AstraZeneca PLC
25 July 2019 07:00 BST

H1 2019 Results

Continuing strong top-line performance underpins confidence in sustainable growth

First-half Product Sales growth of 12% (17% at CER[1]) to $11,183m included an acceleration in second-quarter Product Sales to $5,718m (+14%, +19% at CER). The second quarter saw every sales region and all three therapy areas deliver an encouraging performance, including:

- The sustained performance of new medicines[2] (+66%, +72% at CER) to $2,385m
- Sales growth by therapy area in the quarter: Oncology +51% (+57% at CER) to $2,167m, New CVRM[3] +9% (+13% at CER) to $1,061m and Respiratory +2% (+7% at CER) to $1,252m
- Sales growth by region in the quarter: total Emerging Markets sales grew by 17% (27% at CER) to $1,947m, with China sales growth of 34% (44% at CER) to $1,166m, ahead of recent trends. US sales increased by 16% to $1,877m; Europe sales returned to growth, increasing by 1% (8% at CER) to $1,047m. Japan sales increased by 30% (34% at CER) to $672m

These results were accompanied by further positive pipeline developments, with the second half of the year anticipated to be an exceptionally busy period for the pipeline.

	H1 2019			Q2 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Product Sales	11,183	12	17	5,718	14	19
Collaboration Revenue	131	(59)	(57)	105	(17)	(12)
Total Revenue	11,314	9	14	5,823	13	18
Reported[4] Operating Profit	1,590	9	12	493	(35)	(37)
Core[5] Operating Profit	3,011	39	44	1,361	7	8
Reported EPS[6]	$0.56	3	-	$0.09	(64)	(71)
Core EPS	$1.62	38	40	$0.73	5	1

Pascal Soriot, Chief Executive Officer, commenting on the results said:
"The momentum generated last year continued into the first half, consolidating AstraZeneca's return to growth based on the strength of our new medicines. Five of these new medicines are anticipated to be blockbusters this year, supporting sales across both Oncology and BioPharmaceuticals. Emerging Markets, the US and Japan all grew strongly, and we delivered an encouraging turnaround in Europe in the second quarter. Selective investment in sustainable growth also continued, particularly in Emerging Markets and in our launch programmes. Additional regulatory approvals for *Lynparza* in ovarian cancer in the EU and Japan, together with approvals for *Breztri* and *Bevespi* in COPD in Japan, illustrated further progress from our pipeline.

Accompanying earnings growth this year, we are pleased to upgrade our Product Sales guidance and we are committed to working on our operating leverage and driving cash generation over the long term."

Financial summary

- Product Sales increased by 12% in the half (17% at CER) to $11,183m

- The Reported Gross Margin increased by two percentage points in the half to 80%, partly reflecting the mix of Product Sales and manufacturing efficiencies; the Core Gross Margin increased by one percentage point to 81%

- Reported Operating Expenses increased by 5% in the half (10% at CER) to $8,238m and represented 73% of Total Revenue (H1 2018: 76%). Core Operating Expenses increased by 1% (5% at CER) to $6,922m and represented 61% of Total Revenue (H1 2018: 67%), demonstrating operating leverage

- Reported R&D Expenses declined by 1% (an increase of 3% at CER) to $2,622m. Core R&D Expenses declined by 2% (an increase of 2% at CER) to $2,505m

- Reported SG&A Expenses increased by 9% (14% at CER) to $5,457m; Core SG&A Expenses increased by 3% (7% at CER) to $4,258m, primarily reflecting growth in China, as well as ongoing additional support for new medicines

- Reported Other Operating Income and Expense declined by 35% in the half (34% at CER) to $706m; Core Other Operating Income and Expense increased by 1% (2% at CER) to $708m; in the second quarter, Core Other Operating Income and Expense declined by 80% to $114m

- The Reported Operating Margin was stable in the half at 14%; the Core Operating Margin increased by six percentage points (five at CER) to 27%

- Reported EPS of $0.56 in the half, based on a weighted-average number of shares of 1,289m, represented an increase of 3% (stable at CER); Core EPS increased by 38% (40% at CER) to $1.62. The difference between the Reported and Core performance partly reflected the impact of a favourable $346m legal settlement in H1 2018, recognised as income in Reported Other Operating Income and Expense, as well as the commencement of the amortisation of *Lokelma* and fair-value adjustments arising on acquisition-related liabilities recognised in Reported SG&A Expense in Q2 2019

- The Reported Tax Rate was 25% (H1 2018: 19%); the Core Tax Rate was 21% (H1 2018: 19%). The tax rates in the half reflected the geographical mix of profits and the impact of collaboration and divestment activity

- An unchanged first interim dividend of $0.90 per share

- The Company today upgrades part of its financial guidance for the year (see page four)

Commercial summary

Oncology
Sales growth of 52% in the half (58% at CER) to $4,059m, including:

- *Tagrisso* sales of $1,414m, representing growth of 86% in the half (92% at CER) that was driven by 2018 regulatory approvals in the 1st-line EGFR[7]-mutated (EGFRm) NSCLC[8] setting. There was a sequential quarterly increase of 16% in US sales of *Tagrisso* from the first to the second quarter, partly reflecting continued underlying demand growth. Japan sales increased by 147% (151% at CER) to $291m

- *Imfinzi* sales of $633m, representing growth of 244% (248% at CER). While the majority of sales were in the US, Europe sales amounted to $60m (H1 2018: $3m), with Japan sales of $86m ($nil in H1 2018)

- *Lynparza* sales of $520m, representing growth of 93% (100% at CER), driven by expanded use in the treatment of ovarian and breast cancer in the US and Europe. The performance included growth in Emerging Markets of 228% (267% at CER) to $59m and growth in Japan of 480% (490% at CER) to $58m

- The performance from more-mature Oncology medicines in the half included *Faslodex* growth of 4% (8% at CER) to $521m and an 8% decline in *Iressa* sales (3% at CER) to $252m. The Company anticipates increased

challenges for both medicines in the second half, partly reflecting additional generic *Faslodex* competition in the US and the pricing impact on *Iressa* from centralised procurement in China

- Oncology sales growth in Emerging Markets of 40% (52% at CER) to $1,048m

New CVRM
Sales growth of 12% in the half (16% at CER) to $2,094m, including:

- *Brilinta* sales of $737m, representing growth of 21% (26% at CER). Patient uptake continued in the treatment of acute coronary syndrome and high-risk post-myocardial infarction

- *Farxiga* sales of $726m, with growth of 14% (19% at CER), ahead of an anticipated label update in major markets to reflect results from the DECLARE CV outcomes trial

- *Bydureon* sales of $283m, a decline of 4% (3% at CER), driven by production constraints that are now resolved

- New CVRM sales growth in Emerging Markets of 31% (44% at CER) to $521m

Respiratory
Sales growth of 5% in the half (10% at CER) to $2,535m, including:

- A *Symbicort* sales decline of 10% (6% at CER) to $1,170m, reflecting continued pricing pressure and the impact of managed-market rebates in the US. This was partially offset by positive volumes from US government-buying patterns

- *Pulmicort* sales growth of 13% (19% at CER) to $716m; the majority of *Pulmicort* sales were in Emerging Markets. Q2 2019 global sales increased by 16% (23% at CER) to $333m

- *Fasenra* sales of $296m, representing growth of 244% (249% at CER). New-to-brand prescription data showed that *Fasenra* was generally the preferred novel-biologic medicine for the treatment of severe asthma during the period, in markets where *Fasenra* is established, despite being the third such medicine to launch

- Respiratory sales growth in Emerging Markets of 22% (30% at CER) to $956m

Emerging Markets
As the Company's largest region, at 35% of total Product Sales, Emerging Markets sales increased by 15% in the half (24% at CER) to $3,951m, including:

- A China sales increase of 27% in the half (35% at CER) to $2,408m. Highlights included Oncology sales growth of 58% (68% at CER) to $635m and New CVRM growth of 72% (83% at CER) to $218m

- An ex-China sales increase of 1% in the half (10% at CER) to $1,543m. The performance was negatively impacted by product divestments and developments in Brazil. Positive developments, however, included sales of $569m in (non-China) Asia-Pacific (+5%, +9% at CER) and $112m in Russia (+67%, +85% at CER)

Pipeline highlights
The following table highlights significant developments in the late-stage pipeline since the prior results announcement:

Regulatory approvals	- *Lynparza* - ovarian cancer (1st line, BRCAm[9]): regulatory approval (EU, JP) - *Qternmet XR* - T2D[10]: regulatory approval (US) - *Bevespi* - COPD[11]: regulatory approval (JP) - *Breztri* (formerly PT010) - COPD: regulatory approval (JP)
Regulatory submissions and/or acceptances	- *Lynparza* - pancreatic cancer (BRCAm): regulatory submission acceptance (EU) - *Forxiga* - T2D CVOT[12]: regulatory submission (CN) - *Lokelma* - hyperkalaemia: regulatory submission (JP, CN)
Major Phase III data readouts or other significant developments	- *Imfinzi* - SCLC[13]: met Phase III primary endpoint - *Imfinzi* - SCLC: Orphan Drug Designation (US) - trastuzumab deruxtecan - breast cancer (3rd line, HER2+): met pivotal Phase II primary endpoint - *Calquence* - CLL[14] (relapsed/refractory): met Phase III primary endpoint - *Calquence* - CLL (treatment-naïve): met Phase III primary endpoint - *Forxiga* - T2D CVOT: positive opinion (EU) - *Farxiga* - T1D[15]: complete response letter (US) - *Lokelma* - hyperkalaemia: priority review (CN) - roxadustat - anaemia of CKD[16]: pooled Phase III CV safety confirmed - *Breztri* - COPD: priority review (CN) - *Fasenra* - severe asthma (self-administration and auto-injector): positive opinion (EU)

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

All guidance and indications provided assume that the UK's anticipated exit from the European Union (EU), even in the event of a no-deal exit, proceeds in an orderly manner such that the impact is within the range expected, following the Company's extensive preparations for such an eventuality.

AstraZeneca anticipates strong and sustainable long-term Product Sales growth to be accompanied by operating leverage, leading to an improvement in profitability and cash generation.

Product Sales
Reflecting the performance in the first half and the return to Product Sales growth in H2 2018, Product Sales in FY 2019 are now expected to increase by a low double-digit percentage; the prior guidance was for a high single-digit percentage increase.

Core EPS
As a key part of its long-term growth strategy, the Company is committed to focusing on appropriate cash-generating and value-accretive collaboration activities that reflect the ongoing productivity of the pipeline. Separately, AstraZeneca will, from time to time, also focus its medicine portfolio through divestments.

AstraZeneca reiterates its Core EPS guidance of $3.50 to $3.70 over the full year. This guidance includes the anticipation of a lower sum of Collaboration Revenue and Core Other Operating Income and Expense versus the prior year.

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.

Operating leverage

The Company expects to deliver significant operating leverage over the long term. Encouraging progress was made in the half, with the Reported Operating Margin stable at 14% and the Core Operating Margin increasing by six percentage points (five at CER) to 27%. Core Operating Profit is anticipated to increase in the year by a mid-teens percentage versus FY 2018, ahead of Product Sales.

Cash generation

In FY 2019, the cash performance is expected to include a number of payments relating to prior business-development transactions; the majority of the value of these payments in the year was settled in the first half. AstraZeneca generated a net cash inflow from operating activities of $491m in the half, compared to an outflow of $75m in H1 2018.

Other indications

The Company also provides other indications for FY 2019:

- Capital expenditure is expected to be broadly stable and restructuring expenses are targeted to reduce versus the prior year

- A Core Tax Rate of 18-22% (FY 2018: 11%)

Currency impact

If foreign-exchange rates were to remain at the average of rates seen in the period from January to June 2019, it is anticipated that there would be a low single-digit percentage adverse impact on Product Sales and Core EPS. In addition, the Company's foreign-exchange rate sensitivity analysis is contained within the operating and financial review.

Sustainability

AstraZeneca's sustainability ambition is founded on making science accessible and operating in a way that recognises the interconnection between the health of the business, people and the planet and that each of these impact one another. The Company's sustainability ambition is reinforced by its purpose and values, which are intrinsic to its business model and ensures that the delivery of its strategy broadens access to healthcare, minimises the environmental footprint of its activities and products of medicines and processes and ensures that all business activities are underpinned by the highest levels of ethics and transparency. A full update on the Company's sustainability progress is shown in the Sustainability section of this announcement.

Notes

The following notes refer to pages 1-5:

1. Constant exchange rates. These are financial measures that are not accounted for according to generally-accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.

2. *Tagrisso*, *Imfinzi*, *Lynparza*, *Calquence*, *Farxiga*, *Brilinta*, *Lokelma*, *Fasenra*, *Bevespi* and *Breztri*. These new medicines are pillars in the main therapy areas and are important platforms for future growth.

3. New Cardiovascular (CV), Renal and Metabolism, incorporating Diabetes medicines, *Brilinta* and *Lokelma*.

4. Reported financial measures are the financial results presented in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board and adopted by the EU.

5. Core financial measures. These are non-GAAP financial measures because, unlike Reported performance,

they cannot be derived directly from the information in the Company Financial Statements. See the operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.

6. Earnings per share.

7. Epidermal growth factor receptor.

8. Non-small cell lung cancer.

9. Breast cancer susceptibility genes 1/2, mutated.

10. Type-2 diabetes.

11. Chronic obstructive pulmonary disease.

12. CV outcomes trial.

13. Small cell lung cancer.

14. Chronic lymphocytic leukaemia.

15. Type-1 diabetes.

16. Chronic kidney disease.

Pipeline: anticipated 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 and sustainable results from the pipeline.

H2 2019	- *Tagrisso* - NSCLC (1st line, EGFRm): regulatory decision (CN) - *Tagrisso* - NSCLC (1st line, EGFRm): data readout (final OS[17]) - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC): regulatory decision (CN) - *Imfinzi* + treme - NSCLC (1st line) (NEPTUNE): data readout - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): data readout, regulatory submission - *Imfinzi* +/- treme - small cell lung cancer: regulatory submission - *Imfinzi* +/- treme - head & neck cancer (1st line): data readout - *Imfinzi* +/- treme - bladder cancer (1st line): data readout - *Lynparza* - ovarian cancer (1st line, BRCAm) (SOLO-1): regulatory decision (CN) - *Lynparza* - pancreatic cancer (BRCAm): regulatory submission - *Lynparza* - ovarian cancer (3rd line, BRCAm): regulatory submission (US) - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): data readout, regulatory submission - *Lynparza* - prostate cancer (2nd line, castration-resistant): data readout, regulatory submission - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2[18]-positive): regulatory submission (US) - *Calquence* - CLL: regulatory submission - selumetinib - NF1[19]: regulatory submission - *Farxiga* - T2D CVOT: regulatory decision (US, EU) - *Farxiga* - heart failure CVOT: data readout - *Brilinta* - CAD[20]/T2D CVOT: regulatory submission - roxadustat - anaemia of CKD: regulatory submission (US) - *Symbicort* - mild asthma: regulatory submission (CN) - *Bevespi* - COPD: regulatory decision (CN) - *Fasenra* - self-administration and auto-injector: regulatory decision (US) - *Breztri* - COPD: data readout (ETHOS)

[17] Overall survival.
[18] Human epidermal growth factor receptor 2.
[19] Neurofibromatosis type 1.
[20] Coronary artery disease.

H1 2020	- *Imfinzi* + treme - NSCLC (1st line) (NEPTUNE): regulatory submission - *Imfinzi* +/- treme - head & neck cancer (1st line): regulatory submission - *Imfinzi* +/- treme - bladder cancer (1st line): regulatory submission - *Lynparza* - breast cancer (BRCAm): regulatory decision (CN) - *Lynparza* + cediranib - ovarian cancer (2nd line): data readout, regulatory submission - trastuzumab deruxtecan - advanced/refractory, metastatic gastric cancer (HER2-positive): data readout - *Farxiga* - heart failure CVOT: regulatory submission - *Brilinta* - stroke (THALES): data readout - *Lokelma* - hyperkalaemia: regulatory decision (JP, CN) - *Breztri* - COPD: regulatory decision (US, EU, CN)
H2 2020	- *Imfinzi* - neo-adjuvant NSCLC: data readout - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-2): data readout - *Imfinzi* +/- treme - liver cancer: data readout - *Brilinta* - stroke (THALES): regulatory submission - *Epanova* - hypertriglyceridaemia CVOT: data readout - roxadustat - anaemia of myelodysplastic syndrome: data readout - *Fasenra* - nasal polyposis: data readout, regulatory submission - PT027 - asthma: data readout - tezepelumab - severe asthma: data readout

Conference call
A conference call and webcast for investors and analysts will begin at 12pm UK time today. Details can be accessed via astrazeneca.com.

Reporting calendar
The Company intends to publish its year-to-date and third-quarter financial results on 24 October 2019.

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 therapy areas - Oncology, CVRM and Respiratory. 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.

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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), unless stated otherwise. The performance shown in this announcement covers the six-month period to 30 June 2019 (the half or H1 2019) and three-month period to 30 June 2019 (the quarter or Q2 2019) compared to the six-month period to 30 June 2018 (H1 2018) and three-month period to 30 June 2018 (Q2 2018) respectively, unless stated otherwise.

Core financial measures, EBITDA, Net Debt, Initial Collaboration Revenue and Ongoing Collaboration Revenue are non-GAAP financial measures because they cannot be derived directly from the Company Condensed Consolidated Financial Statements. Management believes that these non-GAAP financial measures, when provided in combination with Reported results, will provide investors and analysts with helpful supplementary information to understand better 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 restructuring programmes, which includes charges that relate to the impact of 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 and legal settlements

Details on the nature of Core financial measures are provided on page 76 of the Annual Report and Form 20-F Information 2018. Reference should be made to the reconciliation of Core to Reported financial information and the Reconciliation of Reported to Core financial measures table included in the financial performance section of this announcement.

EBITDA is defined as Reported Profit Before Tax after adding back Net Finance Expense, 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 and lease liabilities, net of cash and cash equivalents, other investments and net derivative financial instruments. Reference should be made to Note 3 ‘Net Debt’ included in the Notes to the Interim Financial Statements section of this announcement.

Ongoing Collaboration Revenue is defined as Collaboration Revenue excluding Initial Collaboration Revenue (which is defined as Collaboration Revenue that is recognised at the date of completion of an agreement or transaction, in respect of upfront consideration). Ongoing Collaboration Revenue comprises, among other items, royalties, milestone revenue and profit-sharing income. Reference should be made to the Collaboration Revenue table in this operating and financial review.

The Company strongly encourages investors and analysts not to rely on any single financial measure, but to review AstraZeneca’s financial statements, including the notes thereto and other available Company reports, carefully and in their entirety.

Due to rounding, the sum of a number of percentages may not agree to totals.

