PD-L1 mAb + CXCR2 antagonist	pancreatic ductal adenocarcinoma	ΙΙ	Q2 2017
Imfinzi# + AZD5069 or Imfinzi# + AZD9150#	PD-L1 mAb + CXCR2 antagonist or PD-L1 mAb + STAT3 inhibitor	HNSCC	Π	Q3 2015
		melanoma	Ι	Q1 2014

Imfinzi# + dabrafenib + trametinib	PD-L1 mAb + BRAF inhibitor + MEK inhibitor			
Imfinzi# + AZD1775# Imfinzi# + MEDI0680	PD-L1 mAb + Wee1 inhibitor PD-L1 mAb + PD-1 mAb	solid tumours solid tumours	I II	Q4 2015 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	Ι	Q3 2016
Imfinzi# + Iressa	PD-L1 mAb + EGFR inhibitor	NSCLC	Ι	Q2 2014
Imfinzi# + MEDI0562#	PD-L1 mAb + humanised OX40 agonist	) solid tumours	Ι	Q2 2016
Imfinzi# + MEDI9197#	PD-L1 mAb + TLR 7/8 agonist	solid tumours	Ι	Q2 2017
Imfinzi# + oleclumab (MEDI9447)	PD-L1 mAb + CD73 mAb	solid tumours	Ι	Q1 2016
Imfinzi# + monalizumab	PD-L1 mAb + NKG2a mAb	solid tumours	Ι	Q1 2016
Imfinzi# + selumetinib	PD-L1 mAb + MEK inhibitor	solid tumours	I	Q4 2015
	PD-L1 mAb + CTLA-4 mAb	solid tumours	Ι	Q4 2013
tremelimumab + MEDI0562#	CTLA-4 mAb + humanised OX40 agonist	solid tumours	Ι	Q2 2016
Imfinzi# + azacitidine	PD-L1 mAb + azacitidine	myelodysplastic syndrome	Ι	Q2 2016
Imfinzi# + MEDI0457#	PD-L1 mAb + DNA HPV vaccine	HNSCC	II	Q4 2017
Imfinzi + RT (platform) CLOVER	PD-L1 mAb + RT	locally-advanced HNSCC, NSCLC, SCLC	Ι	Q1 2018
Lynparza# + AZD6738	PARP inhibitor + ATR inhibitor	rgastric cancer	II	Q3 2016
Lynparza# + AZD1775#	PARP inhibitor + Wee1 inhibitor	solid tumours	Ι	Q3 2015
Lynparza# + Imfinzi 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	Q1 2015
AZD1775#	Wee1 inhibitor	solid tumours	Ι	Q3 2015
vistusertib	mTOR inhibitor	solid tumours	II	Q1 2013
AZD5363#	AKT inhibitor	breast cancer	II	Q1 2014
AZD4547	FGFR inhibitor	solid tumours	II	Q4 2011
AZD0156	ATM inhibitor	solid tumours	Ι	Q4 2015
AZD1390	ATM inhibitor	healthy volunteer trial	Ι	Q4 2017
AZD2811#	Aurora B inhibitor	solid tumours	Ι	Q4 2015
AZD4573	CDK9 inhibitor	haematological malignancies	Ι	Q4 2017
AZD4635	A2aR inhibitor	solid tumours	Ι	Q2 2016
AZD4785	KRAS inhibitor	solid tumours	I	Q2 2017
AZD5153	BRD4 inhibitor	solid tumours	I	Q3 2017
AZD5991	MCL1 inhibitor	haematological malignancies	1	Q3 2017
Calquence + vistusertib	B-cell malignancy + mTor inhibitor	haematological malignancies	Ι	Q3 2017
AZD6738	ATR inhibitor	solid tumours	Ι	Q4 2013
AZD8186	PI3k inhibitor	solid tumours	Ι	Q2 2013

