AstraZeneca PLC
24 October 2019 07:00 BST

Year-to-date and Q3 2019 results

Patients to benefit from further pipeline progress; sales-growth momentum driving operating leverage

Year-to-date Product Sales growth of 13% (17% at CER[1]) to $17,315m included third-quarter Product Sales of $6,132m (+16%, +18% at CER). The third quarter again saw all three therapy areas and every sales region produce encouraging performances, including:

- The continued performance of new medicines[2], with sales growth in the quarter of 62% (+64% at CER) to $2,707m, including new-medicine growth in Emerging Markets of 85% (90% at CER) to $539m

- Sales growth by therapy area in the quarter: Oncology +46% (+48% at CER) to $2,334m, New CVRM[3] +8% (+11% at CER) to $1,113m and Respiratory +15% (+18% at CER) to $1,319m

- Sales growth by region in the quarter: total Emerging Markets sales grew by 25% (29% at CER) to $2,123m, with China sales growth of 35% (40% at CER) to $1,283m, ahead of longer-term trends. US sales increased by 17% to $2,025m; Europe sales continued their return to growth, increasing by 1% (4% at CER) to $1,139m; Japan sales increased by 31% (27% at CER) to $657m

The Company today upgrades its Product Sales guidance at CER for the year.

	YTD 2019			Q3 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Product Sales	17,315	13	17	6,132	16	18
Collaboration Revenue	405	3	6	274	n/m	n/m
Total Revenue	17,720	13	17	6,406	20	22
Reported[4] Operating Profit	2,347	2	3	757	(11)	(13)
Core[5] Operating Profit	4,891	41	42	1,880	43	41
Reported EPS[6]	$0.79	(11)	(15)	$0.23	(33)	(38)
Core EPS	$2.61	39	38	$0.99	40	36

Pascal Soriot, Chief Executive Officer, commenting on the results said:
"With AstraZeneca growing at pace, our sales guidance has been upgraded for the second consecutive quarter. Another strong performance from our new medicines accompanied impressive results in our key markets, most notably in China, the US and Japan. The performance reinforces our confidence in delivering sustainable earnings growth.

We delivered further positive news for patients. *Lynparza* demonstrated its potential as a treatment for prostate cancer and as an expanded treatment for ovarian cancer. *Tagrisso*, *Imfinzi* and PT010 also had positive data, and we delivered breakthrough data in heart failure for *Farxiga*.

We are continuing to ensure that we capture the benefits of our growth by balancing reinvesting in our business, delivering on our sustainability commitments, continuing to improve our operating leverage and cash generation."

Financial summary

- Product Sales increased by 13% in the year to date (17% at CER) to $17,315m. The performance in the quarter was supported by favourable inventory and gross-to-net movements which are not expected in the final quarter of the year

- The Reported Gross Profit Margin increased by one percentage point in the year to date to 80%, partly reflecting the mix of sales; the Core Gross Profit Margin increased by one percentage point in the year to date to 81%

- Reported Operating Expense increased by 11% in the year to date (15% at CER) to $12,871m and represented 73% of Total Revenue (YTD 2018: 74%). Core Operating Expense increased by 3% (6% at CER) to $10,537m and represented 59% of Total Revenue (YTD 2018: 65%), demonstrating a significant improvement in operating leverage

- Reported R&D Expense increased by 1% in the year to date (5% at CER) to $3,968m. Core R&D Expense increased by 1% (4% at CER) to $3,826m, partly a result of investment in the development of the potential new oncology medicine, trastuzumab deruxtecan

- Reported SG&A Expense increased by 16% (20% at CER) in the year to date to $8,656m, due to an increase in legal provisions and revaluation movements on acquisition-related liabilities in the year to date; Core SG&A Expense increased by 4% (8% at CER) to $6,464m, primarily reflecting growth in China, as well as ongoing additional support for new medicines. An update on legal matters and subsequent events is disclosed in Note 5 and Note 6

- Reported Other Operating Income and Expense declined by 32% in the year to date (31% at CER) to $1,041m; Core Other Operating Income and Expense declined by 7% (6% at CER) to $1,060m

- The Reported Operating Profit Margin declined in the year to date by one percentage point (two at CER) to 13%; the Core Operating Profit Margin increased by five percentage points to 28%

- The Reported Tax Rate in the year to date was 27% (YTD 2018: 18%); the Core Tax Rate was 22% (YTD 2018: 19%). The tax rates in the year to date reflected the geographical mix of profits and the impact of collaboration and divestment activity

- Reported EPS of $0.79 in the year to date, based on a weighted-average number of shares of 1,297m, represented a decline of 11% (15% at CER); Core EPS increased by 39% (38% at CER) to $2.61. In 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