Table 1: Total Revenue

	H1 2019			Q2 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Product Sales	11,183	12	17	5,718	14	19
Collaboration Revenue	131	(59)	(57)	105	(17)	(12)
Total Revenue	**11,314**	**9**	**14**	**5,823**	**13**	**18**

Table 2: Product Sales

	H1 2019				Q2 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	4,059	36	52	58	2,167	38	51	57
BioPharmaceuticals	4,629	42	8	13	2,313	41	5	10
New CVRM	*2,094*	*19*	*12*	*16*	*1,061*	*19*	*9*	*13*
Respiratory	*2,535*	*23*	*5*	*10*	*1,252*	*22*	*2*	*7*
Other medicines	2,495	22	(19)	(14)	1,238	22	(11)	(6)
Total	**11,183**	**100**	**12**	**17**	**5,718**	**100**	**14**	**19**

Table 3: Top-ten medicines by Product Sales

Medicine	Therapy Area	H1 2019				Q2 2019			
		$m	% of total	% change		$m	% of total	% change	
				Actual	CER			Actual	CER
Tagrisso	Oncology	1,414	13	86	92	784	14	86	92
Symbicort	Respiratory	1,170	10	(10)	(6)	585	10	(13)	(9)
Nexium	Other medicines	756	7	(15)	(11)	393	7	(11)	(7)
Brilinta	CVRM	737	7	21	26	389	7	23	28
Farxiga	CVRM	726	6	14	19	377	7	11	16
Pulmicort	Respiratory	716	6	13	19	333	6	16	23
Crestor	CVRM	645	6	(11)	(6)	310	5	(8)	(3)
Imfinzi	Oncology	633	6	n/m	n/m	338	6	n/m	n/m
Faslodex	Oncology	521	5	4	8	267	5	8	12
Lynparza	Oncology	520	5	93	n/m	283	5	89	95
Total		**7,838**	**70**	**20**	**25**	**4,059**	**71**	**22**	**27**

Table 4: Collaboration Revenue

	H1 2019				Q2 2019			
			% change				% change	
	$m	% of total	Actual	CER	$m	% of total	Actual	CER
Initial Collaboration Revenue	-	-	n/m	n/m	-	-	n/m	n/m
Ongoing Collaboration Revenue	131	100	(40)	(36)	105	100	(17)	(12)
Royalties	*32*	*24*	*52*	*60*	*15*	*14*	*19*	*26*
Milestones/Other	*99*	*76*	*(49)*	*(47)*	*90*	*86*	*(21)*	*(16)*
Total	**131**	**100**	**(59)**	**(57)**	**105**	**100**	**(17)**	**(12)**

Product Sales

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

Table 5: H1 2019 therapy area and medicine performance

Therapy Area	Medicine	H1 2019			
		$m	% of total	% change	
				Actual	CER
Oncology	*Tagrisso*	1,414	13	86	92
	Imfinzi	633	6	n/m	n/m
	Lynparza	520	5	93	n/m
	Iressa	252	2	(8)	(3)
	Calquence	64	1	n/m	n/m
	Legacy:				
	Faslodex	521	5	4	8
	Zoladex	391	3	4	11
	Arimidex	111	1	-	7
	Casodex	105	1	1	7
	Others	48	-	(25)	(23)
	Total Oncology	**4,059**	**36**	**52**	**58**
BioPharmaceuticals: CVRM	*Farxiga*	726	6	14	19
	Brilinta	737	7	21	26
	Onglyza	269	2	5	10
	Bydureon	283	3	(4)	(3)
	Byetta	55	-	(8)	(5)
	Symlin	15	-	(6)	(6)
	Legacy:				
	Crestor	645	6	(11)	(6)
	Seloken/Toprol-XL	393	4	5	14
	Atacand	106	1	(21)	(16)
	Others	143	1	(10)	(6)
	BioPharmaceuticals: total CVRM	**3,372**	**30**	**3**	**8**

Therapy Area	Medicine	H1 2019			
		$m	% of total	% change	
				Actual	CER
BioPharmaceuticals: Respiratory	*Symbicort*	1,170	10	(10)	(6)
	Pulmicort	716	6	13	19
	Fasenra	296	3	n/m	n/m
	Daliresp/*Daxas*	104	1	25	27
	Tudorza/*Eklira*	33	-	(55)	(52)
	Duaklir	37	-	(26)	(20)
	Bevespi	20	-	54	54
	Others	159	3	(2)	4
	BioPharmaceuticals: total Respiratory	**2,535**	**23**	**5**	**10**
Other medicines	*Nexium*	756	7	(15)	(11)
	Losec/*Prilosec*	144	1	(1)	6
	Synagis	149	1	(40)	(40)
	Seroquel XR/IR	69	1	(70)	(68)
	Movantik/*Moventig*	47	-	(10)	(10)
	Others	52	-	(53)	(49)
	Total other medicines	**1,217**	**11**	**(27)**	**(24)**
	Total Product Sales	**11,183**	**100**	**12**	**17**

Specialty-care medicines comprise all Oncology medicines and *Fasenra*. At 39% of Product Sales (H1 2018: 27%), specialty-care medicine sales increased by 58% in the half (64% at CER) to $4,355m.

Table 6: Q2 2019 therapy area and medicine performance

Therapy Area	Medicine	Q2 2019			
		$m	% of total	% change	
				Actual	CER
Oncology	*Tagrisso*	784	14	86	92
	Imfinzi	338	6	n/m	n/m
	Lynparza	283	5	89	95
	Iressa	118	2	(17)	(13)
	Calquence	35	1	n/m	n/m
	Legacy:				
	Faslodex	267	5	8	12
	Zoladex	197	3	3	10
	Arimidex	60	1	5	14
	Casodex	57	1	10	17
	Others	28	-	(24)	(24)
	Total Oncology	**2,167**	**38**	**51**	**57**
BioPharmaceuticals: CVRM	*Farxiga*	377	7	11	16
	Brilinta	389	7	23	28
	Onglyza	116	2	(8)	(4)
	Bydureon	141	2	(9)	(8)
	Byetta	25	-	(14)	(10)
	Symlin	8	-	14	14
	Legacy:				
	Crestor	310	5	(8)	(3)
	Seloken/Toprol-XL	168	3	(3)	5
	Atacand	56	1	(14)	(9)
	Others	68	1	(7)	(4)
	BioPharmaceuticals: total CVRM	**1,658**	**29**	**2**	**7**

Therapy Area	Medicine	Q2 2019			
		$m	% of total	% change	
				Actual	CER
BioPharmaceuticals: Respiratory	*Symbicort*	585	10	(13)	(9)
	Pulmicort	333	6	16	23
	Fasenra	167	3	n/m	n/m
	Daliresp/*Daxas*	56	1	24	24
	Tudorza/*Eklira*	13	-	(71)	(69)
	Duaklir	17	-	(23)	(14)
	Bevespi	10	-	25	25
	Others	71	1	(13)	7
	BioPharmaceuticals: total Respiratory	**1,252**	**22**	**2**	**7**
Other medicines	*Nexium*	393	7	(11)	(7)
	Losec/*Prilosec*	68	1	(11)	(4)
	Synagis	96	2	n/m	n/m
	Seroquel XR/IR	32	1	(76)	(74)
	Movantik/*Moventig*	22	-	(8)	(8)
	Others	30	1	(36)	(26)
	Total Other medicines	**641**	**11**	**(14)**	**(10)**
	Total Product Sales	**5,718**	**100**	**14**	**19**

Product Sales summary

Oncology

Product Sales of $4,059m; an increase of 52% (58% at CER). Oncology Product Sales represented 36% of total Product Sales, up from 27% in H1 2018.

Oncology: lung cancer

Tagrisso
Tagrisso has been approved and launched in 84 countries, including the US, in Europe, Japan and China for the 2nd-line treatment of patients with Stage IV EGFR T790M[21]-mutated NSCLC. By the end of the half, *Tagrisso* had been approved in 74 countries, including the US, in Europe and Japan for the 1st-line treatment of patients with EGFRm NSCLC; a number of additional regulatory reviews are also underway.

Product Sales in the half of $1,414m represented growth of 86% (92% at CER), partly driven by regulatory approvals and reimbursements in the 1st-line setting. Continued growth was also delivered in the 2nd-line indication in other countries, including in Europe and in Emerging Markets.

Sales in the US increased by 64% in the half to $559m. With a high penetration rate, *Tagrisso* is now established as the standard of care (SoC) in the 1st-line setting, following regulatory approval in 2018. There was a 16% sequential quarterly increase in US sales of *Tagrisso* within the half, partly reflecting continued underlying demand growth.

In Emerging Markets, *Tagrisso* sales increased by 107% in the half (121% at CER) to $329m, with notable growth in China, where the medicine was added to the National Reimbursement Drug List (NRDL) with effect from January 2019 in the 2nd-line setting. The Asia-Pacific region has a relatively high prevalence of lung-cancer patients with an EGFR mutation; at c.30-40% of the total, this contrasts with c.10-15% in the Western Hemisphere.

In Europe, sales of $212m in the half represented an increase of 53% (64% at CER), driven by emerging use in the 1st-line setting as more countries gained reimbursement, as well as continued strong levels of demand in the 2nd-line setting. Sales of *Tagrisso* in Japan increased by 147% in the half (151% at CER) to $291m, reflecting the increasing use of *Tagrisso* as a 1st-line treatment, where *Tagrisso* has reached a very high penetration rate.

Imfinzi
Imfinzi is approved in 49 countries, including the US, in Europe and Japan for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy (CRT). It is also approved for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer) in 10 countries, including the US.

Global Product Sales of *Imfinzi* increased by 244% in the half (248% at CER) to $633m, of which $473m were in the US, almost entirely for the treatment of unresectable, Stage III NSCLC. Sales of $86m in Japan ($nil in H1 2018) reflected strong demand, supported by higher CRT and treatment rates. Sales in Europe of $60m (H1 2018: $3m) followed recent regulatory approvals and launches; additional regulatory decisions are expected in due course.

Iressa
Product Sales in the half of $252m; a decline of 8% (3% at CER).

Emerging Markets sales increased by 11% in the half (18% at CER) to $164m; *Iressa* entered the NRDL in China in 2017 and was included in the China '4+7' pilot tender scheme in 2018. This scheme, focused on centralised procurement, centres on 11 major cities (four municipalities and seven provincial cities). Given the growing use of *Tagrisso*, sales of *Iressa* declined by 43% to $8m in the US and by 25% (20% at CER) to $46m in Europe. Japan sales amounted to $31m, reflecting a decline of 34% (32% at CER).

[21] Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.

Oncology: *Lynparza*

By the end of the half, *Lynparza* was approved in 64 countries for the treatment of ovarian cancer. Launches for the treatment of metastatic breast cancer took place in the US and Japan in 2018 and regulatory approval was granted in the EU in April 2019. *Lynparza* has now been approved in 40 countries for the treatment of metastatic breast cancer.

Product Sales of *Lynparza* amounted to $520m in the half, an increase of 93% (100% at CER). The strong performance was geographically spread, with launches continuing in Emerging Markets and the Established Rest of World region (RoW). Ongoing MSD[22] co-promotion efforts also contributed to sales.

US sales increased by 76% to $262m, driven by the launch in the 1st-line BRCAm ovarian cancer indication at the end of 2018 and increased demand that reflected continued growth in the treatment with *Lynparza* of patients suffering from ovarian or breast cancer. *Lynparza* remained the leading US medicine in the poly ADP ribose polymerase (PARP)-inhibitor class, as measured by total prescription volumes and in both ovarian and breast cancer.

The Company received approval during the period for the 1st-line BRCAm ovarian cancer indication in both Europe and Japan, as well as approval for BRCAm breast cancer in Europe. Sales in Europe increased by 51% (61% at CER) to $131m, driven by increasing levels of reimbursement and BRCA-testing rates; sales also benefitted from clinical-trial supply. The Company continues to implement a number of launches in the broad, 2nd-line, maintenance ovarian-cancer indication, regardless of BRCA-mutation status.

Following the initial launch in April 2018, Japan sales of *Lynparza*, as a treatment for 2nd-line maintenance ovarian cancer and BRCAm breast cancer, amounted to $58m. Emerging Markets sales of $59m reflected the regulatory approval of *Lynparza* as a 2nd-line maintenance treatment of patients with ovarian cancer by the China National Medical Products Administration (NMPA), resulting in the subsequent launch of *Lynparza* in China, the first PARP inhibitor to be approved in the country.

Oncology: haematology and other Oncology medicines

Calquence
Product Sales in the half of $64m; an increase of 220%. The overwhelming majority of sales were in the US.

Calquence was approved and launched in the US in October 2017. The medicine delivered a promising performance in the half, with c.45% of new patients now treated with *Calquence* in the approved indication of 2nd-line mantle cell lymphoma (MCL). At the end of 2018, the first regulatory approvals outside the US for the treatment of patients with MCL were granted.

Legacy: *Faslodex*
Product Sales in the half of $521m; an increase of 4% (8% at CER).

Emerging Markets sales of *Faslodex* increased by 35% in the half (49% at CER) to $96m. US sales declined by 3% to $251m, reflecting the launch of a generic *Faslodex* medicine in the second quarter; additional generic competition is expected. Europe sales declined by 7% (stable at CER) to $110m, driven by the continued impact of generic medicines in certain countries. In Japan, sales increased by 22% (24% at CER) to $61m.

Legacy: *Zoladex*
Product Sales in the half of $391m; an increase of 4% (11% at CER).

Emerging Markets sales of *Zoladex* increased by 16% (27% at CER) to $235m. Sales in Europe declined by 4% (up by 1% at CER) to $65m. In the Established RoW region, sales declined by 16% (13% at CER) to $87m, driven by the effects of increased competition.

[22] Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.

BioPharmaceuticals: CVRM

Total CVRM sales, which include *Crestor* and other legacy medicines, increased by 3% in the half (8% at CER) to $3,372m and represented 30% of total Product Sales (H1 2018: 33%).

New CVRM sales increased by 12% in the half (16% at CER) to $2,094m, reflecting strong performances from *Farxiga* and *Brilinta*. New CVRM sales represented 19% of Product Sales (H1 2018: 19%).

CVRM: Diabetes

Farxiga
Product Sales in the half of $726m; an increase of 14% (19% at CER).

Emerging Markets sales of *Forxiga* increased by 31% (45% at CER) to $206m, fuelled by growth in China. US sales increased by 2% to $270m, impacted by changes in formulary access for competitor medicines. AstraZeneca anticipates a potential label update in the second half in the US and the EU to reflect results from the DECLARE CVOT.

Sales in Europe increased by 17% (26% at CER) to $178m. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales in Japan, increased by 32% to $37m.

Onglyza
Product Sales in the half of $269m; an increase of 5% (10% at CER).

The performance was partly driven by favourable prior year gross-to-net adjustments in the US, where sales increased by 22% in the half to $120m. Sales in Emerging Markets increased by 7% (16% at CER) to $87m, driven by the performance in China. Europe sales declined by 23% (17% at CER) to $36m, highlighting the broader trend of a shift away from the dipeptidyl peptidase-4 inhibitor class. Given the significant future potential of *Farxiga*, the Company continues to prioritise commercial support over *Onglyza*.

Bydureon
Product Sales of $283m; a decline of 4% (3% at CER).

Sales were adversely impacted by production constraints that are now resolved. US sales of $234m were stable in the period where favourable sales volumes were driven by continued growth in the glucagon-like peptide-1 class, at the expense of insulin, for more-advanced T2D patients. *Bydureon* sales in Europe declined by 21% (19% at CER) to $34m.

CVRM: other medicines

Brilinta
Product Sales of $737m; an increase of 21% (26% at CER).

Patient uptake continued in the treatment of acute coronary syndrome and high-risk post-myocardial infarction. Emerging Markets sales of *Brilinta* increased by 47% (58% at CER) to $217m. US sales of *Brilinta*, at $321m, represented an increase of 24%, driven primarily by increasing levels of demand in both hospital and retail settings, as well as a lengthening in the average-weighted duration of treatment, reflecting the growing impact of 90-day prescriptions. Sales of *Brilique* in Europe declined by 1% in the half (up by 7% at CER) to $171m.

Lokelma
Product Sales of $2m, predominantly in the US, where *Lokelma* was recently launched.

Lokelma is approved in the US and EU for the treatment of hyperkalaemia, a serious condition characterised by elevated potassium levels in the blood associated with CV, renal and metabolic diseases. Launches in a number of other markets are expected soon.

Legacy: *Crestor*
Product Sales of $645m; a decline of 11% (6% at CER).

Sales in China declined by 2% (up by 5% at CER) to $234m; the CER growth came despite the impact from the aforementioned '4+7' pilot tender scheme. US sales declined by 40% to $54m, underlining the ongoing effect of generic *Crestor* medicines. In Europe, sales declined by 32% (27% at CER) to $75m, reflecting a similar impact that began in Europe in 2017. In Japan, where AstraZeneca collaborates with Shionogi Co. Ltd, sales increased by 12% (14% at CER) to $85m. This followed a period of decline resulting from the entry of multiple generic *Crestor* medicines in the Japan market at the end of 2017.

BioPharmaceuticals: Respiratory

Product Sales of $2,535m; an increase of 5% (10% at CER). Respiratory represented 23% of total Product Sales (H1 2018: 24%).

Symbicort
Product Sales in the half of $1,170m; a decline of 10% (6% at CER).

Symbicort continued to lead the global market by volume within the inhaled corticosteroid (ICS) / long-acting beta agonist (LABA) class. Emerging Markets sales of *Symbicort* increased by 9% (18% at CER) to $263m. In contrast, US sales declined by 13% to $382m, reflecting continued pricing pressure and the impact of managed-market rebates. This was partially offset by positive volumes from government-buying patterns.

In Europe, sales declined by 14% in the half (7% at CER) to $354m, reflecting price competition from other branded and *Symbicort*-analogue medicines, plus government pricing interventions. *Symbicort*, however, continued to retain its class-leadership position, with volume growth achieved in a number of markets.

In Japan, sales declined by 33% (32% at CER) to $67m following destocking by Astellas Pharma Co. Ltd (Astellas). In January 2019, AstraZeneca and Astellas announced that the sale and distribution of *Symbicort*, conducted by Astellas in Japan was to be transferred back to AstraZeneca and that the co-promotion conducted by Astellas and AstraZeneca will be terminated on 30 July 2019. The Company will solely distribute and promote the medicine in Japan from 31 July 2019. In addition, during the period, the first generic *Symbicort* medicine received regulatory approval, and multiple generic *Symbicort* medicines are anticipated to enter the Japanese market in due course.

Pulmicort
Product Sales in the half of $716m; an increase of 13% (19% at CER).

Emerging Markets, where sales increased by 20% (27% at CER) to $576m, represented 80% of global sales of *Pulmicort*. China, making up the overwhelming majority of *Pulmicort* sales in Emerging Markets, delivered a particularly strong double-digit performance, strengthened by higher demand and underpinned by the impact of AstraZeneca's support to build capacity in over 17,000 nebulisation centres.

Sales in the US and Europe declined by 5% to $56m and by 12% (6% at CER) to $44m, respectively, a consequence of the medicine's legacy status.

Fasenra
Product Sales of $296m, an increase of 244% (249% at CER).

Sales in the US increased by 210% to $208m in the half. New-to-brand prescription data showed that *Fasenra* was the preferred novel-biologic medicine for the treatment of severe asthma during the period, despite being the third medicine to enter the market.

In Europe and Japan, AstraZeneca was granted regulatory approval in January 2018 on a similar basis to that in the US. In Europe, sales of $45m in the half represented an increase of 463% (488% at CER), which included strong sales in Germany. Sales in Japan increased by 245% (255% at CER) to $38m, following its launch in the second quarter of 2018. In addition, *Fasenra* led the novel severe asthma biologic-medicine class by new patient share in Germany and Japan during the period.

Daliresp/Daxas
Product Sales in the half of $104m; an increase of 25% (27% at CER).

US sales, representing 86% of the global total, increased by 33% to $89m, driven by favourable affordability-programme changes and inventory movements. It is the only oral, selective, long-acting inhibitor of phosphodiesterase-4, an inflammatory enzyme associated with COPD.

Duaklir
Product Sales in the half of $37m; a decline of 26% (20% at CER).

Duaklir, the Company's first inhaled dual bronchodilator medicine, is now available for patients in over 25 countries. In the first half, the overwhelming majority of sales were in Europe, where sales declined by 23% (19% at CER) to $36m, predominately as a result of the performance in Germany.

In Q1 2019, the medicine received US regulatory approval. As part of the collaboration agreement announced in March 2017, Circassia Pharmaceuticals plc (Circassia) will be responsible for the commercialisation of *Duaklir* in the US, with AstraZeneca continuing to manufacture and supply the medicine. Circassia expects to launch the medicine in the US in H2 2019.

Bevespi
Product Sales in the half of $20m; an increase of 54%.

Bevespi saw prescriptions in the period track in line with other LAMA/LABA launches; the class in the US, however, continued to grow more slowly than anticipated previously. *Bevespi* was the first medicine launched using the Company's proprietary *Aerosphere* delivery technology.

Other medicines (outside the main therapy areas)

Product Sales of $1,217m in the half; a decline of 27% (24% at CER), partly reflecting the recent divestment of US rights to *Synagis* and the divestment of the prescription medicine rights to *Nexium* in Europe to Grünenthal GmbH. Other Product Sales represented 11% of total Product Sales, down from 17% in H1 2018.

Nexium
Product Sales in the half of $756m; a decline of 15% (11% at CER).

Emerging Markets sales of *Nexium* increased by 8% (15% at CER) to $369m. In Europe, sales declined by 74% to $32m reflecting the aforementioned divestment. Sales in the US declined by 36% to $119m and in Japan, where AstraZeneca collaborates with Daiichi Sankyo Company, Limited (Daiichi Sankyo), sales increased by 1% (3% at CER) to $207m.

Regional Product Sales

Table 7: Regional Product Sales, H1 2019

	H1 2019				Q2 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Emerging Markets	3,951	35	15	24	1,947	34	17	27
China	*2,408*	*22*	*27*	*35*	*1,166*	*20*	*34*	*44*
Ex-China	*1,543*	*14*	*1*	*10*	*781*	*14*	*(1)*	*7*
US	3,663	33	18	18	1,877	33	16	16
Europe	2,029	18	(6)	1	1,047	18	1	8
Established RoW	1,540	14	16	19	847	15	17	21
Japan	*1,173*	*10*	*28*	*31*	*672*	*12*	*30*	*34*
Canada	*225*	*2*	*(8)*	*(3)*	*111*	*2*	*(6)*	*(2)*
Other Established RoW	*142*	*1*	*(18)*	*(11)*	*64*	*1*	*(26)*	*(20)*
Total	**11,183**	**100**	**12**	**17**	**5,718**	**100**	**14**	**19**

Table 8: Regional Product Sales, Emerging Markets

Product Sales of $3,951m in the half; an increase of 15% (24% at CER), continuing the strong performance seen in prior periods. New medicines represented 21% of Emerging Markets sales (H1 2018: 14%). Notable performances included *Tagrisso* ($329m, +107%, 121% at CER), *Farxiga* ($206m, +31%, +45% at CER), *Brilinta* ($217m, 47%, 58% at CER). Ex-China Emerging Market sales increased by 1% (10% at CER) to $1,543m.