	1			
AZD9496	selective oestrogen receptor	oestrogen receptor +ve breast	ι	Q4 2014
	degrader	cancer		-
MEDI-565#	CEA BiTE mAb	solid tumours	I	Q1 2011
MEDI0562#	humanised OX40 agonist	solid tumours	I	Q1 2015
MEDI1873	GITR agonist fusion protein	solid tumours	I	Q4 2015
MEDI3726#	PSMA antibody drug conjugate		Ι	Q1 2017
MEDI4276	HER2 bi-specific antibody drug conjugate	solid tumours	Ι	Q4 2015
MEDI5083	immune activator	solid tumours	Ι	Q1 2017
MEDI7247	antibody drug conjugate	haematological malignancies	Ι	Q2 2017
MEDI9197#	TLR 7/8 agonist	solid tumours	Ι	Q4 2015
oleclumab (MEDI9447)	CD73 mAb	solid tumours	Ι	Q3 2015
CVMD				
verinurad	URAT1 inhibitor	CKD	II	Q2 2017
MEDI0382	GLP-1/	type-2 diabetes / obesity	II	Q3 2016
	glucagon dual agonist			-
MEDI6012	LCAT	CV disease	II	Q4 2015
AZD4831	myeloperoxidase	HF with a preserved ejection	Ι	Q3 2016
		fraction		-
AZD5718	FLAP	coronary artery disease	II	Q4 2017
AZD8601#	VEGF-A	CV disease	Ι	Q1 2017
MEDI5884#	cholesterol modulation	CV disease	II	Q4 2017
Respiratory				
abediterol#	LABA	asthma / COPD	II	Q4 2007
tezepelumab#	TSLP mAb	atopic dermatitis	II	Q2 2015
AZD1419#	inhaled TLR9 agonist	asthma	II	Q4 2016
AZD7594	inhaled SGRM	asthma / COPD	II	Q3 2015
AZD8871#	MABA	COPD	II	Q1 2017
PT010	LABA/LAMA/ICS	asthma	II	Q2 2014
AZD5634	inhaled ENaC	cystic fibrosis	Ι	Q1 2016
AZD7594 + abediterol#	inhaled SGRM + LABA	asthma / COPD	Ι	Q4 2016
AZD7986#	DPP1	COPD	II	Q4 2017
		rheumatoid arthritis /		-
AZD9567	oral SGRM	respiratory	Ι	Q4 2015
AZD1402#	Inhaled IL-4Ra	asthma	Ι	Q4 2017
MEDI3506	IL-33 mAb	COPD	I	Q1 2017 Q2 2017
Other		COLD	1	Q2 2017
anifrolumab#	Type 1 IFN receptor mAb	lupus nephritis	II	Q4 2015
ammorannaon	Type Three plot mixe	systemic lupus erythematosu		Q+ 2015
anifrolumab#	Type 1 IFN receptor mAb	(subcutaneous)	<sup>5</sup> II	Q1 2017
		(subcutaneous)	II	
			(Orphan	Q1 2015
inebilizumab#	CD19 mAb	neuromyelitis optica	drug US,	Q1 2013
			0	
.1. 1.1		1 1 .1	EU)	01 0010
mavrilimumab#	GM-CSFR mAb	rheumatoid arthritis	II	Q1 2010
		prevention of nosocomial	II	Q2 2016
MEDI3902	Psl/PcrV bispecific mAb	Pseudomonas aeruginosa	(Fast Track	
		pneumonia	US)	
suvratoxumab		prevention of nosocomial	II	Q4 2014
(MEDI4893)	mAb binding to S. aureus toxin		(Fast Track	.,
		pneumonia	US)	

prezalumab# (MEDI5872#)	B7	/RP1 mAb		primary	Sjögren's synd	drome	II	Q3 202	15
MEDI8852	inf	fluenza A mAb		influenz	za A treatment		II (Fast 1 US)	Frack, Q4 201	15
MEDI8897#	RS	SV mAb-YTE		passive	RSV prophyla	xis	II (Fast 1 US)	Frack, Q1 202	15
AZD0284 MEDI0700# MEDI1814# MEDI4920 MEDI7352 MEDI7734 MEDI9314 # Colla	BA an an NG IL	DRg AFF/B7RP1 bispecific m hyloid beta mAb ti-CD40L-Tn3 fusion pr GF/TNF bi-specific mAb T7 mAb -4R mAb	otein	systemic Alzhein primary osteoart myositis	hritis pain	natosus drome	I I I	Q4 202 Q1 202 Q2 202 Q2 202 Q1 202 Q3 202 Q1 202	16 14 14 16 16
	Lifecycle M	lanagement							
Compound	Mechanism	Area Under Investigation	Date Con Phas	nmenced	Estimated Reg Submission S US			ptance Date / Japan	/ China
Oncology									
Calquence# (acalabrutinib)	BTK inhibitor	1st-line chronic lymphocytic leukaemia	aQ32	2015	2020 (Orphan Drug Designation)	-			
Calquence# (acalabrutinib)	BTK inhibitor	relapsed/refractory chronic lymphocytic leukaemia, high risk	Q4 2	2015	2019 (Orphan Drug Designation)	2019 g (Orpha	in		
Calquence# (acalabrutinib)	BTK inhibitor	1st-line mantle cell lymphoma	Q1 2	2017	2023	8	,		
Faslodex FALCON	oestrogen receptor antagonist	1st-line hormone receptor +ve advanced breast cancer			Approved	Appro	ved	Approved	Approved
Imfinzi# PACIFIC	PD-L1 mA	b <sup>locally-advanced</sup> (Stage III), NSCLC	Q2 2	2014	Accepted (Breakthrough Therapy Designation & Priority Review)	n Accept	ted	Accepted	
Imfinzi# PEARL (China)	PD-L1 mA	b1st-line NSCLC	Q1 2	2017					2020
Lynparza# OlympiAD	PARP inhibitor	gBRCA metastatic breast cancer	Q2 2	2014	Approved (Priority Review)	H1 201	18	Accepted (Orphan drug designation, Priority Review)	H2 2018
Lynparza# SOLO-2	PARP inhibitor	2nd-line or greater BRCAm PSR ovarian cancer, maintenance monotherapy	Q3 2	2013	Approved (Priority Review)	Accept	ted	Approved (Orphan drug designation)	Accepted
		monomerupy	Q3 2	2013	H2 2018	H2 20		H2 2018	2019