- The difference between the Reported and Core EPS year-on-year performance partly reflected the impact of a favourable $346m legal settlement in YTD 2018 that was recognised as income in Reported Other Operating Income and Expense. It was also a result of the aforementioned increase in legal provisions and revaluation movements on acquisition-related liabilities in 2019

- The Company today upgrades its Product Sales guidance at CER for the year. Product Sales are now expected to increase by a low to mid-teens percentage; the prior guidance was for a low double-digit percentage increase

Commercial summary

Oncology
Sales growth of 50% in the year to date (54% at CER) to $6,393m, including:

— *Tagrisso* sales of $2,305m, representing growth of 82% in the year to date (86% at CER). The performance included growth in Emerging Markets of 108% (120% at CER) to $553m that partly reflected the early-2019 inclusion of *Tagrisso* as a 2nd-line treatment for EGFR[7]-mutated (EGFRm) NSCLC[8] on the China National Reimbursement List (NRDL). *Tagrisso* is now approved as a 1st-line treatment in most major markets

— *Imfinzi* sales of $1,045m, representing growth of 182% (184% at CER). Commercial execution and favourable reimbursement decisions supported sales growth outside of the US. Europe sales increased significantly to $115m (YTD 2018: $9m), accompanying encouraging Japan sales of $149m (YTD 2018: $9m)

— *Lynparza* sales of $847m, representing growth of 93% (98% at CER). The performance included growth in the US of 86% to $432m and Emerging Markets of 205% (227% at CER) to $101m as the medicine consolidated its leadership position in the poly ADP ribose polymerase (PARP)-inhibitor class

— The performance from more-mature Oncology medicines in the year to date included a decline in *Faslodex* sales of 4% (1% at CER) to $726m and a 16% decline in *Iressa* sales (11% at CER) to $343m. The Company anticipates continued declines for both medicines, partly reflecting generic *Faslodex* competition in the US and the pricing impact on *Iressa* from centralised procurement in China and the success of *Tagrisso*; both medicines saw significant declines in the third quarter

— Oncology sales growth in Emerging Markets of 42% (51% at CER) to $1,665m

New CVRM
Sales growth of 11% in the year to date (14% at CER) to $3,207m, including:

— *Brilinta* sales of $1,153m, representing growth of 22% (26% at CER). The performance was bolstered by results in Emerging Markets, where sales grew by 50% in the year to date (59% at CER) to $348m. Patient uptake continued in the treatment of acute coronary syndrome and high-risk post-myocardial infarction

— *Farxiga* sales of $1,124m, with growth of 13% (17% at CER), ahead of the impact of label updates to reflect results from the DECLARE CV outcomes trial (CVOT). The level of sales growth in the US was adversely impacted by gross-to-net adjustments; underlying demand remained strong

— *Bydureon* sales of $410m, a decline of 8% (7% at CER), partly driven by the impact of production constraints in the first half for the new *Bydureon BCise* device and declining volumes for the dual-chamber pen

— New CVRM sales growth in Emerging Markets of 37% (46% at CER) to $835m

Respiratory
Sales growth of 9% in the year to date (13% at CER) to $3,854m, including:

— A *Symbicort* sales decline of 7% (4% at CER) to $1,783m, reflecting continued pricing pressure and the impact of managed-market rebates in the US. This was partially offset by Emerging Markets growth of 10% (18% at CER) to $401m

— *Pulmicort* sales growth of 17% (23% at CER) to $1,053m; the majority of *Pulmicort* sales were in Emerging Markets. Q3 2019 global sales increased by 28% (31% at CER) to $337m

— *Fasenra* sales of $498m, representing growth of 189% (193% at CER). *Fasenra* leads the medicine class for the treatment of severe eosinophilic asthma by new patient share in a number of key markets

— Respiratory sales growth in Emerging Markets of 24% (31% at CER) to $1,419m

Emerging Markets

As the Company's largest region, at 35% of total Product Sales, Emerging Markets sales increased by 19% in the year to date (26% at CER) to $6,074m, including:

— A China sales increase of 30% (37% at CER) to $3,691m. Highlights included:
  - Oncology sales growth of 58% (67% at CER) to $1,023m
  - New CVRM growth of 78% (88% at CER) to $359m

— An ex-China sales increase of 5% (12% at CER) to $2,382m (Q3 2019: $839m, +12%, +15% at CER). All regions were in CER sales growth in the year to date, including: (ex-China) Asia-Pacific, Middle East and Africa, Brazil and Russia