	H1 2019				Q2 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	1,048	27	40	52	558	29	45	57
BioPharmaceuticals	2,404	61	13	22	1,139	58	16	25
CVRM	*1,448*	*37*	*9*	*18*	*701*	*36*	*10*	*19*
Respiratory	*956*	*24*	*22*	*30*	*438*	*22*	*26*	*36*
Other medicines	499	13	(11)	(7)	250	13	(14)	(8)
Total Emerging Markets	**3,951**	**100**	**15**	**24**	**1,947**	**100**	**17**	**27**

China sales, comprising 61% of total Emerging Markets sales, increased by 27% in the half (35% at CER) to $2,408m. New medicines delivered particularly encouraging sales growth, supported by strong performances from *Pulmicort*, *Seloken*, *Nexium* and *Symbicort*. New medicines represented 17% of China sales, up from 9% in H1 2018.

Table 9: Regional Product Sales, US

Product Sales in the half of $3,663m; an increase in the half of 18%. New medicines represented 59% of US Product Sales, up from 42% in H1 2018. The performance reflected, in particular, the success of the new Oncology medicines, including *Tagrisso*, *Imfinzi* and *Lynparza*, *Brilinta* in New CVRM, plus the strong performance of *Fasenra* in Respiratory.

	H1 2019			Q2 2019		
	$m	**% of total**	**% change**	**$m**	**% of total**	**% change**
Oncology	1,621	44	68	851	45	58
BioPharmaceuticals	1,841	51	8	937	50	-
CVRM	*1,085*	*30*	*5*	*527*	*28*	*(1)*
Respiratory	*756*	*21*	*12*	*410*	*22*	*1*
Other medicines	201	5	(54)	89	5	(37)
Total US	**3,663**	**100**	**18**	**1,877**	**100**	**16**

Table 10: Regional Product Sales, Europe

Product Sales in the half of $2,029m; a decline of 6% (up by 1% at CER). This partly reflected adverse continued pricing pressures, the impact of the divestment of the prescription medicine rights to *Nexium* in H2 2018 and declining sales of *Crestor*. New medicines represented 39% of Product Sales, up from 26% in H1 2018.

In Q2 2019, however, the sales performance was more encouraging. Oncology delivered particularly strong growth, with *Tagrisso* and *Lynparza*, representing 53% of Oncology sales in Europe, growing by 60% (73% at CER) to $112m and by 47% (60% at CER) to $66m, respectively. This performance was augmented by the successes of *Brilinta* and *Forxiga* in New CVRM and *Fasenra* in Respiratory.

	H1 2019				Q2 2019			
	$m	**% of total**	**% change**		**$m**	**% of total**	**% change**	
			Actual	**CER**			**Actual**	**CER**
Oncology	650	32	29	37	336	32	31	41
BioPharmaceuticals	1,127	56	(12)	(6)	559	53	(10)	(4)
CVRM	*566*	*28*	*(10)*	*(5)*	*283*	*27*	*(8)*	*(1)*
Respiratory	*561*	*28*	*(13)*	*(7)*	*276*	*26*	*(13)*	*(7)*
Other medicines	252	12	(33)	(28)	152	15	(1)	3
Total Europe	**2,029**	**100**	**(6)**	**1**	**1,047**	**100**	**1**	**8**

Table 11: Regional Product Sales, Established RoW

Product Sales in the half of $1,540m; an increase of 16% (19% at CER). New medicines represented 40% of Established RoW sales, up from 18% in H1 2018. The performance during the half reflected, in particular, the successes of *Tagrisso*, *Imfinzi* and *Forxiga*.

	H1 2019				Q2 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	740	48	65	69	422	50	65	70
BioPharmaceuticals	535	35	(7)	(4)	275	32	(10)	(7)
CVRM	*273*	*18*	*-*	*3*	*147*	*17*	*(1)*	*2*
Respiratory	*262*	*17*	*(14)*	*(11)*	*128*	*15*	*(18)*	*(15)*
Other medicines	265	17	(14)	(10)	150	18	(6)	(3)
Total Established RoW	**1,540**	**100**	**16**	**19**	**847**	**100**	**17**	**21**

Japan sales, comprising 76% of total Established RoW, increased by 28% (31% at CER) to $1,173m. *Crestor* sales in Japan increased by 12% (14% at CER) to $85m and represented 7% of Japan sales. New medicines represented 42% of Japan sales, up from 18% in H1 2018, particularly reflecting the strong performance of *Tagrisso* as a 1st-line treatment for patients with EGFRm NSCLC, following regulatory approval in this setting in the third quarter of 2018.

Financial performance

Table 12: H1 2019 Reported Profit and Loss

	Reported			
	H1 2019 $m	H1 2018 $m	% change Actual	% change CER
Product Sales	11,183	10,015	12	17
Collaboration Revenue	131	318	(59)	(57)
Total Revenue	11,314	10,333	9	14
Cost of Sales	(2,192)	(2,146)	2	7
Gross Profit	9,122	8,187	11	16
Gross Margin	*80.4%*	*78.6%*	*+2*	*+2*
Distribution Expense	(159)	(165)	(4)	3
% Total Revenue	*1.4%*	*1.6%*	-	-
R&D Expense	(2,622)	(2,641)	(1)	3
% Total Revenue	*23.2%*	*25.6%*	*+2*	*+2*
SG&A Expense	(5,457)	(5,008)	9	14
% Total Revenue	*48.2%*	*48.5%*	-	-
Other Operating Income & Expense	706	1,086	(35)	(34)
% Total Revenue	*6.2%*	*10.5%*	*-4*	*-4*
Operating Profit	1,590	1,459	9	12
Operating Profit Margin	*14.1%*	*14.1%*	-	-
Net Finance Expense	(632)	(640)	(1)	10
Joint Ventures and Associates	(59)	(33)	78	78
Profit Before Tax	899	786	14	11
Taxation	(229)	(151)	52	47
Tax Rate	25%	19%		
Profit After Tax	670	635	6	2
EPS	$0.56	$0.54	3	-

Table 12: Q2 2019 Reported Profit and Loss

	Reported			
	Q2 2019 $m	Q2 2018 $m	% change Actual	% change CER
Product Sales	5,718	5,030	14	19
Collaboration Revenue	105	125	(17)	(12)
Total Revenue	5,823	5,155	13	18
Cost of Sales	(1,063)	(1,012)	5	14
Gross Profit	4,760	4,143	15	19
Gross Margin	*81.4%*	*79.9%*	*+2*	*+1*
Distribution Expense	(81)	(84)	(4)	3
% Total Revenue	*1.4%*	*1.6%*	-	-
R&D Expense	(1,356)	(1,362)	-	4
% Total Revenue	*23.3%*	*26.4%*	*+3*	*+3*
SG&A Expense	(2,943)	(2,551)	15	21
% Total Revenue	*50.6%*	*49.5%*	*-1*	*-1*
Other Operating Income & Expense	113	617	(82)	(81)
% Total Revenue	*2.0%*	*12.0%*	*-10*	*-10*
Operating Profit	493	763	(35)	(37)
Operating Profit Margin	*8.5%*	*14.8%*	*-6*	*-7*
Net Finance Expense	(320)	(332)	(4)	15
Joint Ventures and Associates	(32)	(19)	69	69
Profit Before Tax	141	412	(66)	(73)
Taxation	(34)	(93)	(64)	(71)
Tax Rate	24%	23%		
Profit After Tax	107	319	(66)	(74)
EPS	$0.09	$0.27	(64)	(71)

Table 13: H1 2019 reconciliation of Reported Profit Before Tax to EBITDA[23]

	H1 2019 $m	H1 2018 $m	% change Actual	% change CER
Reported Profit Before Tax	899	786	14	11
Net Finance Expense	632	640	(1)	10
Joint Ventures and Associates	59	33	78	78
Depreciation, Amortisation and Impairment	1,403	1,393	1	5
EBITDA	2,993	2,852	5	9

Table 14: Q2 2019 reconciliation of Reported Profit Before Tax to EBITDA

	Q2 2019 $m	Q2 2018 $m	% change Actual	% change CER
Reported Profit Before Tax	141	412	(66)	(73)
Net Finance Expense	320	332	(4)	15
Joint Ventures and Associates	32	19	69	69
Depreciation, Amortisation and Impairment	727	684	7	11
EBITDA	1,220	1,447	(16)	(15)

[23] EBITDA is a non-GAAP financial measure and is defined in the operating and financial review.

Table 15: H1 2019 Reconciliation of Reported to Core financial measures

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other[24]	Core[25]	Core % change	
	$m	$m	$m	$m	$m	$m	Actual	CER
Gross Profit	9,122	52	51	-	-	9,225	11	15
Gross Margin	*80.4%*					*81.3%*	1	1
Distribution Expense	(159)	-	-	-	-	(159)	(4)	3
R&D Expense	(2,622)	64	53	-	-	(2,505)	(2)	2
SG&A Expense	(5,457)	110	682	198	209	(4,258)	3	7
Other Operating Income & Expense	706	-	2	-	-	708	1	2
Operating Profit	1,590	226	788	198	209	3,011	39	44
Operating Profit Margin	*14.1%*					*26.6%*	*6*	*5*
Net Finance Expense	(632)	-	-	144	101	(387)	6	19
Taxation	(229)	(47)	(165)	(71)	(20)	(532)	61	62
EPS	$0.56	$0.14	$0.49	$0.21	$0.22	$1.62	38	40

[24] Other adjustments include fair-value adjustments relating to contingent consideration on business combinations (see Note 4) and other acquisition related liabilities, discount unwind on acquisition-related liabilities (see Note 4) and provision movements related to certain legal matters (see Note 5).
[25] Each 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.

Table 16: Q2 2019 Reconciliation of Reported to Core financial measures

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other[26]	Core[27]	Core % change	
	$m	$m	$m	$m	$m	$m	Actual	CER
Gross Profit	4,760	14	26	-	-	4,800	14	18
Gross Margin	*81.4%*					*82.1%*	1	-
Distribution Expense	(81)	-	-	-	-	(81)	(4)	3
R&D Expense	(1,356)	30	46	-	-	(1,280)	(3)	1
SG&A Expense	(2,943)	79	345	93	234	(2,192)	3	8
Other Operating Income & Expense	113	-	1	-	-	114	(80)	(80)
Operating Profit	493	123	418	93	234	1,361	7	8
Operating Profit Margin	*8.5%*					*23.4%*	*(1)*	*(2)*
Net Finance Expense	(320)	-	-	72	51	(197)	-	30
Taxation	(34)	(25)	(90)	(35)	(18)	(202)	(1)	(5)
EPS	$0.09	$0.08	$0.26	$0.10	$0.20	$0.73	5	1

[26] Other adjustments include fair-value adjustments relating to contingent consideration on business combinations (see Note 4) and other acquisition related liabilities, discount unwind on acquisition-related liabilities (see Note 4) and provision movements related to certain legal matters (see Note 5).
[27] Each 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.

Profit and loss commentary

Gross Profit
Reported Gross Profit increased by 11% in the half (16% at CER) to $9,122m; Core Gross Profit increased by 11% (15% at CER) to $9,225m, reflecting the growth in Product Sales. The calculation of Reported and Core Gross Margin excludes the impact of Collaboration Revenue and any associated costs, thereby reflecting the underlying performance of Product Sales. The Reported Gross Margin increased by two percentage points to 80.4%, partly reflecting the mix of Product Sales and manufacturing efficiencies; the Core Gross Margin increased by one percentage point to 81.3%.

Operating Expenses
Reported Operating Expenses, including Distribution Expenses, increased by 5% in the half (10% at CER) to $8,238m and represented 73% of Total Revenue (H1 2018: 76%). Core Operating Expenses increased by 1% (5% at CER) to $6,922m and represented 61% of Total Revenue (H1 2018: 67%).

Reported R&D Expenses declined by 1% in the half (an increase of 3% at CER) to $2,622m. Core R&D Expenses declined by 2% (up by 2% at CER) to $2,505m and represented 22% of Total Revenue (H1 2018: 25%).

Reported SG&A Expenses increased by 9% in the half (14% at CER) to $5,457m; Core SG&A Expenses increased by 3% (7% at CER) to $4,258m and represented 38% of Total Revenue (H1 2018: 40%), primarily reflecting investment in additional colleagues to support the China expansion strategy, as well as further support for new medicines. The difference between the growth of Reported and Core SG&A Expenses partly reflected the commencement of the amortisation of *Lokelma* and fair-value adjustments arising on acquisition-related liabilities recognised in Q2 2019.

Other Operating Income and Expense
Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from divestments is reported within Other Operating Income and Expense in the Company's financial statements. Reported Other Operating Income and Expense declined by 35% in the half (34% at CER) to $706m and included $515m that reflected an agreement to sell US rights to *Synagis* to Swedish Orphan Biovitrum AB (publ) (Sobi). Core Other Operating Income and Expense increased by 1% (2% at CER) to $708m.

Operating Profit
Reported Operating Profit increased by 9% in the half (12% at CER) to $1,590m, partly driven by the increases in Product Sales and the Reported Gross Margin; the Reported Operating Margin was stable at 14%. Core Operating Profit increased by 39% (44% at CER) to $3,011m; the Core Operating Margin increased by six percentage points to 27%. The difference between the Reported and Core growth performance partly reflected the impact of a favourable $346m legal settlement, recognised only in Reported Other Operating Income and Expense, in H1 2018 and fair-value adjustments arising on acquisition-related liabilities recognised in Reported SG&A Expense in Q2 2019.

Net Finance Expense
Reported Net Finance Expense declined by 1% in the half (up by 10% at CER) to $632m. The charge partly reflected higher Net Debt, as well as the effect of the adoption of IFRS 16 (see Note 1). There was also an adverse impact from a higher cost of debt, plus a higher level of discount unwind due to the profit-participation liability. Excluding the discount-unwind on acquisition-related liabilities, Core Net Finance Expense increased by 6% (19% at CER) to $387m.

Profit Before Tax
Reported Profit Before Tax increased by 14% in the half (11% at CER) to $899m, reflecting the growth in Product Sales and the Reported Gross Margin. Core Profit Before Tax increased by 46% (47% at CER) to $2,565m, also a result of the growth in Product Sales and the Core Gross Margin.

Taxation
The Reported Tax Rate for the half was 25% and the Core Tax Rate was 21% (both 19% in H1 2018). These tax rates were higher than the UK Corporation Tax Rate due to the impact of the geographical mix of profits and the impact of collaboration and divestment activity. The net cash tax paid for the half was $723m, representing 80% of Reported Profit Before Tax (H1 2018: $288m, 37%). Increased net cash payments primarily reflected phasing of tax payments.

EPS

Reported EPS of $0.56 represented an increase of 3% (stable at CER). Core EPS increased by 38% (40% at CER) to $1.62. The difference between the Reported and Core performance partly reflected the impact of the aforementioned favourable $346m legal settlement in H1 2018, recognised as income in Reported Other Operating Income and Expense, as well as the aforementioned commencement of the amortisation of *Lokelma* and fair-value adjustments arising on acquisition-related liabilities recognised in Reported SG&A Expense in Q2 2019.

Dividends

The Board has recommended an unchanged first interim dividend of $0.90 (71.9 pence, 8.49 SEK) per Ordinary Share.

Table 17: Cash Flow

	H1 2019 $m	H1 2018 $m	Change $m
Reported Operating Profit	1,590	1,459	131
Depreciation, Amortisation and Impairment	1,403	1,393	10
Increase in Working Capital and Short-Term Provisions	(634)	(1,440)	806
Gains on Disposal of Intangible Assets	(590)	(593)	3
Non-Cash and Other Movements	(177)	(310)	133
Interest Paid	(378)	(296)	(82)
Taxation Paid	(723)	(288)	(435)
Net Cash Inflow/(Outflow) From Operating Activities	**491**	**(75)**	**566**
Net Cash (Outflow)/Inflow Before Financing Activities	(298)	102	(400)
Net Cash Inflow/(Outflow) From Financing Activities	941	(481)	1,422

A net cash inflow from operating activities of $491m in the half compared to an outflow of $75m in H1 2018, partly a result of movements in Working Capital and Short-Term Provisions. The reduction centred on favourable trends in Trade and other receivables and Trade and other payables. The improvement in the performance was partly offset by an increase in Tax Paid, at $723m (H1 2018: $288m); the increase reflected the phasing of tax payments.

Net cash outflows before financing activities of $298m compared with an inflow of $102m in H1 2018. The difference partly reflected the impact of historic business-development transactions and subsequent payments reported within Payment of Contingent Consideration on Business Combinations, as well as within the Purchase of Intangible Assets. The latter included:

1. the first of two $675m upfront payments to Daiichi Sankyo as part of the agreement on trastuzumab deruxtecan, and
2. the impact of a final true-up net payment of $413m to MSD, based on actual sales of *Nexium* and *Prilosec* from 2014 to 2018; this was accrued over the same period

A payment from Pfizer, Inc. of $175m was received in the half, recorded within Disposal of Intangible Assets, as part of a prior agreement to sell the commercialisation and development rights to AstraZeneca's late-stage small-molecule antibiotics business in most markets globally outside the US. Reflecting strong sales growth and a pre-

defined increase in royalty rates, the cash payment of contingent consideration, in respect of the Bristol-Myers Squibb share of the global Diabetes alliance, amounted to $225m in the half (H1 2018: $151m).

As part of the total consideration of $821m included in Disposal of Intangible Assets received in respect of the aforementioned agreement to sell US rights to *Synagis*, $150m related to the rights to participate in the future cash flows from the US profits or losses for nirsevimab (MEDI8897). This was recognised as financial liability and is presented in Other Payables within Non-current Liabilities. The associated cash flow is presented within Investing Activities.

In April 2019, the Company completed an equity placing of $3.5bn, in conjunction with the recent strategic collaboration with Daiichi Sankyo. The purpose of the placing was to fund the initial upfront and near-term milestone commitments arising from the collaboration, as well to strengthen AstraZeneca's balance sheet. The placing was recorded in the second quarter.

Capital expenditure

Capital expenditure amounted to $438m in the half, compared to $486m in H1 2018. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK.

The Company completed the transition to Mace Group as new construction manager for the aforementioned centre at the end of 2018. Following a detailed review of the construction programme presented to the Board, the targeted initial occupation date is unchanged at late 2020, with an overall full completion of the building expected in late 2021. Partly reflecting an element of remedial work, as well as a longer build phase than originally anticipated, AstraZeneca has revised the expected level of associated capital expenditure to c.$1,270m (c.£980m, translated at average exchange rates in the half); capital expenditure on the project to the end of H1 2019 amounted to c.$840m (c.£650m, translated at average exchange rates in the half). The Company has made other progress on its transition to Cambridge; as of the end of June 2019, c.3,000 colleagues were based in the city.

The Company maintains its anticipation of a broadly stable level of total capital expenditure in FY 2019.

Table 18: Debt and capital structure

	At 30 June 2019 $m	At 31 Dec 2018 $m	At 30 June 2018 $m
Cash and Cash Equivalents	5,428	4,831	2,978
Other Investments	875	895	881
Cash and Investments	**6,303**	**5,726**	**3,859**
Overdrafts and Short-Term Borrowings	(629)	(755)	(2,818)
Leases[28]	(720)	-	-
Current Instalments of Loans	(1,000)	(999)	(1,397)
Loans Due After One Year	(17,355)	(17,359)	(15,452)
Interest-Bearing Loans and Borrowings (Gross Debt)	**(19,704)**	**(19,113)**	**(19,667)**
Net Derivatives	321	384	465
Net Debt	**(13,080)**	**(13,003)**	**(15,343)**

[28] Reflects the adoption of IFRS 16 (see Note 1).

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
The Company'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 companies' reporting currency. In addition, the Company'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 or loss.

Table 19: Currency sensitivities
The Company provides the following currency-sensitivity information:

		Average Exchange Rates versus USD			Annual Impact Of 5% Strengthening in Exchange Rate versus USD ($m)[29]	
Currency	**Primary Relevance**	**FY 2018[30]**	**H1 2019[31]**	**% change**	**Product Sales**	**Core Operating Profit**
CNY	Product Sales	6.62	6.80	(3)	221	126
EUR	Product Sales	0.85	0.89	(4)	145	66
JPY	Product Sales	110.45	109.99	-	114	74
Other[32]					216	105
GBP	Operating Expenses	0.75	0.77	(3)	26	(72)
SEK	Operating Expenses	8.69	9.30	(7)	4	(73)

Related-Party Transactions
There have been no significant related-party transactions in the period.