Lynparza# SOLO-1 Lynparza#	PARP inhibitor PARP	1st-line BRCAm ovarian cancer gBRCA PSR ovarian					
SOLO-3	inhibitor	cancer	Q1 2015	H2 2018			
Lynparza# POLO	PARP inhibitor	pancreatic cancer	Q1 2015	2019	2019		
Lynparza# PROfound	PARP inhibitor	prostate cancer	Q1 2017	2020 (Breakthroug Therapy Designation)		2020	2020
Lynparza# OlympiA	PARP inhibitor	gBRCA adjuvant breast cancer	Q2 2014	2020	2020	2020	
Tagrisso FLAURA	EGFR inhibitor	1st-line advanced EGFRm NSCLC	Q1 2015	Accepted (Breakthroug Therapy designation)	<sup>h</sup> Accepted	Accepted	H2 2018
Tagrisso ADAURA CVMD	EGFR inhibitor	adjuvant EGFRm NSCLC	Q4 2015	2022	2022	2022	2022
Brilinta1 THALES	P2Y12 receptor antagonist	acute ischaemic stroke or transient ischaemic attack CV outcomes trial in		2020	2020	2020	2020
Brilinta1 THEMIS	P2Y12 receptor antagonist	patients with type-2 diabetes and coronary artery disease without previous history of M or stroke		2019	2019	2019	2020
Brilinta1 HESTIA	P2Y12 receptor antagonist	prevention of vaso-occlusive crises i paediatric patients with sickle cell disease	nQ1 2014	2021	2021		
Farxiga2 DECLARE- TIMI 58	SGLT2 inhibitor	CV outcomes trial in patients with type-2 diabetes	Q2 2013	2019	2019		
Farxiga2	SGLT2 inhibitor	type-1 diabetes	Q4 2014	H2 2018	H1 2018	H2 2018	
Farxiga2	SGLT2 inhibitor	worsening HF or CV death in patients with chronic HF	Q1 2017	2020	2020	2020	2020
Farxiga2	SGLT2 inhibitor	renal outcomes and CV mortality in patients with CKD	Q1 2017	2021	2021	N/A	2021
Xigduo XR/ Xigduo3	SGLT2 inhibitor/ metformin FDC	type-2 diabetes		Launched	Launched		2020
Qtern	DPP-4 inhibitor / SGLT2 inhibitor	type-2 diabetes		Launched	Launched		

FDC Bydureon GLP-1 BCise / Bydureonrecepto autoinjector4 agonist	type-2 diabetes	Q1 2013	Launched	Accepted		
Bydureon EXSCEL GLP-1 recepto agonist	type-2 diabetes outcomes trial	Q2 2010	H1 2018	H1 2018		H2 2018
saxagliptin/ dapagliflozin/ metformin DPP-4 inhibito SGLT2 inhibito	type-2 diabetes	Q2 2017	H1 2018	H1 2018		
Epanova omega- STRENGTH carboxy acids	CV outcomes trial in statin-treated patients at high CV risk, with	Q4 2014 a	2020	2020	2020	2020
Respiratory Fasenra# (benralizumab#) TERRANOVA GALATHEA	nAb COPD	Q3 2014	H2 2018	H2 2018	2019	
Symbicort ICS/LA SYGMA	BA as-needed use in mild asthma					