Sustainability summary

In the year to date, AstraZeneca was recognised as a global sustainability leader:

— The Company achieved fourth position overall in the pharmaceutical industry in the 2019 Dow Jones Sustainability Indices (DJSI). AstraZeneca maintained its 2018 overall score and achieved a perfect score of 100 in the areas of environmental reporting, labour-practice indicators, social reporting and health-outcome contribution. This marked the 18th time that AstraZeneca was included in the indices

— The Company was again named as a member of the FTSE4Good Index Series, ranking in the 94th percentile of the healthcare industry, with perfect scores in climate change, anti-corruption, corporate governance and customer responsibility

Recent developments and progress against the Company's sustainability priorities are reported below:

— Access to healthcare: the Company celebrated the fifth anniversary of its Healthy Heart Africa (HHA) programme, conducting over 12 million blood-pressure screenings and identifying over two million elevated readings since its launch in 2014, working with collaborators across Kenya, Ethiopia, Tanzania and Ghana

— Environmental protection: AstraZeneca participated in Climate Week, taking part in events such as The Climate Group's 'Step Up: The Business Case for Greater Government Ambition' panel, as the first pharmaceutical-company member of the global EV100 initiative

— Ethics and transparency: the Company launched an employee campaign, 'Speak Up - Your Voice Matters' using internal social-media channels. The campaign encouraged honest and open dialogue in support of a healthy business culture, where people feel able to make their voices heard

A more extensive Sustainability update is provided later in this announcement.

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

Regulatory approvals	- *Tagrisso* - NSCLC (1st line, EGFRm): regulatory approval (CN) - *Farxiga*/*Forxiga* - T2D[10] CVOT: regulatory approval (US, EU) - roxadustat - anaemia of CKD[11], NDD[12]: regulatory approval (CN) - *Fasenra Pen* - severe eosinophilic asthma; auto-injector and self-administration: regulatory approval (US)
Regulatory submissions and/or acceptances	- *Lynparza* - pancreatic cancer (1st line, BRCAm): regulatory submission acceptance (US, EU) - *Calquence* - CLL[13]: regulatory submission under review (US) - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2[14]-positive): regulatory submission acceptance (US, JP); Priority Review designation (US) - *Brilinta*/*Brilique* - CAD[15]/T2D CVOT: regulatory submission acceptance (US, EU)
Major Phase III data readouts or other significant developments	- *Tagrisso* - NSCLC (1st line, EGFRm): met Phase III key secondary endpoint (OS[16]) - *Imfinzi* + treme - NSCLC (1st line) (NEPTUNE): did not meet Phase III primary endpoint - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): met Phase III primary endpoint - *Lynparza* - prostate cancer (2nd line, castration-resistant): met Phase III primary endpoint - *Calquence* - CLL: Breakthrough Therapy Designation (US) - *Farxiga* - HF[17] CVOT: met Phase III primary endpoint; Fast Track designation (US) - *Farxiga* - CKD: Fast Track designation (US) - *Qtrilmet* - T2D: positive opinion (EU) - PT010 - COPD[18] (ETHOS): met Phase III primary endpoint - PT010 - COPD: complete response letter (US) - *Fasenra* - eosinophilic oesophagitis: Orphan Drug Designation (US) - anifrolumab - lupus (SLE[19]) (TULIP 2): met Phase III primary endpoint

Guidance and financial priorities
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 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.

Guidance: Product Sales
Reflecting the performance over the year to date, guidance for Product Sales in FY 2019 has been upgraded. Product Sales are now expected to increase by a low to mid-teens percentage; the prior guidance was for a low double-digit percentage increase.

Guidance: 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 significantly lower sum of Collaboration Revenue and Core Other Operating Income and Expense versus the prior year. It also reflects the opportunities being taken to reinvest in the business, particularly in China and in the Company's new medicines, in order to strengthen AstraZeneca's long-term growth profile.

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 year to date. The Reported Operating Profit Margin declined in the year to date by one percentage point (two at CER) to 13%; the Core Operating Profit Margin, however, increased by five percentage points to 28%. Core Operating Profit in FY 2019 is anticipated to increase 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 $1,594m in the year to date, compared to an inflow of $394m in YTD 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

- The Core Tax Rate range has been narrowed to 20-22% for FY 2019 from the previously anticipated range of 18-22% (FY 2018: 11%). Variations in the Core Tax Rate between quarters can be expected to continue

Currency impact
If foreign-exchange rates were to remain at the average of rates seen in the nine months to 30 September 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.

Footnotes
The following notes refer to pages 1-6:

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*, roxadustat, *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, Lokelma* and roxadustat.

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.