Principal Risks and Uncertainties
It is not anticipated that the nature of the principal risks and uncertainties that affect the business, and which are set out on pages 70 to 73 of the Annual Report and Form 20-F Information 2018, will change in respect of the second six months of the financial year. The potential impact of Brexit continues to be treated as an integral part of the Principal Risks rather than as a stand-alone risk, as summarised on page 71 of the Annual Report and 20F information 2018. Further information on the Company's key risk-management and assurance processes are set out on pages 220 to 230 of the Annual Report and 20-F Information 2018.

On 23 June 2016, the UK held a referendum on continuing membership of the EU, the outcome of which was a decision for the UK to leave the EU (Brexit). Unless and until the Brexit negotiation and parliamentary-ratification processes are complete, it is difficult to anticipate the potential impact on AstraZeneca's market share, sales, profitability and results of operations. The Board reviews the potential impact of Brexit regularly as an integral part of its principal risks rather than as a standalone risk.

[29] As per the Q4 2018 results announcement.
[30] Based on average daily spot rates in FY 2018.
[31] Based on average daily spot rates in from 1 January 2019 to 30 June 2019.
[32] Other currencies include AUD, BRL, CAD, KRW and RUB.

In summary, the principal risks and uncertainties listed in the Annual Report and 20-F Information 2018 are:

1. Medicine pipeline and intellectual property risks: failure or delay in delivery of pipeline and new medicines; failure to meet quality, regulatory and ethical medicine approval and disclosure requirements; failure to secure and protect medicine intellectual property.

2. Commercialisation risks: competitive pressures including externally-driven demand, pricing and access; failures or delays in quality execution of commercial strategies.

3. Supply-chain and business-execution risks: failure to maintain supply of compliant, quality medicines; failure of information security, data protection and cybercrime; failure to attract, develop, engage and retain talented and capable employees at all levels.

4. Legal, regulatory and compliance risks: safety and efficacy of marketed products is questioned; adverse outcome of defence of product, pricing and practices litigation; failure to meet regulatory and ethical expectations on commercial practices, including bribery and corruption, and scientific exchanges.

5. Economic and financial risks: failure to achieve strategic plans and meet targets and expectations.

Corporate and business development

AstraZeneca and BenevolentAI announce a long-term collaboration

In April 2019, AstraZeneca and BenevolentAI announced a long-term collaboration to use artificial intelligence and machine-learning for the discovery and development of new treatments for CKD and idiopathic pulmonary fibrosis. Scientists from the two organisations will work side-by-side to combine AstraZeneca's genomics, chemistry and clinical data with BenevolentAI's target-identification platform and biomedical knowledge graph - a network of contextualised scientific data (genes, proteins, diseases and compounds) and the relationship between them.

Sustainability

AstraZeneca's sustainability ambition has three priority areas[33], aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

Recent developments and progress against the priorities are reported below:

a) Access to healthcare

During the period, the Company celebrated the expansion of its Healthy Heart Africa (HHA) programme into Ghana with an official launch event in collaboration with the Ghana Health Service, in July 2019 in Accra. Healthy Heart Africa is an innovative programme committed to tackling hypertension and the increasing burden of CV disease across Africa. The event brought together stakeholders from government and the medical community for a panel discussion entitled 'Working in Partnership to combat NCDs' (non-communicable diseases). By the end of May 2019, HHA had conducted over 11 million blood-pressure screenings and identified over two million elevated readings since launch in 2014, working with collaborators across Kenya, Ethiopia and Tanzania.

In May 2019, a new report titled '*Adolescent Health: The Missing Population In Universal Health Coverage*' was published and shared at the 72nd World Health Organisation's World Health Assembly. The report was produced with funding from the AstraZeneca Young Health Programme (YHP) and added to the body of evidence that calls for increased awareness of, and investment in, the area of adolescent health and disease prevention.

In June 2019, the Company launched its YHP in Vietnam in collaboration with the National Youth Centre and Hanoi Centre for Disease Prevention and Control, and with the official approval of the Vietnamese Government. With an aim to reach more than 46,000 young people in two high-risk communities in Hanoi, this was the third programme to be implemented in Asia and the 24th programme to be implemented globally.

b) Environmental protection

During the period, the Company received approval from the Science Based Targets initiative that the targets covering greenhouse-gas emissions from elements that directly impact the Company's operations, referred to as Scope 1 (all direct)[34] and Scope 2 (indirect)[34] emissions, are consistent with reductions required to keep warming to 1.5 degrees centigrade, the most ambitious goal of the Paris Agreement. In addition, AstraZeneca's Scope 3 (other indirect)[35] emissions, that the Company can influence, are in line with current best practice. AstraZeneca were also announced by the UN Global Compact as a supporter of the Business Ambitions for 1.5°C - Our Only Future campaign

During the period, it was announced that the Company had made a commitment to switch its 16,000 business-vehicle fleet in Europe, North America and Japan to electric by 2030. AstraZeneca is the first pharmaceutical company to join the global EV100 initiative[36] from The Climate Group, an international non-profit organisation focused on accelerating climate action. The Company is already a member of The Climate Group's RE100 initiative, in collaboration with CDP (formerly the Carbon Disclosure Project), where it has committed to sourcing 100% renewable electricity by 2020 in Europe and the US, and for its global operations by 2025.

c) Ethics and transparency

During the period, the Company continued to evolve its compliance training, ensuring employees are equipped to play a positive role in preserving AstraZeneca's reputation through understanding and empowerment. A new

[33] These priorities were determined, along with a set of nine foundational areas, through a materiality assessment with external and internal stakeholders, respectively. Combined, they ensure the maximum possible benefit to patients, the Company, broader society and the planet. AstraZeneca's sustainability priorities, foundations and commitments align with the United Nations Sustainable Development Goals (SDG), and, in particular, SDG three for 'Good Health'.

[34] Scope 1 and Scope 2 emissions generally include manufacturing processes, transportation of people and goods, purchased energy, the operating procedures of suppliers and collaborators and how patients use the Company's medicines.

[35] Scope 3 emissions generally include ancillary services that the Company may use and goods it might purchase.

[36] EV100 is a global initiative bringing together forward-looking companies committed to accelerating the transition to electric vehicles (EVs) and making electric transport the new normal by 2030.

Anti-Bribery, Anti-Corruption (ABAC) standard was published on the Company's website and training was launched to over 32,000 employees, with a completion rate of 38% in the first week. The course, covering topics around perception and identifying red flags, will roll out to other business areas later in the year.

During the period, the Company entered into a new collaboration with a member of the Hope for Justice group Slave-Free Alliance, with a view to broadening knowledge of best practices in the industry and constantly challenging the Company's approach to ongoing risk mitigation in the anti-slavery space. AstraZeneca is the first life-sciences company to collaborate with the alliance.

Other developments

During the period, the Company celebrated 'Sustainability Matters Week', with thousands of colleagues from over 40 countries actively engaged in sharing local activities and ideas through live events, videos and posts across internal communication and social channels, raising awareness and generating colleague engagement with AstraZeneca's sustainability strategy and focus areas.

For more details on AstraZeneca's sustainability ambition, approach and targets, please refer to the latest Sustainability Report 2018 and Sustainability Data Summary 2018, available at astrazeneca.com/sustainability.

Research and development

A comprehensive data pack comprising AstraZeneca's pipeline of medicines in human trials can be found in the clinical-trials appendix, available on astrazeneca.com. Highlights of developments in the Company's late-stage pipeline since the prior results announcement are shown below:

Table 20: Update from the late-stage pipeline

Regulatory approvals	5	- *Lynparza* - ovarian cancer (1st line, BRCAm): regulatory approval (EU, JP) - *Qternmet XR* - T2D: regulatory approval (US) - *Bevespi* - COPD: regulatory approval (JP) - *Breztri* (formerly PT010) - COPD: regulatory approval (JP)
Regulatory submissions and/or acceptances	4	- *Lynparza* - pancreatic cancer (BRCAm): regulatory submission acceptance (EU) - *Forxiga* - T2D CVOT: regulatory submission (CN) - *Lokelma* - hyperkalaemia: regulatory submission (JP, CN)
Major Phase III data readouts or other major developments	11	- *Imfinzi* - SCLC: met Phase III primary endpoint - *Imfinzi* - SCLC: Orphan Drug Designation (US) - trastuzumab deruxtecan - breast cancer (3rd line, HER2+): met pivotal Phase II primary endpoint - *Calquence* - CLL (relapsed/refractory): met Phase III primary endpoint - *Calquence* - CLL (treatment-naïve): met Phase III primary endpoint - *Forxiga* - T2D CVOT: positive opinion (EU) - *Farxiga* - T1D: complete response (US) - *Lokelma* - hyperkalaemia: priority review (CN) - roxadustat - anaemia of CKD: pooled Phase III CV safety confirmed - *Breztri* - COPD: priority review (CN) - *Fasenra* - severe asthma (self-administration and auto-injector): positive opinion (EU)
New molecular entities and major lifecycle medicines in Phase III trials or under regulatory review	14	**Oncology** - *Tagrisso* - NSCLC - *Imfinzi* - multiple cancers - *Lynparza* - multiple cancers - trastuzumab deruxtecan - breast and other cancers - capivasertib - breast cancer - *Calquence* - blood cancers - tremelimumab - multiple cancers - selumetinib - NF1[37] - savolitinib - NSCLC[37] **CVRM** - roxadustat - anaemia of CKD **Respiratory** - *Breztri* - COPD - PT027 - asthma - tezepelumab - severe asthma **Other medicines** (outside main therapy areas) - anifrolumab - lupus
Total projects in clinical pipeline	142	

[37] Phase II trial data, with potential for registration.

Oncology

AstraZeneca has a deep-rooted heritage in Oncology and offers a new generation of medicines that have 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 *Tagrisso*, *Imfinzi*, *Lynparza*, *Calquence* and *Lumoxiti* are already benefitting patients. An extensive pipeline of small-molecule and biologic medicines is in development, and the Company is committed to advancing Oncology medicines, primarily focused on the treatment of patients with lung, ovarian, breast and blood cancers.

At the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, the Company presented 93 abstracts spanning multiple tumour types, including 12 oral presentations with one plenary session and four late-breaking abstracts. Highlights included late-breaking results from the Phase III *Lynparza* POLO trial in metastatic pancreatic cancer, and results of the Phase III *Lynparza* SOLO3 trial in late-line, germline BRCA-mutated (gBRCAm) advanced ovarian cancer. Three-year OS data from the *Imfinzi* Phase III PACIFIC trial in unresectable, Stage III NSCLC were also presented.

Oncology: lung cancer

a) *Tagrisso*

Tagrisso has now received approval in 74 countries, including in the US, Japan and in the EU, for the 1st-line treatment of patients with Stage IV EGFRm NSCLC. Multiple other similar reviews are underway, including in China, where a decision is anticipated during the second half of 2019, based on a priority review granted in December 2018. Regulatory approvals have been achieved in 84 countries, including the US, in the EU, Japan and in China for the 2nd-line treatment of patients with EGFR T790M-mutated NSCLC.

Table 21: Key *Tagrisso* trials in lung cancer

Name	Phase	Population	Design	Timelines	Status
LAURA	III	Locally-advanced, unresectable EGFRm NSCLC	Placebo or *Tagrisso*	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
ADAURA	III	Adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD[38] Q4 2015 LPCD[39] Q1 2019 First data anticipated 2020+[40]	Recruitment ongoing
SAVANNAH	II	EGFRm, MET+ locally-advanced or metastatic NSCLC patients who have progressed on *Tagrisso*	*Tagrisso* + savolitinib	FPCD Q1 2019 First data anticipated 2020+	Recruitment initiating

[38] First patient commenced dosing.
[39] Last patient commenced dosing.
[40] Based on current expectations and event rates, data from the ADAURA trial can be expected in 2022.

Name	Phase	Population	Design	Timelines	Status
ORCHARD	II	1st-line EGFRm NSCLC post *Tagrisso*	SoC chemotherapy or *Tagrisso* + savolitinib or *Tagrisso* + *Iressa* or *Tagrisso* + necitumumab or *Imfinzi* + chemotherapy	FPCD Q2 2019 First data anticipated 2020+	Recruitment initiating

b) *Imfinzi*

During the period, AstraZeneca announced positive OS results from the Phase III CASPIAN trial with *Imfinzi* in 1st-line, extensive-stage SCLC. A planned interim analysis conducted by an Independent Data Monitoring Committee concluded that the trial had met its primary endpoint, by showing a statistically-significant and clinically-meaningful improvement in OS in patients treated with *Imfinzi* in combination with etoposide and platinum-based chemotherapy options versus SoC chemotherapy alone. The safety and tolerability for this *Imfinzi* combination was consistent with the known safety profiles of these medicines. AstraZeneca intends to submit these results for presentation at a forthcoming medical meeting and regulatory interactions are underway. During the period, the Company also announced that the US FDA had granted Orphan Drug Designation to *Imfinzi* for the treatment of SCLC.

AstraZeneca presented three-year OS results from the Phase III PACIFIC trial of *Imfinzi* in unresectable, Stage III NSCLC during the aforementioned 2019 ASCO Annual Meeting. The results demonstrated a durable and sustained OS benefit for patients with unresectable, Stage III NSCLC who had not progressed following concurrent CRT, a previous SoC treatment. The OS rate was 57% at three years for patients receiving *Imfinzi*, versus 43.5% for placebo following concurrent CRT. Median OS had not yet been reached with the *Imfinzi* arm, versus 29.1 months for placebo. The US FDA subsequently approved the inclusion of OS data for patients with unresectable, Stage III NSCLC whose disease has not progressed following concurrent platinum-based CRT on the label.

During the period, the Company updated the primary endpoint of the NEPTUNE trial of SoC chemotherapy or *Imfinzi* + tremelimumab in Stage IV, 1st-line NSCLC to focus on OS with blood tumour mutation burden (bTMB, ≥ 20mut/Mb), an evolving strategy for tremelimumab.

Table 22: Key *Imfinzi* trials in lung cancer

Name	Phase	Population	Design	Timelines	Status
AEGEAN	III	Neo-adjuvant (before surgery) NSCLC	SoC chemotherapy +/- *Imfinzi*, followed by surgery followed by placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated H2 2020	Recruitment ongoing
ADJUVANT BR.31[41]	III	Stage Ib-IIIa NSCLC	Placebo or *Imfinzi*	FPCD Q1 2015 First data anticipated 2020+	Recruitment ongoing

[41] Conducted by the Canadian Cancer Trials Group.

Name	Phase	Population	Design	Timelines	Status
PACIFIC	III	Unresectable, Stage III NSCLC	Concurrent CRT, followed by placebo or *Imfinzi*	FPCD Q2 2014 LPCD Q2 2016	PFS[42] and OS primary endpoints both met
PACIFIC-2	III	Unresectable, Stage III NSCLC	Concurrent CRT concurrent with placebo or *Imfinzi*, followed by placebo or *Imfinzi*	FPCD Q2 2018 First data anticipated H2 2020	Recruitment ongoing
PACIFIC-4	III	Unresectable, Stage I-II NSCLC	Stereotactic body radiation therapy followed by placebo or *Imfinzi*	FPCD Q2 2019 First data anticipated 2020+	Recruitment ongoing
PACIFIC-5	III	Unresectable, Stage III NSCLC (Asia predominant)	Concurrent or sequential CRT, followed by placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
ADRIATIC	III	Limited-disease stage SCLC	Concurrent CRT, followed by placebo or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2018 First data anticipated 2020+	Recruitment ongoing
PEARL	III	Stage IV, 1st-line NSCLC (Asia)	SoC chemotherapy or *Imfinzi*	FPCD Q1 2017 LPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
NEPTUNE	III	Stage IV, 1st-line NSCLC	SoC chemotherapy or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q2 2017 First data anticipated H2 2019	Recruitment completed
POSEIDON	III	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q2 2017 LPCD Q3 2018 First data anticipated H2 2019	Recruitment completed
CASPIAN	III	Extensive-disease stage SCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q1 2017 LPCD Q2 2018	OS primary endpoint met for *Imfinzi* monotherapy arm

[42] Progression-free survival.

***Imfinzi* as a potential new medicine in other tumour types**

The Company continues to advance multiple monotherapy trials of *Imfinzi* and combination trials of *Imfinzi* with tremelimumab and other potential new medicines in tumour types other than lung cancer.

Imfinzi has received regulatory approval for the 2nd-line treatment of patients with locally-advanced or metastatic urothelial carcinoma (bladder cancer) in 10 countries.

Table 23: Key *Imfinzi* trials in tumour types other than lung cancer

Name	Phase	Population	Design	Timelines	Status
Stage I, II & III (non-metastatic disease)					
POTOMAC	III	Non-muscle invasive bladder cancer	SoC BCG[43] or SoC BCG + *Imfinzi*	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
NIAGARA	III	Muscle-invasive bladder cancer	Neo-adjuvant cisplatin and gemcitabine SoC chemotherapy or SoC + *Imfinzi* followed by adjuvant placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
EMERALD-1	III	Locoregional hepatocellular carcinoma (liver cancer)	TACE[44] followed by placebo or TACE + *Imfinzi* followed by *Imfinzi* + bevacizumab or TACE + *Imfinzi* followed by *Imfinzi*	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
EMERALD-2	III	Locoregional hepatocellular carcinoma at high risk of recurrence after surgery or radiofrequency ablation	Adjuvant *Imfinzi* or *Imfinzi* + bevacizumab	FPCD Q2 2019 First data anticipated 2020+	Recruitment ongoing
CALLA	III	Locally-advanced cervical cancer	CRT or CRT + *Imfinzi* followed by placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing
Stage IV (metastatic disease)					
DANUBE	III	Stage IV, 1st-line cisplatin chemotherapy-eligible/ineligible bladder cancer	SoC chemotherapy or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H2 2019	Recruitment completed

[43] Bacillus Calmette-Guerin.
[44] Transarterial chemoembolisation.

Name	Phase	Population	Design	Timelines	Status
NILE	III	Stage IV, 1st-line cisplatin chemotherapy-eligible bladder cancer	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
KESTREL	III	Stage IV, 1st-line HNSCC	SoC or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H2 2019	Recruitment completed
EAGLE	III	Stage IV, 2nd-line HNSCC	SoC or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q3 2017	Recruitment completed OS primary endpoints not met
HIMALAYA	III	Stage IV, 1st-line unresectable hepatocellular carcinoma	Sorafenib or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2017 LPCD Q3 2019 First data anticipated H2 2020	Recruitment ongoing
TOPAZ-1	III	Stage IV, 1st-line biliary-tract cancers	Gemcitabine and cisplatin SoC chemotherapy or SoC + *Imfinzi*	FPCD Q2 2019	Initiating

Oncology: *Lynparza* (multiple cancers)
In June 2019, AstraZeneca and MSD announced that the European Commission (EC) had approved *Lynparza* as a 1st-line maintenance treatment for patients with BRCAm advanced ovarian cancer. Following approval in the EU, the two companies announced that *Lynparza* had been approved in Japan as a maintenance treatment after 1st-line chemotherapy in patients with BRCAm advanced ovarian cancer, as detected by an approved companion-diagnostic test. The approvals were based on data from the pivotal Phase III SOLO-1 trial, which tested *Lynparza* as maintenance monotherapy compared with placebo in patients with BRCAm advanced ovarian cancer following 1st-line platinum-based chemotherapy.

At the aforementioned 2019 ASCO Annual Meeting, AstraZeneca and MSD presented detailed results from two *Lynparza* Phase III trials in pancreatic and ovarian cancer. In pancreatic cancer, detailed results from the Phase III POLO trial were presented, coinciding with a publication in *The New England Journal of Medicine*. The POLO trial tested *Lynparza* tablets as 1st-line maintenance monotherapy for patients with gBRCAm metastatic pancreatic cancer whose disease had not progressed, following SoC platinum-based 1st-line chemotherapy. Results from the trial showed a statistically-significant and clinically-meaningful improvement in PFS for *Lynparza* versus placebo, improving the time without disease progression by a median of 7.4 months for patients treated with *Lynparza* versus 3.8 months for those on placebo (HR 0.53 [95% CI, 0.35-0.82], p=0.004). More than twice as many patients showed no disease progression both at one year (34% on *Lynparza* versus 15% on placebo) and two years (22% versus 10%, respectively). During the period, a regulatory submission based on the data from the POLO trial, was accepted in the EU.

In ovarian cancer, the Company presented full results from the Phase III SOLO3 trial, which compared *Lynparza* with physician's choice of chemotherapy in the treatment of patients with gBRCAm advanced ovarian cancer who had received two or more prior lines of chemotherapy. The results from the trial showed a statistically-significant and clinically-meaningful improvement in objective response rate (ORR) for *Lynparza* versus SoC chemotherapy (72.2% versus 51.4% [95% CI, 1.40-4.58], p=0.002). ORR measures the proportion of patients with a reduction in tumour burden by a predefined percentage. The trial also met the key secondary endpoint of PFS, demonstrating a statistically-significant and clinically-meaningful improvement in the time patients lived without disease progression for *Lynparza* (13.4 months) versus chemotherapy (9.2 months [HR 0.62], p=0.013).

Table 24: Key *Lynparza* trials

Name	Phase	Population	Design	Timelines	Status
OlympiA	III	Adjuvant BRCAm breast cancer	SoC placebo or *Lynparza*	FPCD Q2 2014 LPCD Q2 2019 First data anticipated 2020+	Recruitment completed
PROfound	III	Metastatic castration-resistant prostate cancer, HRRm 2nd-line+	SoC (abiraterone or enzalutamide) or *Lynparza*	FPCD Q2 2017 LPCD Q4 2018 First data anticipated H2 2019	Recruitment completed
PAOLA-1[45]	III	Stage IV, 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + *Lynparza* maintenance	FPCD Q2 2015 LPCD Q2 2018 First data anticipated H2 2019	Recruitment completed
GY004[46]	III	Recurrent platinum-sensitive ovarian cancer	SoC chemotherapy or cediranib or cediranib + *Lynparza*	FPCD Q1 2016 First data anticipated H1 2020	Recruitment ongoing
GY005[46]	II/III	Recurrent platinum-resistant/refractory ovarian cancer	SoC chemotherapy or cediranib or cediranib + *Lynparza*	FPCD Q2 2016 (Phase II) FPCD Q1 2019 (Phase III) First data anticipated 2020+	Recruitment ongoing (Phase III component)
DuO-O	III	Stage IV, 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + *Imfinzi* +/- *Lynparza* maintenance	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing

[45] Conducted by the ARCAGY/Groupe d'Investigateurs National des Etudes des Cancers Ovariens et du sein.
[46] Conducted by the National Cancer Institute (US).

Name	Phase	Population	Design	Timelines	Status
MEDIOLA	I/II	Advanced, 2nd-line gBRCAm ovarian cancer Stage IV, 1st to 3rd-line gBRCAm, HER2-negative breast cancer Stage IV, 2nd-line SCLC Stage IV, 2nd-line gastric cancer	*Lynparza* + *Imfinzi*	FPCD Q2 2016 LPCD Q1 2019 (all except one cohort)	Recruitment ongoing in one expansion cohort Initial data from lung, breast, prostate and ovarian-cancer cohorts presented in 2017 and 2018
LYNK-002	II	HRRm advanced solid tumours	*Lynparza*	FPCD Q1 2019	Recruitment ongoing
VIOLETTE	II	Stage IV, advanced, triple-negative breast cancer: -HRRm[47] (BRCA) -HRRm (non-BRCA) -Non-HRRm	*Lynparza* *Lynparza* + ATR (AZD6738) *Lynparza* + WEE1 (AZD1775)	FPCD Q2 2018 First data anticipated 2020+	Recruitment ongoing
PROpel	III	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + *Lynparza*	FPCD Q4 2018 First data anticipated 2020+	Recruitment ongoing
BAYOU	II	Stage IV, 1st-line cis-platinum chemotherapy-ineligible urothelial bladder cancer	*Imfinzi* or *Imfinzi* + *Lynparza*	FPCD Q1 2018 First data anticipated 2020+	Recruitment ongoing
DuO-L ORION	II	Stage IV, 1st-line NSCLC	SoC chemotherapy + *Imfinzi*, followed by *Imfinzi* or *Imfinzi* + *Lynparza* maintenance	FPCD Q1 2019 First data anticipated 2020+	Recruitment ongoing

Trastuzumab deruxtecan (breast and other cancers)
During the period, AstraZeneca and Daiichi Sankyo announced positive top-line results for the pivotal Phase II DESTINY-Breast01 trial of trastuzumab deruxtecan, the HER2-targeting antibody drug conjugate for patients with HER2-positive, unresectable and/or metastatic breast cancer previously treated with trastuzumab emtansine. The safety and tolerability profile of trastuzumab deruxtecan was also consistent with previous experience. These results are expected to support planned global regulatory submissions, including a Biologics License Application with the US FDA anticipated in the second half of 2019.

During the period, the Company announced the publication of two manuscripts in *The Lancet Oncology*, reporting long-term Phase I safety and preliminary efficacy results of trastuzumab deruxtecan in heavily-pretreated patients with HER2-positive metastatic breast cancer and gastric cancer. In the first manuscript, in HER-2 positive

[47] Homologous recombination repair mutated.

metastatic breast-cancer patients previously treated with trastuzumab emtansine, trastuzumab deruxtecan demonstrated a confirmed ORR of 59.5% (95% CI: 49.7, 68.7) and a disease control rate (DCR) of 93.7% (95% CI: 87.4, 97.4). Median duration of response (DoR) was 20.7 months (0.0 to 21.8), median PFS was 22.1 months (0.8 to 27.9), and median OS had not yet been reached in the trial. In the second manuscript, in HER-2 positive advanced gastric-cancer patients previously treated with trastuzumab, trastuzumab deruxtecan demonstrated a confirmed ORR of 43.2% (95% CI: 28.3, 59.0) and a DCR of 79.5% (95% CI: 64.7, 90.2) were seen with trastuzumab deruxtecan. The median DoR was 7.0 months (4.4 to 16.6), median PFS was 5.6 months (95% CI: 3.0, 8.3), and median OS was 12.8 months (1.4 to 25.4).

Table 25: Key trastuzumab deruxtecan trials

Name	Phase	Population	Design	Timelines	Status
DESTINY-Breast01	II	Stage IV, HER2-positive breast cancer post trastuzumab emtansine	Trastuzumab deruxtecan	FPCD Q3 2017 Data readout Q2 2019	Breakthrough Therapy Designation (US) status awarded
DESTINY-Breast02	III	Stage IV, HER2-positive breast cancer post trastuzumab emtansine	SoC or trastuzumab deruxtecan	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
DESTINY-Breast03	III	Stage IV, HER2-positive breast cancer	Trastuzumab emtansine or trastuzumab deruxtecan	FPCD Q3 2018 First data anticipated 2020+	Recruitment ongoing
DESTINY-Breast04	III	Stage IV, HER2-low breast cancer	SoC or trastuzumab deruxtecan	FPCD Q4 2018 First data anticipated 2020+	Recruitment ongoing
DESTINY-Gastric01	II	Stage IV, HER2-positive gastric cancer	SoC or trastuzumab deruxtecan	FPCD Q4 2017 First data anticipated H1 2020	Recruitment completed

Capivasertib (breast cancer)

During the period capivasertib commenced a Phase III trial in 1st-line patients with locally advanced or metastatic triple-negative breast cancer. The trial will randomise c.800 patients to receive placebo and paclitaxel or capivasertib and paclitaxel.

***Calquence* (blood cancers)**

During the period, AstraZeneca received regulatory approval for *Calquence* in relapsed MCL in Mexico and Argentina; approval was achieved in prior periods in the US, Brazil, Qatar and the UAE. The Company also announced positive high-level results from two pivotal *Calquence* Phase III trials in CLL, in front-line and relapsed/recurrent disease.

AstraZeneca recently announced and presented positive results from the Phase III ASCEND trial of *Calquence* in patients with relapsed/recurrent CLL, where the trial met its primary endpoint. The detailed results were presented at the European Hematology Association Annual Congress in Amsterdam. At a median follow-up of 16.1 months, results from the trial showed a statistically-significant and clinically-meaningful improvement in PFS for patients treated with *Calquence* versus idelalisib (IdR) or bendamustine (BR), reducing the risk of disease progression or death by 69% (HR, 0.31; 95% CI, 0.20-0.49, p<0.0001). The median time without disease progression for patients treated with *Calquence* had not yet been reached, versus 16.5 months in the control arm. At 12 months, 88% of patients on *Calquence* showed no disease progression, compared to 68% for the control arm. The safety and tolerability of *Calquence* was consistent with its established profile. A summary of the adverse events (AEs) of interest is highlighted below:

Table 26: ASCEND adverse events of interest

AEs of interest, n (%)	*Calquence* (n=154)		IdR (n=118)		BR (n=35)	
	Any	Grade ≥3	Any	Grade ≥3	Any	Grade ≥3
Atrial fibrillation	8 (5%)	2 (1%)	4 (3%)	1 (1%)	1 (3%)	1 (3%)
Bleeding	40 (26%)	3 (2%)	9 (8%)	3 (3%)	2 (6%)	1 (3%)
Hypertension	5 (3%)	3 (2%)	5 (4%)	1 (1%)	0	0
SPM[48] excluding NMSC[49]	10 (6%)	5 (3%)	3 (3%)	0	1 (3%)	1 (3%)

The Company also announced positive results from the Phase III ELEVATE-TN trial of *Calquence* in patients with previously-untreated CLL, where the trial met its primary endpoint. *Calquence*, in combination with obinutuzumab, demonstrated a statistically-significant and clinically-meaningful improvement in PFS when compared with the chemotherapy-based combination of chlorambucil and obinutuzumab. The trial also met a key secondary endpoint, showing *Calquence* monotherapy achieved a statistically-significant and clinically-meaningful improvement in PFS compared to the chemotherapy and obinutuzumab regimen. The safety and tolerability of *Calquence* was consistent with its established profile. AstraZeneca plans to present detailed results from ELEVATE-TN at a forthcoming medical meeting.

Table 27: Key *Calquence* trials in CLL

Name	Phase	Population	Design	Timelines	Status
ACE-CL-007 ELEVATE-TN	III	Previously-untreated CLL	Chlorambucil + obinutuzumab or obinutuzumab + *Calquence* or *Calquence*	FPCD Q2 2015 Data readout Q2 2019	Primary endpoint met
ACE CL-311	III	Previously-untreated CLL	Fludarabine, cyclophosphamide and rituximab or *Calquence* + venetoclax +/- obinutuzumab	FPCD Q2 2019 First data anticipated 2020+	Recruitment ongoing
ACE-CL-309 ASCEND	III	Relapsed/refractory CLL	BR or IdR + rituximab or *Calquence*	FPCD Q3 2016 Data readout Q2 2019	Primary endpoint met
ACE-CL-006 ELEVATE-RR	III	Relapsed/refractory high risk CLL	Ibrutinib or *Calquence*	FPCD Q2 2015 First data anticipated 2020+	Recruitment ongoing

[48] Secondary primary malignancy.
[49] Non-melanoma skin cancer.

CVRM

CVRM forms one of AstraZeneca's main therapy areas and a key growth driver for the Company. By following the science to understand more clearly the underlying links between the heart, kidneys and pancreas, AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling co-morbidities. The Company's ambition is to modify or halt the natural course of CVRM diseases and potentially regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and CV health for millions of patients.

a) *Farxiga* (diabetes)
At the recent American Diabetes Association 79th Scientific Sessions in San Francisco, US, the Company presented a pre-specified exploratory analysis of renal data from the Phase III DECLARE-TIMI 58 trial, the broadest CVOT of a sodium-glucose co-transporter 2 (SGLT2) inhibitor, showing that *Farxiga* reduced the progression of kidney disease or renal death in patients with T2D.

Farxiga showed a 47% reduction in the relative risk of the composite renal-specific outcome of kidney-function decline (sustained ≥40% decrease in estimated glomerular filtration rate (eGFR) to <60 mL/min/1.73m2), end-stage renal disease (ESRD), or renal death (excluding CV death) compared to placebo (1.5% versus 2.8%; HR 0.53 [95% CI 0.43-0.66]). Additionally, *Farxiga* reduced the relative risk of a cardio-renal composite of kidney-function decline, ESRD, or renal or CV death by 24% compared to placebo (4.3% versus 5.6%; HR 0.76 [95% CI 0.67-0.87]).

During the period, the Company received submission acceptance from the China NMPA for the application to include CV outcomes data from the DECLARE-TIMI 58 trial for *Forxiga*. The DECLARE data was also added to *Forxiga*'s label in Brazil during the period. In July 2019, the Company announced that the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) had recommended a change to the European marketing authorisation for *Forxiga* in patients with T2D to include CV outcomes data from the DECLARE-TIMI 58 trial.

During the period, the first of c.700 patients were dosed in the DETERMINE trials. DETERMINE consists of two double-blinded, randomised, placebo-controlled Phase III trials which will evaluate the effect of 16 weeks of treatment with *Farxiga* compared to placebo, as measured by a six-minute walk test, a standard assessment of exercise capacity in patients with heart failure (HF). The key secondary outcome will be the measurement of a patient-reported outcome, assessing the impact of HF on patient wellbeing and the ability to lead a normal and active life. One trial will enrol HF patients with preserved ejection fraction and the other will enrol HF patients who have reduced ejection fraction.

In July 2019, AstraZeneca announced that the US FDA had issued a complete response letter regarding the supplemental New Drug Application (NDA) for *Farxiga* as an adjunct treatment to insulin to improve glycaemic control in adult patients with T1D, when insulin alone does not provide adequate glycaemic control. The Company will work closely with the US FDA to discuss the next steps. *Forxiga* was recently approved in Europe (5mg) and Japan (5mg, potential up-titration to 10mg), as an adjunct to insulin in adults with T1D.

b) *Qternmet XR* (T2D)
During the period, the Company received US FDA approval for *Qternmet XR* as an oral adjunct treatment to diet and exercise to improve glycaemic control in adults with T2D. The approval was based on data from two Phase III trials which evaluated combinations of dapagliflozin and saxagliptin on a background of metformin over 24 weeks, in patients with inadequately-controlled T2D.

Table 28: Key large CVRM trials
Major CVRM outcomes trials are highlighted in the following table:

Medicine	Trial	Mechanism	Population	Primary endpoint(s)	Timeline
Farxiga	DECLARE	SGLT2 inhibitor	c.17,000[50] patients with type-2 diabetes	Superiority for MACE[51] or superiority for the composite endpoint of CV death or hHF[52]	Primary safety endpoint met One of two primary efficacy endpoints met
Farxiga	DAPA-HF	SGLT2 inhibitor	c.4,500 patients with HF and reduced ejection fraction, with and without type-2 diabetes	Time to first occurrence of CV death or hHF or an urgent HF visit	FPCD Q1 2017 LPCD Q3 2018 First data anticipated H2 2019
Farxiga	DELIVER	SGLT2 inhibitor	c.4,700 patients with HF and preserved ejection fraction, with and without type-2 diabetes	Time to first occurrence of CV death or worsening heart failure	FPCD Q3 2018 First data anticipated 2020+
Farxiga	DAPA-CKD	SGLT2 inhibitor	c.4,000 patients with CKD, with and without T2D	Time to first occurrence of ≥ 50% sustained decline in eGFR or reaching ESRD or CV death or renal death	FPCD Q1 2017 LPCD Q1 2019 First data anticipated 2020+
Brilinta	THEMIS	P2Y12 receptor antagonist	c.19,000 patients with T2D and CAD without a history of MI[53] or stroke	Composite of CV death, non-fatal MI and non-fatal stroke	Primary endpoint met Details to be presented at a forthcoming medical meeting
Brilinta	THALES	P2Y12 receptor antagonist	c.11,000 patients with acute ischaemic stroke or transient ischaemic attack	Prevention of the composite of subsequent stroke and death at 30 days	FPCD Q1 2018 First data anticipated H1 2020

[50] Included c.10,000 patients who had no prior index event and c.7,000 patients who had suffered an index event.
[51] Major adverse cardiac events.
[52] Hospitalisation for heart failure.
[53] Myocardial infarction.

Medicine	Trial	Mechanism	Population	Primary endpoint(s)	Timeline
Epanova	STRENGTH	Omega-3 carboxylic acids	c.13,000 patients with mixed dyslipidaemia/ hypertriglyceride-aemia	Time to first occurrence of CV death, non-fatal MI or non-fatal stroke	FPCD Q4 2014 LPCD Q2 2017 First data anticipated H2 2020

c) *Lokelma* (hyperkalaemia)
In May 2019, AstraZeneca submitted an NDA in Japan for *Lokelma* to the Pharmaceuticals and Medical Devices Agency. The regulatory submission was based on data from four Phase III trials and the Company anticipates a regulatory decision during H1 2020.

In China, the Center for Drug Evaluation (CDE) published its second *List of Overseas New Drugs in Urgent Clinical Need*, which can use global data to apply to an NDA; *Lokelma* was included in this list. In June 2019, the Company submitted an NDA for *Lokelma* that was accepted by the CDE of the NMPA for accelerated approval. The Company anticipates a regulatory decision in H1 2020.

During the period, positive results from the Phase IIIb DIALIZE trial were presented as a late-breaking abstract at the 56th European Renal Association - European Dialysis and Transplant Association congress in Budapest, Hungary. The trial demonstrated that 41.2% of patients maintained normal potassium levels (pre-dialysis), compared to 1% receiving placebo; this was a statistically-significant and clinically-meaningful improvement. The data was simultaneously published in the *Journal of the American Society of Nephrology*. The DIALIZE data has been submitted to both regulatory agencies in the US and EU for potential inclusion in the label.

d) Roxadustat (anaemia)
In May 2019, AstraZeneca announced positive top-line results from the pooled CV safety analyses of the global Phase III programme for roxadustat, a first-in-class hypoxia-inducible-factor prolyl hydroxylase inhibitor. The global pivotal Phase III trials evaluated roxadustat for treatment of anaemia in patients with CKD across the non-dialysis-dependent (NDD), incident (newly-initiated) dialysis, and stable-dialysis patient groups.

AstraZeneca and its collaborator, FibroGen Inc. anticipate a US FDA regulatory submission in the second half of 2019. Roxadustat is currently approved in China for the treatment of patients with anaemia in dialysis-dependent CKD, with a regulatory decision in NDD anticipated in the second half of 2019.

Respiratory

AstraZeneca's Respiratory focus is aimed at transforming the treatment of patients with asthma and COPD through combined inhaled therapies and biologic medicines for the unmet medical needs of specific populations and an early pipeline focused on disease modification. The growing range of medicines includes a number of anticipated launches between 2017 and 2020; of these, *Bevespi* and *Fasenra* are already benefitting patients, with regulatory reviews for *Symbicort* as an anti-inflammatory reliever in mild asthma and *Breztri* in COPD underway. The capability in inhalation technology spans both pressurised metered-dose inhalers (pMDIs) and dry-powder inhalers to serve patient needs, including the innovative *Aerosphere* delivery technology, a focus of AstraZeneca's future-platform development for respiratory-disease combination therapies.

AstraZeneca attended the American Thoracic Society (ATS) International Conference in May 2019 in Dallas, US. The Company presented new data from the *Symbicort* Novel START trial, among 73 AstraZeneca abstracts accepted for oral or poster presentation.

a) *Symbicort* (asthma)
New data from the aforementioned Novel START, an open-label trial designed to reflect real-world practice, demonstrated the effectiveness of *Symbicort* as a potential anti-inflammatory reliever in mild asthma. These results were published in *The New England Journal of Medicine* and were presented at the aforementioned ATS conference.

The trial compared *Symbicort* with two commonly-used treatment regimens in mild asthma. In real-world practice, patients typically use a short-acting beta2-agonist (SABA) reliever in response to symptoms, or daily low-dose ICS maintenance therapy with a SABA reliever. In this trial, patients with mild asthma were randomised to receive either albuterol (a SABA reliever, also known as salbutamol in many countries) taken as-needed, or budesonide (an ICS maintenance treatment) plus albuterol as-needed, or *Symbicort* used as an anti-inflammatory reliever therapy taken as-needed.

Symbicort demonstrated a 51% reduction in the rate of annual asthma exacerbations, compared to albuterol. There was no difference in the exacerbation rate between *Symbicort* and twice-daily maintenance budesonide plus albuterol, despite a 52% reduction in the mean steroid dose with *Symbicort*. These data supported the findings of the SYGMA 1 and 2 trials, published in May 2018.

Earlier this year, the Global Initiative for Asthma published the updated *Global Strategy for Asthma Management and Prevention* guidelines, recommending low-dose ICS-formoterol combination therapy as-needed as the preferred reliever therapy across all asthma severities instead of SABA-reliever monotherapy.

In Europe, the regulatory submission to expand the indication for *Symbicort Turbuhaler* as an anti-inflammatory reliever in mild asthma is ongoing. In July 2019, AstraZeneca received a negative assessment from the Medical Products Agency, Sweden, the EU reference member state leading the mutual-recognition procedure. The procedure is expected to complete by 31 July 2019. *Symbicort* is approved as an anti-inflammatory reliever as-needed in patients with mild asthma in Brazil and Russia and, most recently, in New Zealand and Australia.

b) *Bevespi* (COPD)
In June 2019, the Japanese Ministry of Health, Labour and Welfare granted regulatory approval for *Bevespi*. This was the first approval for a maintenance fixed-dose, long-acting dual bronchodilator in a pMDI. The approval was based on positive results from the Phase III PINNACLE 4 trial, which demonstrated the efficacy and safety of *Bevespi Aerosphere* in c.1,800 patients with moderate to very severe COPD across Asia, Europe and the US, as well as the broader PINNACLE clinical programme that involved more than 5,000 patients. *Bevespi* is approved in the US, the EU, Canada, Australia and other countries for the maintenance treatment of moderate to very severe COPD.

c) *Breztri* (COPD)
During the period, AstraZeneca announced that *Breztri*, formerly PT010, was approved in Japan as a triple-combination therapy to relieve symptoms of COPD. This was the first global regulatory approval for *Breztri* and the first approval by the Japanese Ministry of Health, Labour and Welfare for a triple-combination therapy in a pMDI, which uses the innovative *Aerosphere* delivery technology. The approval was based on positive results from the Phase III KRONOS trial, in which *Breztri* demonstrated a statistically-significant improvement in trough forced expiratory volume in one second, the primary endpoint for Japan, compared with the dual comparators *Bevespi* and PT009 (budesonide/formoterol fumarate).

During the period, the China NMPA granted a priority review to *Breztri*, with a regulatory decision anticipated in H1 2020. The medicine is also under regulatory review in the US and the EU, based on data only from the KRONOS trial, with anticipated regulatory decisions in H1 2020.

d) *Fasenra* (severe asthma)
In May 2019, at the aforementioned ATS conference, the Company presented new data from a two-year integrated efficacy and safety analysis from the *Fasenra* one-year Phase III SIROCCO and CALIMA exacerbation trials, the one-year Phase III BORA extension trial and the 28-week Phase III ZONDA OCS-sparing trial.

In July 2019, AstraZeneca announced that the CHMP had issued a positive opinion to add a self-administration option and a new delivery method as a pre-filled, single-use auto-injector to the medicine's product information in the EU. The opinion was implemented without the need for an EC decision, due to the nature of the type-II label variation. AstraZeneca anticipates a regulatory decision by the US FDA on self-administration and the auto-injector in the second half of 2019. *Fasenra* is currently approved as an add-on maintenance treatment for severe eosinophilic asthma in the US, in the EU, Japan and other countries.

e) Nirsevimab (lower respiratory tract infection)
In May 2019, at the European Society for Paediatric Infectious Diseases Congress, Phase IIb trial results were presented in a satellite symposium for nirsevimab, an extended half-life respiratory syncytial virus (RSV) F monoclonal antibody for the treatment of lower respiratory tract infection. The results showed that nirsevimab had met its primary and secondary endpoints, with a good safety profile. Nirsevimab is being developed in

collaboration between AstraZeneca and Sanofi Pasteur (part of Sanofi S.A.). Both collaborators anticipate full data publication in a peer-reviewed journal in the second half of 2019. A Phase III trial has been confirmed to begin imminently, upon which the Company anticipates a €30m milestone payment from Sanofi Pasteur to be recorded within Collaboration Revenue in the third quarter.

Other medicines

There were no research & development updates for medicines outside of the three main therapy areas in the period.

For more details on the development pipeline, including anticipated timelines for regulatory submission/acceptances, please refer to the latest Clinical Trials Appendix available on astrazeneca.com.

Condensed consolidated statement of comprehensive income

For the **half year** ended 30 June	**2019 $m**	**2018 $m**
Product Sales	11,183	10,015
Collaboration Revenue	131	318
Total Revenue	11,314	10,333
Cost of sales	(2,192)	(2,146)
Gross Profit	9,122	8,187
Distribution costs	(159)	(165)
Research and development expense	(2,622)	(2,641)
Selling, general and administrative costs	(5,457)	(5,008)
Other operating income and expense	706	1,086
Operating profit	1,590	1,459
Finance income	96	78
Finance expense	(728)	(718)
Share of after-tax losses in associates and joint ventures	(59)	(33)
Profit before tax	**899**	**786**
Taxation	(229)	(151)
Profit for the period	670	635
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(247)	187
Net (losses)/gains on equity investments measured at fair value through other comprehensive income	(54)	156
Fair-value movements related to own credit risk on bonds designated as fair-value through profit or loss	(2)	(2)
Tax on items that will not be reclassified to profit or loss	17	(67)
	(286)	274
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(86)	(284)
Foreign exchange arising on designating borrowings in net investment hedges	(186)	(516)
Fair-value movements on cash flow hedges	(43)	19
Fair-value movements on cash flow hedges transferred to profit or loss	14	69
Fair-value movements on derivatives designated in net investment hedges	(9)	(4)
Costs of hedging	3	(33)
Tax on items that may be reclassified subsequently to profit or loss	20	55
	(287)	(694)
Other comprehensive loss for the period, net of tax	(573)	(420)
Total comprehensive income for the period	97	215
Profit attributable to:		
Owners of the Parent	723	690
Non-controlling interests	(53)	(55)
	670	635
Total comprehensive income attributable to:		
Owners of the Parent	150	270
Non-controlling interests	(53)	(55)
	97	215
Basic earnings per $0.25 Ordinary Share	$0.56	$0.54
Diluted earnings per $0.25 Ordinary Share	$0.56	$0.54
Weighted average number of Ordinary Shares in issue (millions)	1,289	1,267
Diluted weighted average number of Ordinary Shares in issue (millions)	1,290	1,267

Condensed consolidated statement of comprehensive income

For the **quarter** ended 30 June	Unreviewed[54] 2019 $m	Unreviewed[54] 2018 $m
Product Sales	5,718	5,030
Collaboration Revenue	105	125
Total Revenue	5,823	5,155
Cost of sales	(1,063)	(1,012)
Gross Profit	4,760	4,143
Distribution costs	(81)	(84)
Research and development expense	(1,356)	(1,362)
Selling, general and administrative costs	(2,943)	(2,551)
Other operating income and expense	113	617
Operating profit	493	763
Finance income	41	43
Finance expense	(361)	(375)
Share of after-tax losses in associates and joint ventures	(32)	(19)
Profit before tax	**141**	**412**
Taxation	(34)	(93)
Profit for the period	107	319
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(257)	160
Net (losses)/gains on equity investments measured at fair value through other comprehensive income	(174)	38
Fair-value movements related to own credit risk on bonds designated as fair value through profit or loss	(1)	(1)
Tax on items that will not be reclassified to profit or loss	60	(40)
	(372)	157
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(139)	(451)
Foreign exchange arising on designating borrowings in net investment hedges	(6)	(417)
Fair-value movements on cash flow hedges	11	(92)
Fair-value movements on cash flow hedges transferred to profit or loss	(33)	149
Fair-value movements on derivatives designated in net investment hedges	(12)	42
Costs of hedging	9	(23)
Tax on items that may be reclassified subsequently to profit or loss	(3)	35
	(173)	(757)
Other comprehensive loss for the period, net of tax	(545)	(600)
Total comprehensive loss for the period	(438)	(281)
Profit attributable to:		
Owners of the Parent	130	350
Non-controlling interests	(23)	(31)
	107	319
Total comprehensive income attributable to:		
Owners of the Parent	(415)	(250)
Non-controlling interests	(23)	(31)
	(438)	(281)
Basic earnings per $0.25 Ordinary Share	$0.09	$0.27
Diluted earnings per $0.25 Ordinary Share	$0.10	$0.27
Weighted average number of Ordinary Shares in issue (millions)	1,311	1,267
Diluted weighted average number of Ordinary Shares in issue (millions)	1,312	1,267

[54] The Q2 2019 and Q2 2018 information in respect of the three months ended 30 June 2019 and 30 June 2018 respectively included in the interim financial statements has not been reviewed by PricewaterhouseCoopers LLP.

Condensed consolidated statement of financial position

	At 30 Jun 2019 $m	At 31 Dec 2018 $m	At 30 Jun 2018 $m
Assets			
Non-current assets			
Property, plant and equipment	7,442	7,421	7,514
Right-of-use assets	702	-	-
Goodwill	11,668	11,707	11,717
Intangible assets	22,257	21,959	24,887
Investments in associates and joint ventures	73	89	157
Other investments	1,362	833	1,089
Derivative financial instruments	124	157	459
Other receivables	454	515	738
Deferred tax assets	2,588	2,379	2,334
	46,670	45,060	48,895
Current assets			
Inventories	3,197	2,890	3,118
Trade and other receivables	5,319	5,574	5,257
Other investments	819	849	799
Derivative financial instruments	210	258	33
Income tax receivable	246	207	264
Cash and cash equivalents	5,428	4,831	2,978
Assets held for sale	-	982	-
	15,219	15,591	12,449
Total assets	61,889	60,651	61,344
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(1,629)	(1,754)	(4,215)
Lease liabilities	(206)	-	-
Trade and other payables	(12,637)	(12,841)	(10,913)
Derivative financial instruments	(11)	(27)	(23)
Provisions	(410)	(506)	(777)
Income tax payable	(1,141)	(1,164)	(1,273)
	(16,034)	(16,292)	(17,201)
Non-current liabilities			
Interest-bearing loans and borrowings	(17,355)	(17,359)	(15,452)
Lease liabilities	(514)	-	-
Derivative financial instruments	(2)	(4)	(4)
Deferred tax liabilities	(2,932)	(3,286)	(3,740)
Retirement benefit obligations	(2,632)	(2,511)	(2,209)
Provisions	(376)	(385)	(391)
Other payables	(6,973)	(6,770)	(8,075)
	(30,784)	(30,315)	(29,871)
Total liabilities	(46,818)	(46,607)	(47,072)
Net assets	15,071	14,044	14,272
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	328	317	317
Share premium account	7,911	4,427	4,409
Other reserves	2,044	2,041	2,040
Retained earnings	3,265	5,683	5,879
	13,548	12,468	12,645
Non-controlling interests	1,523	1,576	1,627
Total equity	15,071	14,044	14,272

Condensed consolidated statement of changes in equity

	Share capital $m	Share premium account $m	Other reserves $m	Retained earnings $m	Total attributable to owners of the parent $m	Non-controlling interests $m	Total equity $m
At 1 Jan 2018	317	4,393	2,029	8,221	14,960	1,682	16,642
Adoption of new accounting standards	-	-	-	(91)	(91)	-	(91)
Profit for the period	-	-	-	690	690	(55)	635
Other comprehensive loss	-	-	-	(420)	(420)	-	(420)
Transfer to other reserves	-	-	11	(11)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,402)	(2,402)	-	(2,402)
Issue of Ordinary Shares	-	16	-	-	16	-	16
Share-based payments change for the period	-	-	-	105	105	-	105
Settlement of share plan awards	-	-	-	(213)	(213)	-	(213)
Net movement	-	16	11	(2,342)	(2,315)	(55)	(2,370)
At 30 June 2018	**317**	**4,409**	**2,040**	**5,879**	**12,645**	**1,627**	**14,272**
At 1 Jan 2019	**317**	**4,427**	**2,041**	**5,683**	**12,468**	**1,576**	**14,044**
Adoption of new accounting standards[55]	-	-	-	54	54	-	54
Profit for the period	-	-	-	723	723	(53)	670
Other comprehensive loss	-	-	-	(573)	(573)	-	(573)
Transfer to other reserves	-	-	3	(3)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,403)	(2,403)	-	(2,403)
Issue of Ordinary Shares[56]	11	3,484	-	-	3,495	-	3,495
Share-based payments for the period	-	-	-	102	102	-	102
Settlement of share awards	-	-	-	(318)	(318)	-	(318)
Net movements	11	3,484	3	(2,418)	1,080	(53)	1,027
At 30 June 2019	**328**	**7,911**	**2,044**	**3,265**	**13,548**	**1,523**	**15,071**

[55] The Company adopted IFRIC 23 'Uncertainty over Income Tax Treatments' from 1 January 2019. See Note 1.
[56] On 2 April 2019, the Company completed an issue of 44,386,214 new ordinary shares of $0.25 each at a price of £60.50 per share, resulting in an increase in share capital of $11m and an increase in share premium of $3,479m, net of transaction costs of $22m.

Condensed consolidated statement of cash flows

For the **half year** ended 30 June	**2019 $m**	**2018 $m**
Cash flows from operating activities		
Profit before tax	899	786
Finance income and expense	632	640
Share of after-tax losses of associates and joint ventures	59	33
Depreciation, amortisation and impairment	1,403	1,393
Increase in working capital and short-term provisions	(634)	(1,440)
Gains on disposal of intangible assets	(590)	(593)
Non-cash and other movements	(177)	(310)
Cash generated from operations	1,592	509
Interest paid	(378)	(296)
Tax paid	(723)	(288)
Net cash inflow/(outflow) from operating activities	491	(75)
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(368)	(151)
Purchase of property, plant and equipment	(438)	(486)
Disposal of property, plant and equipment	27	12
Purchase of intangible assets	(1,296)	(207)
Disposal of intangible assets	1,071	638
Movement in profit-participation liability[57]	150	-
Purchase of non-current asset investments	(7)	(14)
Disposal of non-current asset investments	18	20
Movement in short-term investments and fixed deposits	21	415
Payments to joint ventures	(39)	(171)
Interest received	72	121
Net cash (outflow)/inflow from investing activities	(789)	177
Net cash (outflow)/inflow before financing activities	(298)	102
Cash flows from financing activities		
Proceeds from issue of share capital	3,495	16
Issue of loans	500	-
Repayment of loans	(500)	-
Dividends paid	(2,432)	(2,363)
Hedge contracts relating to dividend payments	26	(47)
Repayment of obligations under leases	(84)	-
Movement in short-term borrowings	(64)	1,913
Net cash inflow/(outflow) from financing activities	941	(481)
Net increase/(decrease) in cash and cash equivalents in the period	643	(379)
Cash and cash equivalents at the beginning of the period	4,671	3,172
Exchange rate effects	16	(27)
Cash and cash equivalents at the end of the period	5,330	2,766
Cash and cash equivalents consist of:		
Cash and cash equivalents	5,428	2,978
Overdrafts	(98)	(212)
	5,330	2,766

[57] The profit-participation liability relates to the rights to participate in the future cashflows from the US profits or losses for nirsevimab and forms part of the consideration for the disposal of the US rights to *Synagis* to Sobi. This has been recognised as a financial liability and is presented in Other Payables within Non-Current Liabilities.

Responsibility statement of the directors in respect of the half-yearly financial report

We confirm that to the best of our knowledge:

- the condensed interim financial statements have been prepared in accordance with IAS 34 *Interim Financial Reporting* as issued by the International Accounting Standards Board and adopted by the European Union;

- the half-yearly management report includes a fair review of the information required by:

  (a) DTR 4.2.7R of the Disclosure and Transparency Rules, being an indication of important events that have occurred during the first six months of the financial year and their impact on the condensed interim financial statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and

  (b) DTR 4.2.8R of the Disclosure and Transparency Rules, being related party transactions that have taken place in the first six months of the current financial year and that have materially affected the financial position or performance of the enterprise during that period; and any changes in the related party transactions described in the last annual report that could do so.

The Board

The Board of Directors that served during all or part of the six-month period to 30 June 2019 and their respective responsibilities can be found on the Leadership team section of astrazeneca.com.

Approved by the Board and signed on its behalf by

Pascal Soriot
Chief Executive Officer

25 July 2019

Independent review report to AstraZeneca PLC

Report on the condensed consolidated interim financial statements

Our Conclusion
We have reviewed AstraZeneca PLC's condensed consolidated interim financial statements (the 'interim financial statements') in the half-yearly financial report of AstraZeneca PLC for the 6-month period ended 30 June 2019. Based on our review, nothing has come to our attention that causes us to believe that the interim financial statements are not prepared, in all material respects, in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as issued by the International Accounting Standards Board (IASB) and adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

What we have reviewed

The interim financial statements comprise:

- the Condensed Consolidated Statement of Financial Position as at 30 June 2019;
- the Condensed Consolidated Statement of Comprehensive Income for the period then ended;
- the Condensed Consolidated Statement of Cash Flows for the period then ended;
- the Condensed Consolidated Statement of Changes in Equity for the period then ended; and
- the explanatory notes to the interim financial statements.

The interim financial statements included in the half-yearly financial report have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as issued by the IASB and adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

As disclosed in note 1 to the interim financial statements, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the Group is applicable law and International Financial Reporting Standards (IFRSs) as issued by the IASB and adopted by the European Union.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the directors
The half-yearly financial report, including the interim financial statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the half-yearly financial report in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the interim financial statements in the half-yearly financial report based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

What a review of interim financial statements involves
We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the interim financial statements.

PricewaterhouseCoopers LLP
Chartered Accountants
London
25 July 2019

Notes to the interim financial statements

1 Basis of preparation and accounting policies

These unaudited condensed consolidated interim financial statements (Interim Financial Statements) for the six months ended 30 June 2019 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as issued by the International Accounting Standards Board (IASB) and adopted by the EU.

The unaudited condensed consolidated interim financial statements for the six months ended 30 June 2019 were approved by the Board of directors on 25 July 2019.

The annual financial statements of the Group are prepared in accordance with IFRSs as issued by the IASB and adopted by the EU. Except as noted below, the interim financial statements have been prepared applying the accounting policies and presentation that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2018. In addition, from 1 January 2019, AstraZeneca elected to early adopt the October 2018 update to IFRS 3, which changed the definition of a business. The EU has not yet endorsed this update to IFRS 3, but it is considered highly probable that the amendment will be endorsed during 2019 before its effective date of 1 January 2020 with early adoption permitted. The change in definition of a business within IFRS 3 allowed the Group to apply the optional concentration test to perform a simplified assessment of whether an acquired set of activities and assets is or is not a business on a transaction by transaction basis. It is considered that adopting this amendment will provide more reliable and comparable information about certain transactions as it provides more consistency in accounting for substantially similar transactions that under the previous definition may have been accounted for in different ways despite limited differences in substance.

IFRS 16

IFRS 16 'Leases' is effective for accounting periods beginning on or after 1 January 2019 and replaces IAS 17 'Leases'. It eliminates the classification of leases as either operating leases or finance leases and, instead, introduces a single lessee accounting model. The adoption of IFRS 16 resulted in the Group recognising lease liabilities, and corresponding 'right-of-use' assets for arrangements that were previously classified as operating leases.

The Group's principal lease arrangements are for property, most notably a portfolio of office premises, and for a global car fleet, utilised primarily by our sales and marketing teams. The Group has adopted IFRS 16 using a modified retrospective approach with the cumulative effect of initially applying the standard as an adjustment to the opening balance of retained earnings at 1 January 2019. The standard permits a choice on initial adoption, on a lease-by-lease basis, to measure the right-of-use asset at either its carrying amount as if IFRS 16 had been applied since the commencement of the lease, or an amount equal to the lease liability, adjusted for accruals or prepayments. The Group has elected to measure the right-of-use asset equal to the lease liability, with the result of no net impact on opening retained earnings and no restatement of prior period comparatives.

Initial adoption resulted in the recognition of right-of-use assets of $722m and lease liabilities of $720m. The weighted average incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 3%.

The Group is using one or more practical expedients on transition to leases previously classified as operating leases, including electing to not apply the retrospective treatment to leases for which the term ends within 12 months of initial application, electing to apply a single discount rate to portfolios of leases with similar characteristics, reliance on previous assessments on whether arrangements contain a lease and whether leases are onerous, excluding initial direct costs from the initial measurement of the right-of-use asset, and using hindsight in determining the lease term where the contract contains options to extend or terminate the lease.

Key judgements made in calculating the initial impact of adoption include determining the lease term where extension or termination options exist. In such instances, all facts and circumstances that may create an economic incentive to exercise an extension option, or not exercise a termination option, have been considered to determine the lease term. Extension periods (or periods after termination options) are only included in the lease term if the lease is reasonably certain to be extended (or not terminated). Estimates include calculating the discount rate which is based on the incremental borrowing rate.

The Group is applying IFRS 16's low-value and short-term exemptions. While the IFRS 16 opening lease liability is calculated differently from the previous operating lease commitment calculated under the previous standard, there are no material differences between the positions. The adoption of IFRS 16 has had no impact on the Group's net cash flows, although a presentation change has been reflected whereby cash outflows of $84m are

now presented as financing, instead of operating. There is an immaterial benefit to Operating profit and a corresponding increase in Finance expense from the presentation of a portion of lease costs as interest costs. Profit before tax, taxation and EPS have not been significantly impacted.

IFRIC 23

IFRIC 23 'Uncertainty Over Income Tax Treatments' is effective for accounting periods beginning on or after 1 January 2019 and provides further clarification on how to apply the recognition and measurement requirements in IAS 12 'Income Taxes'. It is applicable where there is uncertainty over income tax treatments. The EU endorsed IFRIC 23 on 24 October 2018. The adoption of IFRIC 23 has principally resulted in an adjustment in the value of tax liabilities because IFRIC 23 requires the Group to measure the effect of uncertainty on income tax positions using either the most likely amount or the expected value amount depending on which method is expected to better reflect the resolution of the uncertainty.

The Group has retrospectively applied IFRIC 23 from 1 January 2019 recognising the cumulative effect of initially applying the interpretation as decreases to income tax payable of $51m and to trade and other payables of $3m, and a corresponding adjustment to the opening balance of retained earnings of $54m. There is no restatement of the comparative information as permitted in the interpretation.

Collaboration Revenue

Effective from 1 January 2019, the Group updated the presentation of an element of Total Revenue within the Statement of Comprehensive Income and changed the classification of some income to reflect the increasing importance of collaborations to AstraZeneca. Historically, Externalisation Revenue formed part of Total Revenue and only included income arising from collaborative transactions involving AstraZeneca's medicines, whether internally developed or previously acquired. Such income included upfront consideration, milestones receipts, profit share income and royalties, as well as other income from collaborations. The updated category of Collaboration Revenue includes all income previously included within Externalisation Revenue, as well as income of a similar nature arising from transactions where AstraZeneca has acquired an interest in a medicine and as part of the acquisition entered into an active collaboration with the seller. This change is a result of the growing importance of collaborations to AstraZeneca. Income arising from all collaborations, other than product sales, will be recognised within the Collaboration Revenue element of Total Revenue. Historically there has been no collaboration income arising from such acquisitions, and therefore no prior year restatement of financial results is required as a result of this change.

Income from royalties and disposals of assets and businesses, where the Group does not retain a significant element of continued interest, continue to be recorded in Other Operating Income and Expense.

Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2018.

Going concern

The Group has considerable financial resources available. As at 30 June 2019 the Group has $9.5bn in financial resources (cash balances of $5.4bn and undrawn committed bank facilities of $4.1bn, of which $3.4bn is available until April 2022, $0.5bn is available until November 2020 (extendable to November 2021) and $0.2bn is available until December 2019 (extendable to December 2020), with only $1.8bn of debt due within one year). The Group's revenues are largely derived from sales of products which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of the mature markets. The Group, however, anticipates new revenue streams from both recently launched medicines and products in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully.

On the basis of the above paragraph, the going concern basis has been adopted in these interim financial statements.

Financial information

The comparative figures for the financial year ended 31 December 2018 are not the Group's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and have been delivered to the registrar of companies; their report was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

2 Restructuring costs

Profit before tax for the half year ended 30 June 2019 is stated after charging restructuring costs of $226m ($187m for the half year ended 30 June 2018). These have been charged to profit as follows:

	H1 2019 $m	H1 2018 $m	Unreviewed[58] Q2 2019 $m	Unreviewed[58] Q2 2018 $m
Cost of sales	52	55	14	23
Research and development expense	64	58	30	31
Selling, general and administrative costs	110	84	79	48
Other operating income and expense	-	(10)	-	(10)
Total	**226**	**187**	**123**	**92**

[58] The Q2 2019 and Q2 2018 information in respect of the three months ended 30 June 2019 and 30 June 2018 respectively included in the interim financial statements has not been reviewed by PricewaterhouseCoopers LLP.

3 Net Debt

The table below provides an analysis of net debt and a reconciliation of net cash flow to the movement in net debt. The Group monitors net debt as part of its capital management policy as described in Note 27 of the Annual Report and Form 20-F Information 2018. Net debt is a non-GAAP financial measure.

	At 1 Jan 2019 $m	Adoption of new accounting standards[59] $m	Cash Flow $m	Non-cash & Other $m	Exchange Movements $m	At 30 Jun 2019 $m
Non-current instalments of loans	(17,359)	-	-	(15)	19	(17,355)
Non-current instalments of leases	-	(557)	-	45	(2)	(514)
Total long-term debt	**(17,359)**	**(557)**	**-**	**30**	**17**	**(17,869)**
Current instalments of loans	(999)	-	-	(1)	-	(1,000)
Current instalments of leases	-	(163)	96	(138)	(1)	(206)
Commercial paper	(211)	-	-	-	-	(211)
Bank collateral	(384)	-	66	-	-	(318)
Other short-term borrowings excluding overdrafts	-	-	(2)	-	-	(2)
Overdraft	(160)	-	59	-	3	(98)
Total current debt	**(1,754)**	**(163)**	**219**	**(139)**	**2**	**(1,835)**
Gross borrowings	**(19,113)**	**(720)**	**219**	**(109)**	**19**	**(19,704)**
Net derivative financial instruments	384	-	(26)	(37)	-	321
Net borrowings	**(18,729)**	**(720)**	**193**	**(146)**	**19**	**(19,383)**
Cash and cash equivalents	4,831	-	584	-	13	5,428
Other investments - current	849	-	(21)	(9)	-	819
Other investments - non-current	46	-	-	10	-	56
Cash and investments	**5,726**	**-**	**563**	**1**	**13**	**6,303**
Net debt	**(13,003)**	**(720)**	**756**	**(145)**	**32**	**(13,080)**

Non-cash movements in the period include fair-value adjustments under IFRS 9.

Other investments - non-current are included within the balance of $1,362m (31 December 2018: $833m) in the Statement of Financial Position. The equivalent GAAP measure to net debt is 'liabilities arising from financing activities' which excludes the amounts for cash and overdrafts, other investments and non-financing derivatives shown above and includes the Acerta put option liability of $2,057m (31 December 2018: $1,838m) shown in non-current other payables.

[59] The Company adopted IFRS 16 'Leases' from 1 January 2019. See Note 1.

4 Financial instruments

As detailed in the Group's most recent annual financial statements, the principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, leases and interest-bearing loans and borrowings.

There have been no changes of significance to the categorisation or fair-value hierarchy classification of our financial instruments from those detailed in the Notes to the Group Financial Statements in the Group's Annual Report and Form 20-F Information 2018.

The Group holds certain equity investments that are categorised as Level 3 in the fair-value hierarchy and for which fair-value gains of $50m have been recognised in H1 2019. These are presented in Net gains on equity investments measured at fair value through other comprehensive income in the Condensed Consolidated Statement of Comprehensive Income.

Financial instruments measured at fair value include $2,181m of other investments, $3,960m held in money market funds, $337m of loans designated at fair value through profit or loss, $342m of loans designated in a fair value hedge relationship and $321m of derivatives as at 30 June 2019. The total fair value of interest-bearing loans and borrowings at 30 June 2019 which have a carrying value of $18,984m in the Condensed Consolidated Statement of Financial Position, was $20,867m. Contingent consideration liabilities arising on business combinations have been classified under Level 3 in the fair-value hierarchy and movements in fair value are shown below:

	Diabetes Alliance 2019 $m	Other 2019 $m	Total 2019 $m	Total 2018 $m
At 1 January	3,983	1,123	5,106	5,534
Settlements	(225)	(143)	(368)	(151)
Revaluations	-	-	-	38
Discount unwind	144	35	179	208
At 30 June	**3,902**	**1,015**	**4,917**	**5,629**

Contingent consideration arising from business combinations is fair valued using decision-tree analysis, with key inputs including the probability of success, consideration of potential delays and the expected levels of future revenues.

The contingent consideration balance relating to BMS's share of Global Diabetes Alliance of $3,902m (31 December 2018: $3,983m) would increase/decrease by $390m with an increase/decrease in sales of 10% as compared with the current estimates.

5 Legal proceedings and contingent liabilities

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2018 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

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

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable, and the Company is able to make a reasonable

estimate of the loss, AstraZeneca records the loss absorbed or makes a provision for the best estimate of the expected loss.

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

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

Matters disclosed in respect of the second quarter of 2019 and to 25 July 2019

Patent litigation

Imfinzi
US patent proceedings
As previously disclosed, in July 2017, Bristol-Myers Squibb, E.R. Squibb & Sons LLC, Ono Pharmaceutical Co and Tasuku Honjo filed a patent infringement action in the US District Court for the District of Delaware relating to AstraZeneca's commercialisation of *Imfinzi*. The case was dismissed without prejudice on 14 June 2019.

Faslodex
US patent proceedings
As previously disclosed, in December 2018, AstraZeneca filed a patent infringement lawsuit in the US District Court for the District of New Jersey (the District Court) relating to four patents listed in the FDA Orange Book with reference to *Faslodex* after receiving a Paragraph IV notice relating to an Abbreviated NDA (ANDA) seeking US FDA approval to market a generic version of *Faslodex* prior to the expiration of AstraZeneca's patents. In June 2019, AstraZeneca settled this lawsuit against the ANDA filer, and the District Court entered a consent judgment ending the lawsuit. AstraZeneca has now resolved all US patent infringement lawsuits that it had previously filed relating to the four listed patents that reference *Faslodex*, and the District Court has entered consent judgments ending all of those lawsuits.

Patent proceedings outside the US
In Italy, in May 2016, Actavis Group Ptc ehf and Actavis Italy S.p.A filed an action alleging that the Italian part of AstraZeneca's European Patent No. 2,266,573 (the '573 patent) was invalid. In July 2019, the Court of Milan determined that the '573 patent is invalid.

Symbicort
US patent proceedings
As previously disclosed, beginning in October 2018, AstraZeneca initiated ANDA litigation against Mylan Pharmaceuticals Inc. (Mylan) and 3M Company (3M) and, separately, ANDA litigation against Teva Pharmaceuticals USA, Inc. (Teva) and Catalent Pharma Solutions, LLC (Catalent) in the US District Court for the District of Delaware. In May 2019, AstraZeneca filed a Second Amended Complaint in each of those actions adding allegations that their proposed generic versions of *Symbicort*, if approved and marketed, would infringe AstraZeneca's US Patent No. 10,166,247 (the '247 patent). In June 2019, Teva and Catalent responded to the Second Amended Complaint and alleged that their proposed generic product does not infringe the '247 patent and/or that the '247 patent is invalid and/or unenforceable. AstraZeneca is no longer asserting patent infringement of US Patent No. 7,967,011 against Teva and Catalent. A combined trial of the Mylan and 3M matter and the Teva and Catalent matter has been scheduled for June 2020.

Product liability litigation

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

court in New Jersey for pre-trial purposes. In July 2019, counsel for a similarly defined group of plaintiffs with claims pending in New Jersey state courts petitioned the New Jersey State Administrative Director of the Courts to centralise judicial management of all plaintiffs' claims alleging kidney injuries pending in that State in a co-ordinated multicounty litigation proceeding.

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

Government investigations/proceedings

Toprol-XL
Louisiana Attorney General Litigation
As previously disclosed, in the US, in April 2019, a Louisiana state court (the Court) granted AstraZeneca's motion for summary judgment dismissing a state court civil complaint filed by the Attorney General for the State of Louisiana (the State), alleging that AstraZeneca had engaged in unlawful monopolisation and unfair trade practices in connection with enforcement of its patents for *Toprol-XL* causing the State government to pay increased prices for *Toprol-XL*, and entered judgment in AstraZeneca's favour. The State is appealing the Court's ruling.

Matters disclosed in respect of the first quarter of 2019 and to 26 April 2019

Patent litigation

Imfinzi
US patent proceedings
As previously disclosed, in July 2017, Bristol-Myers Squibb, E.R. Squibb & Sons LLC, Ono Pharmaceutical Co and Tasuku Honjo filed a patent infringement action in the US District Court for the District of Delaware (the District Court) relating to AstraZeneca's commercialisation of *Imfinzi*. A trial has been scheduled for October 2020; discovery is ongoing.

Calquence
US patent proceedings
As previously disclosed, in November 2017, Pharmacyclics LLC (Pharmacyclics, a company in the AbbVie group) filed a patent infringement lawsuit in the US District Court for the District of Delaware (the District Court) against Acerta Pharma and AstraZeneca relating to *Calquence*. A trial has been scheduled for June 2020.

In April 2018, AstraZeneca and Acerta Pharma filed a complaint in the District Court against Pharmacyclics and AbbVie, Inc. alleging that their drug, *Imbruvica*, infringes a US patent owned by Acerta Pharma. In November 2018, Janssen Biotech, Inc. intervened as a defendant. A trial has been scheduled for January 2021.

Faslodex
Patent proceedings outside the US
As previously disclosed, in Germany, in January 2017, the German Federal Patent Court declared the German part of European Patent No. EP 1,250,138 (the '138 patent) invalid. In April 2019, the German Federal Court of Justice upheld the January 2017 decision and determined the '138 patent to be invalid.

Brilinta
Patent proceedings outside the US
As previously disclosed, in Canada, in September 2017, Apotex Inc. (Apotex) challenged the patents listed on the Canadian Patent Register with reference to *Brilinta*. AstraZeneca discontinued the proceeding against Apotex in February 2019 after Apotex withdrew its challenge.

Farxiga
US patent proceedings
As previously disclosed, in May 2018, AstraZeneca initiated ANDA litigation against Zydus Pharmaceuticals (USA) Inc. (Zydus) in the US District Court for the District of Delaware (the District Court). In January 2019, following a stipulation filed by the parties, the District Court dismissed claims related to US Patent Nos. 7,851,502, 7,919,598, 8,221,786, 8,361,972, 8,501,698, and 8,716,251. AstraZeneca continues to allege that Zydus' generic

version of *Farxiga*, if approved and marketed, would infringe AstraZeneca's US Patents Nos. 6,414,126, 6,515,117, and 8,685,934. A trial is scheduled for February 2021.

Symbicort
US patent proceedings
As previously disclosed, in October 2018 AstraZeneca initiated ANDA litigation against Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. in the US District Court for the District of Delaware and in the US District Court for the Northern District of West Virginia. In March 2019, following stipulations filed by the parties, the Delaware and West Virginia Courts dismissed without prejudice Mylan Laboratories Limited, Mylan Inc., and Mylan N.V. from those actions.

Product liability litigation

Farxiga* and *Xigduo XR
As previously disclosed, in several jurisdictions in the US, AstraZeneca has been named as a defendant in lawsuits involving plaintiffs claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with *Farxiga* and/or *Xigduo XR*. In April 2017, the Judicial Panel on Multidistrict Litigation ordered transfer of any currently pending cases as well as of any similar, subsequently filed cases to a co-ordinated and consolidated pre-trial multidistrict litigation proceeding in the US District Court for the Southern District of New York. A majority of these claims have been resolved or dismissed.

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

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

Commercial litigation

Toprol-XL
Aralez litigation
As previously disclosed, in October 2016, AstraZeneca completed its sale of certain assets related to the US rights to *Toprol-XL* and AstraZeneca's authorised generic metoprolol succinate product to Aralez Pharmaceuticals Trading DAC (Aralez). In August 2018, Aralez commenced voluntary insolvency proceedings and AstraZeneca filed a proof of claim in those proceedings asserting its unsecured claims. In October 2018, Aralez filed a motion in the Bankruptcy Court seeking to sell the US rights to *Toprol-XL* and its authorised generic and AstraZeneca filed an objection to the proposed sale. In March 2019, AstraZeneca entered into an agreement with the senior secured creditor and the settlement has now been approved by the Bankruptcy Court, bringing this matter to a close.

Government investigations/proceedings

Toprol-XL
Louisiana Attorney General Litigation
As previously disclosed, in the US, in March 2015, AstraZeneca was served with a state court civil complaint filed by the Attorney General for the State of Louisiana (the State) alleging that, in connection with enforcement of its patents for *Toprol-XL*, it had engaged in unlawful monopolisation and unfair trade practices, causing the State government to pay increased prices for *Toprol-XL*. In April 2019, a Louisiana state court heard oral argument on and granted AstraZeneca's motion for summary judgment, ordering the dismissal of the State's complaint and judgment to be entered in AstraZeneca's favour.

Synagis

Litigation in New York

As previously disclosed, in the US, in June 2011, MedImmune received a demand from the US Attorney's Office for the Southern District of New York requesting certain documents related to the sales and marketing activities of *Synagis*. In July 2011, MedImmune received a similar court order to produce documents from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit pursuant to what the government attorneys advised was a joint investigation. MedImmune has cooperated with these inquiries. In March 2017, MedImmune was served with a lawsuit filed in US Federal Court in New York by the Attorney General for the State of New York alleging that MedImmune inappropriately provided assistance to a single specialty-care pharmacy. In September 2018, the US Federal Court in New York denied MedImmune's motion to dismiss the lawsuit brought by the Attorney General for the State of New York.

In June 2017, MedImmune was served with a lawsuit in US Federal Court in New York by a relator under the *qui tam* (whistleblower) provisions of the federal and certain state False Claims Acts. The lawsuit was originally filed under seal in April 2009 and alleges that MedImmune made false claims about *Synagis*. In November 2017, MedImmune was served with an amended complaint in which the relator set forth additional false claims allegations relating to *Synagis*. In September 2018, the US Federal Court in New York dismissed the relator's lawsuit. In January 2019, relator appealed the decision of the US Federal Court in New York.

Tax

As previously disclosed, on 25 April 2019, the EC issued its decision on the State aid review of UK Controlled Foreign Company Group Financing Exemption (FCPE). The EC has concluded that part of the UK measures were unlawful and incompatible State aid and have instructed recovery of the State aid. The UK Government and the Company have appealed the decision. Given the complexities of the ruling, tax legislation and the ongoing appeal, the Company has been unable to estimate reliably any additional liability at this time; this is not, however, expected to be material.

6 Product Sales analysis - H1 2019

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

	World			Emerging Markets			US		Europe			Established RoW		
	H1 2019 $m	Actual %	CER %	H1 2019 $m	Actual %	CER %	H1 2019 $m	Actual %	H1 2019 $m	Actual %	CER %	H1 2019 $m	Actual %	CER %
Oncology														
Tagrisso	1,414	86	92	329	n/m	n/m	559	64	212	53	64	314	n/m	n/m
Imfinzi	633	n/m	n/m	12	n/m	n/m	473	n/m	60	n/m	n/m	88	n/m	n/m
Lynparza	520	93	n/m	59	n/m	n/m	262	76	131	51	61	68	n/m	n/m
Iressa	252	(8)	(3)	164	11	18	8	(43)	46	(25)	(20)	34	(35)	(33)
Calquence	64	n/m	n/m	-	-	-	64	n/m	-	-	-	-	-	-
Legacy:														
Faslodex	521	4	8	96	35	49	251	(3)	110	(7)	-	64	21	23
Zoladex	391	4	11	235	16	27	4	33	65	(4)	1	87	(16)	(13)
Arimidex	111	-	7	72	1	13	-	-	15	-	-	24	(4)	(4)
Casodex	105	1	7	65	10	19	-	-	8	(27)	(27)	32	(6)	(3)
Others	48	(25)	(23)	16	-	6	-	-	3	-	-	29	(36)	(36)
Total Oncology	**4,059**	**52**	**58**	**1,048**	**40**	**52**	**1,621**	**68**	**650**	**29**	**37**	**740**	**65**	**69**
BioPharmaceuticals: CVRM														
Farxiga	726	14	19	206	31	45	270	2	178	17	26	72	13	16
Brilinta	737	21	26	217	47	58	321	24	171	(1)	7	28	(7)	-
Onglyza	269	5	10	87	7	16	120	22	36	(23)	(17)	26	(10)	(7)
Bydureon	283	(4)	(3)	7	-	29	234	-	34	(21)	(19)	8	(20)	(20)
Byetta	55	(8)	(5)	4	-	50	35	9	10	(38)	(38)	6	(25)	(25)
Symlin	15	(6)	(6)	-	-	-	15	(6)	-	-	-	-	-	-
Legacy:														
Crestor	645	(11)	(6)	407	(4)	2	54	(40)	75	(32)	(27)	109	7	11
Seloken/Toprol-XL	393	5	14	349	6	16	26	-	13	8	8	5	(29)	(29)
Atacand	106	(21)	(16)	76	1	11	6	(40)	15	(63)	(63)	9	(10)	(10)
Others	143	(10)	(6)	95	(13)	(6)	4	n/m	34	(13)	(13)	10	(23)	(23)
BioPharmaceuticals: total CVRM	**3,372**	**3**	**8**	**1,448**	**9**	**18**	**1,085**	**5**	**566**	**(10)**	**(5)**	**273**	**-**	**3**
BioPharmaceuticals: Respiratory														
Symbicort	1,170	(10)	(6)	263	9	18	382	(13)	354	(14)	(7)	171	(20)	(17)
Pulmicort	716	13	19	576	20	27	56	(5)	44	(12)	(6)	40	(5)	(2)
Fasenra	296	n/m	n/m	1	n/m	n/m	208	n/m	45	n/m	n/m	42	n/m	n/m
Daliresp/Daxas	104	25	27	2	n/m	n/m	89	33	12	(14)	(7)	1	-	-
Tudorza/Eklira	33	(55)	(52)	(1)	n/m	n/m	-	n/m	31	(18)	(13)	3	(50)	(50)
Duaklir	37	(26)	(20)	-	n/m	-	-	-	36	(23)	(19)	1	(50)	(50)
Bevespi	20	54	54	-	-	-	20	54	-	-	-	-	-	-
Others	159	(2)	4	115	89	n/m	1	n/m	39	(48)	(47)	4	(85)	(85)
BioPharmaceuticals: total Respiratory	**2,535**	**5**	**10**	**956**	**22**	**30**	**756**	**12**	**561**	**(13)**	**(7)**	**262**	**(14)**	**(11)**
Other medicines														
Nexium	756	(15)	(11)	369	8	15	119	(36)	32	(74)	(74)	236	(1)	2
Losec/Prilosec	144	(1)	6	96	9	17	4	-	31	(14)	(8)	13	(24)	(24)
Synagis	149	(40)	(40)	-	-	-	35	(72)	114	(9)	(9)	-	-	-
Seroquel XR/IR	69	(70)	(68)	24	(74)	(72)	(13)	n/m	47	(16)	(13)	11	(39)	(39)
Movantik/Moventig	47	(10)	(10)	-	n/m	n/m	45	(12)	2	n/m	n/m	-	-	-
Others	52	(53)	(49)	10	(70)	n/m	11	57	26	(26)	14	5	(86)	(69)
Total other medicines	**1,217**	**(27)**	**(24)**	**499**	**(11)**	**(7)**	**201**	**(54)**	**252**	**(33)**	**(28)**	**265**	**(14)**	**(10)**
Total Product Sales	**11,183**	**12**	**17**	**3,951**	**15**	**24**	**3,663**	**18**	**2,029**	**(6)**	**1**	**1,540**	**16**	**19**

7 Product Sales analysis - Q2 2019 (Unreviewed*)

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

** The Q2 2019 information in respect of the three months ended 30 June 2019 included in the interim financial statements has not been reviewed by PricewaterhouseCoopers LLP.*

	World			Emerging Markets			US		Europe			Established RoW		
	Q2 2019 $m	Actual %	CER %	Q2 2019 $m	Actual %	CER %	Q2 2019 $m	Actual %	Q2 2019 $m	Actual %	CER %	Q2 2019 $m	Actual %	CER %
Oncology														
Tagrisso	784	86	92	191	n/m	n/m	300	55	112	60	73	181	n/m	n/m
Imfinzi	338	n/m	n/m	6	n/m	n/m	242	n/m	37	n/m	n/m	53	n/m	n/m
Lynparza	283	89	95	33	n/m	n/m	143	72	66	47	60	41	n/m	n/m
Iressa	118	(17)	(13)	78	1	8	4	(33)	20	(35)	(32)	16	(45)	(41)
Calquence	35	n/m	n/m	-	-	-	35	n/m	-	-	-	-	-	-
Legacy:														
Faslodex	267	8	12	51	59	75	125	-	56	(5)	2	35	13	16
Zoladex	197	3	10	121	20	31	2	-	30	(12)	(6)	44	(20)	(16)
Arimidex	60	5	14	36	-	14	-	-	9	29	29	15	7	7
Casodex	57	10	17	34	21	32	-	-	4	(20)	(20)	19	-	5
Others	28	(24)	(24)	8	(11)	(11)	-	-	2	-	-	18	(31)	(31)
Total Oncology	**2,167**	**51**	**57**	**558**	**45**	**57**	**851**	**58**	**336**	**31**	**41**	**422**	**65**	70
BioPharmaceuticals: CVRM														
Farxiga	377	11	16	111	26	40	139	-	89	14	22	38	9	9
Brilinta	389	23	28	120	67	79	168	17	88	2	10	13	(7)	-
Onglyza	116	(8)	(4)	44	7	10	42	(14)	17	(29)	(17)	13	8	17
Bydureon	141	(9)	(8)	5	(29)	(14)	117	(5)	16	(20)	(20)	3	(40)	(40)
Byetta	25	(14)	(10)	3	n/m	n/m	15	(12)	4	(56)	(56)	3	(25)	(25)
Symlin	8	14	14	-	-	-	8	14	-	-	-	-	-	-
Legacy:														
Crestor	310	(8)	(3)	182	(2)	4	28	(36)	36	(22)	(13)	64	3	8
Seloken/Toprol-XL	168	(3)	5	156	1	10	3	(63)	7	17	17	2	(50)	(50)
Atacand	56	(14)	(9)	37	(3)	5	4	33	11	(42)	(42)	4	(20)	(20)
Others	68	(7)	(4)	43	(12)	(8)	3	n/m	15	(17)	(17)	7	(13)	(13)
BioPharmaceuticals: total CVRM	**1,658**	**2**	**7**	**701**	**10**	**19**	**527**	**(1)**	**283**	**(8)**	**(1)**	**147**	**(1)**	2
BioPharmaceuticals:														
Symbicort	585	(13)	(9)	130	15	25	206	(20)	172	(14)	(7)	77	(26)	(23)
Pulmicort	333	16	23	262	24	32	32	7	19	(17)	(9)	20	(9)	(5)
Fasenra	167	n/m	n/m	1	n/m	n/m	115	n/m	27	n/m	n/m	24	n/m	n/m
Daliresp/Daxas	56	24	24	1	n/m	n/m	48	26	6	(14)	-	1	-	-
Tudorza/Eklira	13	(71)	(69)	(2)	n/m	n/m	(2)	n/m	15	(17)	(11)	2	(50)	(50)
Duaklir	17	(23)	(14)	(1)	n/m	-	-	-	17	(15)	(15)	1	-	-
Bevespi	10	25	25	-	-	-	10	25	-	-	-	-	-	-
Others	71	(13)	(7)	47	96	n/m	1	-	20	(55)	(55)	3	(79)	(79)
BioPharmaceuticals: total Respiratory	**1,252**	**2**	**7**	**438**	**26**	**36**	**410**	**1**	**276**	**(13)**	**(7)**	**128**	**(18)**	(15)
Other medicines														
Nexium	393	(11)	(7)	179	11	19	53	(39)	16	(74)	(74)	145	9	12
Losec/Prilosec	68	(11)	(4)	45	7	17	3	-	13	(35)	(30)	7	(36)	(36)
Synagis	96	n/m	n/m	-	-	-	10	n/m	86	n/m	n/m	-	-	-
Seroquel XR/IR	32	(76)	(74)	10	(81)	(81)	(7)	n/m	24	(14)	(7)	5	(50)	(50)
Movantik/Moventig	22	(8)	(8)	-	n/m	n/m	22	(4)	-	-	-	-	-	-
Others	30	(36)	(26)	16	(53)	(47)	8	n/m	13	30	60	(7)	n/m	n/m
Total other medicines	**641**	**(14)**	**(10)**	**250**	**(14)**	**(8)**	**89**	**(37)**	**152**	**(1)**	**3**	**150**	**(6)**	(3)
Total Product Sales	**5,718**	**14**	**19**	**1,947**	**17**	**27**	**1,877**	**16**	**1,047**	**1**	**8**	**847**	**17**	21

8 Sequential quarterly Product Sales - 2019 (Unreviewed*)

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

** The sequential quarterly product sales information included in the interim financial statements has not been reviewed by PricewaterhouseCoopers LLP.*

	Q1 2019 $m	Actual %	CER %	Q2 2019 $m	Actual %	CER %	Q3 2019 $m	Actual %	CER %	Q4 2019 $m	Actual %	CER %
Oncology												
Tagrisso	630	6	5	784	24	25						
Imfinzi	295	13	13	338	15	15						
Lynparza	237	13	13	283	19	20						
Iressa	134	20	19	118	(12)	(13)						
Calquence	29	21	21	35	21	21						
Legacy:												
Faslodex	254	(6)	(6)	267	5	5						
Zoladex	194	7	5	197	2	2						
Arimidex	51	11	9	60	18	20						
Casodex	48	4	4	57	19	17						
Others	20	(13)	(17)	28	40	42						
Total Oncology	**1,892**	**7**	**6**	**2,167**	**15**	**15**						
BioPharmaceuticals: CVRM												
Farxiga	349	(12)	(12)	377	8	9						
Brilinta	348	(7)	(8)	389	12	12						
Onglyza	153	3	3	116	(24)	(24)						
Bydureon	142	3	3	141	(1)	(1)						
Byetta	30	(6)	(6)	25	(17)	(17)						
Symlin	7	(30)	(30)	8	14	14						
Legacy:												
Crestor	335	(5)	(6)	310	(7)	(7)						
Seloken/Toprol-XL	225	41	39	168	(25)	(25)						
Atacand	50	(14)	(15)	56	12	14						
Others	75	-	-	68	(9)	(8)						
BioPharmaceuticals: total CVRM	**1,714**	**(2)**	**(3)**	**1,658**	**(3)**	**(3)**						
BioPharmaceuticals: Respiratory												
Symbicort	585	(8)	(8)	585	-	1						
Pulmicort	383	(2)	(2)	333	(13)	(13)						
Fasenra	129	3	2	167	29	30						
Daliresp/Daxas	48	(11)	(13)	56	17	19						
Tudorza/Eklira	20	5	-	13	(35)	(30)						
Duaklir	20	(9)	(9)	17	(15)	(14)						
Bevespi	10	-	-	10	-	-						
Others	88	(20)	(19)	71	(19)	(23)						
BioPharmaceuticals: total Respiratory	**1,283**	**(6)**	**(6)**	**1,252**	**(2)**	**(2)**						
Other medicines												
Nexium	363	(7)	3	393	8	9						
Synagis	53	(79)	(90)	96	81	81						
Losec/Prilosec	76	27	27	68	(11)	(11)						
*Seroquel XR/*IR	37	(34)	(32)	32	(14)	(13)						
Movantik/Moventig	25	-	-	22	(12)	(12)						
Others	22	(29)	(54)	30	36	50						
Total other medicines	**576**	**(35)**	**(41)**	**641**	**11**	**13**						
Total Product Sales	**5,465**	**(5)**	**(7)**	**5,718**	**5**	**5**						

9 Sequential quarterly Product Sales - 2018 (Unreviewed*)

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

** The sequential quarterly product sales information included in the interim financial statements has not been reviewed by PricewaterhouseCoopers LLP.*

	Q1 2018 $m	Actual %	CER %	Q2 2018 $m	Actual %	CER %	Q3 2018 $m	Actual %	CER %	Q4 2018 $m	Actual %	CER %
Oncology												
Tagrisso	338	11	10	422	25	25	506	20	23	594	17	19
Iressa	132	2	(1)	143	8	8	131	(8)	(5)	112	(15)	(13)
Lynparza	119	19	18	150	26	26	169	13	15	209	24	25
Imfinzi	62	n/m	n/m	122	98	98	187	53	52	262	40	41
Calquence	8	n/m	n/m	12	51	50	18	50	50	24	33	33
Legacy:												
Faslodex	254	7	5	247	(3)	(2)	258	4	7	269	4	5
Zoladex	184	(2)	(4)	192	4	5	194	1	6	182	(6)	(2)
Arimidex	54	(5)	(7)	57	6	6	55	(4)	-	46	(16)	(13)
Casodex	52	(4)	(6)	52	-	(2)	51	(2)	4	46	(10)	(8)
Others	27	(7)	(20)	37	37	50	28	(24)	(22)	23	(18)	13
Total Oncology	**1,230**	**10**	**8**	**1,434**	**17**	**17**	**1,597**	**11**	**14**	**1,767**	**11**	**13**
BioPharmaceuticals: CVRM												
Farxiga	299	(10)	(11)	340	14	15	355	4	7	397	12	13
Brilinta	293	(2)	(4)	316	8	9	336	6	9	376	12	13
Onglyza	129	(28)	(29)	126	(2)	(2)	140	11	14	148	6	8
Bydureon	139	(5)	(5)	155	12	11	152	(2)	(1)	138	(9)	(9)
Byetta	31	(35)	(38)	29	(7)	(3)	34	17	17	32	(6)	(6)
Symlin	9	(31)	(31)	7	(22)	(22)	8	14	14	10	25	25
Legacy:												
Crestor	389	(35)	(36)	338	(13)	(12)	353	4	8	353	-	2
Seloken/Toprol-XL	200	19	18	173	(14)	(13)	179	3	10	160	(11)	(8)
Atacand	71	(3)	(3)	66	(8)	(8)	65	(2)	5	58	(11)	(9)
Others	85	6	4	73	(13)	(11)	73	(3)	-	75	3	3
BioPharmaceuticals: total CVRM	**1,645**	**(15)**	**(17)**	**1,623**	**(1)**	**-**	**1,695**	**4**	**8**	**1,747**	**3**	**5**
BioPharmaceuticals: Respiratory												
Symbicort	634	(16)	(17)	672	6	6	619	(8)	(5)	636	3	4
Pulmicort	346	(7)	(8)	287	(17)	(17)	264	(8)	(4)	389	47	51
Daliresp/Daxas	38	(28)	(30)	45	19	22	52	16	18	54	4	4
Tudorza/Eklira	34	(19)	(21)	39	15	15	18	(54)	(59)	19	6	11
Duaklir	28	22	17	22	(22)	(19)	23	5	5	22	(4)	-
Fasenra	21	n/m	n/m	65	n/m	n/m	86	32	34	125	45	46
Bevespi	5	(38)	(38)	8	61	60	10	25	25	10	-	-
Others	75	(12)	(20)	88	17	16	70	(20)	(13)	107	53	57
BioPharmaceuticals: total Respiratory	**1,181**	**(11)**	**(13)**	**1,226**	**4**	**4**	**1,142**	**(7)**	**(4)**	**1,362**	**19**	**21**
Other medicines												
Nexium	448	5	3	442	(1)	(1)	422	(5)	97	390	(8)	(7)
Synagis	224	(4)	(4)	26	(89)	(88)	164	n/m	n/m	251	53	n/m
Seroquel XR/IR	97	n/m	40	131	35	37	77	(41)	6	56	(27)	(31)
Losec/Prilosec	69	-	(4)	76	10	11	67	(12)	85	60	(10)	(8)
Movantik/Moventig	28	(7)	(7)	24	(14)	(14)	32	33	167	25	(22)	(22)
FluMist/Fluenz	-	n/m	n/m	-	n/m	n/m	35	n/m	n/m	75	n/m	n/m
Others	63	(62)	(45)	48	(25)	(26)	35	(27)	n/m	35	-	31
Total other medicines	**929**	**(15)**	**(16)**	**747**	**(20)**	**(20)**	**832**	**12**	**15**	**892**	**7**	**22**
Total Product Sales	**4,985**	**(9)**	**(11)**	**5,030**	**1**	**1**	**5,266**	**5**	**8**	**5,768**	**10**	**13**

10 Sequential quarterly Product Sales – 2017 (Unreviewed*)

** The sequential quarterly product sales information included in the interim financial statements has not been reviewed by PricewaterhouseCoopers LLP.*

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

	Q1 2017 $m	Actual %	CER %	Q2 2017 $m	Actual %	CER %	Q3 2017 $m	Actual %	CER %	Q4 2017 $m	Actual %	CER %
Oncology												
Tagrisso	171	16	19	232	36	34	248	7	5	304	23	22
Iressa	124	5	8	137	10	9	137	-	(1)	130	(5)	(6)
Lynparza	57	(8)	(6)	59	4	2	81	37	33	100	23	22
Imfinzi	-	-	-	1	n/m	n/m	-	-	-	18	n/m	n/m
Calquence	-	-	-	-	-	-	-	-	-	3	n/m	n/m
Legacy:												
Faslodex	214	(4)	(3)	248	16	15	241	(3)	(5)	238	(1)	(1)
Zoladex	185	(21)	(12)	178	(4)	(5)	185	4	2	187	1	1
Casodex	56	(7)	(2)	54	(4)	(3)	51	(6)	(9)	54	6	6
Arimidex	52	(9)	(7)	54	4	4	54	-	(2)	57	6	6
Others	26	(10)	(3)	30	15	7	29	(3)	(3)	29	-	3
Total Oncology	**885**	**(5)**	**-**	**993**	**12**	**11**	**1,026**	**3**	**1**	**1,120**	**9**	**9**
BioPharmaceuticals: CVRM												
Brilinta	224	(5)	(4)	272	21	20	284	4	3	299	5	5
Farxiga	207	(13)	(13)	250	21	20	285	14	11	332	16	16
Onglyza	154	3	3	150	(3)	(3)	127	(15)	(17)	180	42	42
Bydureon	153	8	8	146	(5)	(5)	128	(12)	(14)	147	15	15
Byetta	46	(16)	(16)	43	(7)	(7)	39	(9)	(9)	48	23	23
Symlin	14	-	-	11	(21)	(21)	10	(9)	(9)	13	30	30
Qtern	-	-	-	-	-	-	-	-	-	5	n/m	n/m
Legacy:												
Crestor	631	-	3	560	(11)	(12)	580	4	2	594	2	2
Seloken/Toprol-XL	186	4	6	181	(3)	(4)	160	(12)	(14)	168	5	4
Atacand	75	(7)	(6)	72	(4)	(5)	80	11	8	73	(9)	(6)
Others	89	3	12	90	1	(3)	80	(11)	(12)	80	-	(4)
BioPharmaceuticals: total CVRM	**1,779**	**(2)**	**-**	**1,775**	**-**	**(1)**	**1,773**	**-**	**(2)**	**1,939**	**9**	**9**
BioPharmaceuticals: Respiratory												
Symbicort	677	(9)	(7)	706	4	3	668	(5)	(7)	752	13	12
Pulmicort	337	17	19	226	(33)	(33)	242	7	5	371	53	51
Daliresp/Daxas	44	7	10	48	9	9	53	10	8	53	-	(2)
Tudorza/Eklira	37	3	6	34	(8)	(8)	37	9	6	42	14	14
Duaklir	19	-	-	16	(16)	(15)	21	31	18	23	10	10
Bevespi	1	(67)	(50)	3	n/m	n/m	4	33	33	8	n/m	n/m
Others	66	(20)	(19)	66	-	(4)	67	2	4	85	27	30
BioPharmaceuticals: total Respiratory	**1,181**	**(2)**	**(1)**	**1,099**	**(7)**	**(8)**	**1,092**	**(1)**	**(3)**	**1,334**	**22**	**21**
Other medicines												
Nexium	461	(6)	(4)	595	29	28	469	(21)	(22)	427	(9)	(9)
Synagis	230	(24)	(24)	70	(70)	(70)	153	n/m	n/m	234	53	53
*Seroquel XR/*IR	104	(36)	(35)	135	30	30	113	(16)	(16)	156	38	36
Losec/Prilosec	68	15	18	68	-	(3)	66	(3)	(6)	69	5	5
Movantik/Moventig	30	15	15	32	7	7	30	(6)	(6)	30	-	-
FluMist/Fluenz	-	n/m	n/m	-	-	-	20	n/m	n/m	58	n/m	n/m
Others	105	(48)	44	173	65	n/m	140	(19)	(21)	120	(14)	(15)
Total other medicines	**998**	**(24)**	**(22)**	**1,073**	**8**	**7**	**991**	**(8)**	**(9)**	**1,094**	**10**	**10**
Total Product Sales	**4,843**	**(8)**	**(6)**	**4,940**	**2**	**1**	**4,882**	**(1)**	**(3)**	**5,487**	**12**	**12**

Shareholder information

Announcement of nine months and third quarter 2019 results 24 October 2019

Future dividends will normally be paid as follows:

First interim: announced with half-year and second-quarter results and paid in September

Second interim: announced with full-year and fourth-quarter results and paid in March

The record date for the first interim dividend for 2019, payable on 9 September 2019, will be 9 August 2019. The ex-dividend date will be 8 August 2019.

Information on or accessible through AstraZeneca's websites, including astrazeneca.com, does not form part of and is not incorporated into this announcement.

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Cautionary statements regarding forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, we are providing the following cautionary statement:

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although we believe our expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things: the loss or expiration of, or limitations to, patents, marketing exclusivity or trademarks, or the risk of failure to obtain and enforce patent protection; effects of patent litigation in respect of IP rights; the impact of any delays in the manufacturing, distribution and sale of any of our products; the impact of any failure by third parties to supply materials or services; the risk of failure of outsourcing; the risks associated with manufacturing biologics; the risk that R&D will not yield new products that achieve commercial success; the risk of delay to new product launches; the risk that new products do not perform as we expect; the risk that strategic alliances and acquisitions, including licensing and collaborations, will be unsuccessful; the risks from pressures resulting from generic competition; the impact of competition, price controls and price reductions; the risks associated with developing our business in emerging markets; the risk of illegal trade in our products; the difficulties of obtaining and maintaining regulatory approvals for products; the risk that regulatory approval processes for biosimilars could have an adverse effect on future commercial prospects; the risk of failure to successfully implement planned cost reduction measures through productivity initiatives and restructuring programmes; the risk of failure of critical processes affecting business continuity; economic, regulatory and political pressures to limit or reduce the cost of our products; failure to achieve strategic priorities or to meet targets, expectations, guidance or indications; the risk of substantial adverse litigation/government investigation claims and insufficient insurance coverage; the risk of substantial product liability claims; the risk of failure to adhere to applicable laws, rules and regulations; the risk of failure to adhere to applicable laws, rules and regulations relating to anti-competitive behaviour; the impact of increasing implementation and enforcement of more stringent anti-bribery and anti-corruption legislation; taxation risks; exchange rate fluctuations; the risk of an adverse impact of a sustained economic downturn; political and socio-economic conditions; the risk of environmental liabilities; the risk of occupational health and safety liabilities; the risk associated with pensions liabilities; the impact of failing to attract and retain key personnel and to successfully engage with our employees; the risk of misuse of social medial platforms and new technology; and the risk of failure of information technology and cybercrime. Nothing in this document, or any related presentation / webcast, should be construed as a profit forecast.