10. Type-2 diabetes.

11. Chronic kidney disease.

12. Non-dialysis dependent.

13. Chronic lymphocytic leukaemia.

14. Human epidermal growth factor receptor 2.

15. Coronary artery disease.

16. Overall survival.

17. Heart failure.

18. Chronic obstructive pulmonary disease.

19. Systemic lupus erythematosus.

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.

Timing	News flow
Q4 2019	- *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC): regulatory decision (CN) - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): data readout, regulatory submission - *Imfinzi* +/- treme - SCLC[20]: regulatory submission - *Lynparza* - ovarian cancer (1st line, BRCAm) (SOLO-1): regulatory decision (CN) - *Lynparza* - pancreatic cancer (1st line, BRCAm): regulatory decision (US) - selumetinib - NF1[21]: regulatory submission (US) - roxadustat - anaemia of CKD: regulatory submission (US) - *Symbicort* - mild asthma: regulatory submission (CN) - PT010 - COPD: regulatory decision (CN)
H1 2020	- *Imfinzi* +/- treme - head & neck cancer (1st line): data readout, regulatory submission - *Imfinzi* +/- treme - bladder cancer (1st line) (DANUBE): data readout, regulatory submission - *Lynparza* - breast cancer (BRCAm): regulatory decision (CN) - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): regulatory submission - *Lynparza* - prostate cancer (2nd line, castration-resistant): regulatory submission - *Lynparza* + cediranib - ovarian cancer (2nd line): data readout - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2-positive): regulatory decision (US, JP) - trastuzumab deruxtecan - advanced/refractory, metastatic gastric cancer (HER2-positive): data readout, regulatory submission (JP) - *Calquence* - CLL: regulatory decision (US) - *Calquence* - CLL: regulatory submission (EU, JP) - selumetinib - NF1: regulatory submission (EU) - *Forxiga* - T2D CVOT: regulatory decision (CN) - *Farxiga* - HF CVOT: regulatory submission - *Brilinta* - stroke (THALES): data readout - *Lokelma* - hyperkalaemia: regulatory decision (JP, CN) - *Symbicort* - mild asthma: regulatory submission (EU) - *Bevespi* - COPD: regulatory decision (CN) - PT010 - COPD: regulatory decision (US, EU)

[20] Small cell lung cancer.
[21] Neurofibromatosis type 1.

Timing	News flow
H2 2020	- *Imfinzi* - neo-adjuvant NSCLC: data readout - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-2): data readout - *Imfinzi* +/- treme - liver cancer (1st line): data readout - *Lynparza* - ovarian cancer (3rd line, BRCAm): regulatory submission (US) - *Lynparza* - pancreatic cancer (1st line, BRCAm): regulatory decision (EU) - *Brilinta* - stroke (THALES): regulatory submission - *Epanova* - hypertriglyceridaemia CVOT: data readout - roxadustat - anaemia of myelodysplastic syndrome: data readout - *Fasenra* - nasal polyposis: data readout - PT027 - asthma: data readout - tezepelumab - severe asthma: data readout - anifrolumab - lupus (SLE): regulatory submission

Timing	News flow
2021	- *Imfinzi* - neo-adjuvant NSCLC: regulatory submission - *Imfinzi* - adjuvant NSCLC: data readout, regulatory submission - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-2): regulatory submission - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-5): data readout - *Imfinzi* - NSCLC (1st line) (PEARL): data readout, regulatory submission - *Imfinzi* +/- treme - limited-disease stage SCLC: data readout - *Imfinzi* +/- treme - bladder cancer (1st line) (NILE): data readout, regulatory submission - *Imfinzi* +/- treme - liver cancer (1st line): regulatory submission - *Imfinzi* - liver cancer (locoregional): data readout, regulatory submission - *Imfinzi* - biliary tract cancer: data readout - *Lynparza* - adjuvant breast cancer: data readout, regulatory submission - *Lynparza* - prostate cancer (1st line, castration-resistant): data readout, regulatory submission - *Lynparza* + cediranib - ovarian cancer (2nd line): regulatory submission - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2-positive, 3rd line+): data readout, regulatory submission - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2-positive, 2nd line): data readout - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2-low): data readout - *Farxiga* - chronic kidney disease: data readout, regulatory submission - *Epanova* - hypertriglyceridaemia CVOT: regulatory submission - roxadustat - anaemia of myelodysplastic syndrome: regulatory submission - *Fasenra* - nasal polyposis: regulatory submission - PT027 - asthma: regulatory submission - tezepelumab - severe asthma: regulatory submission

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 full year and fourth quarter financial results on 14 February 2020.

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 the Company 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 nine-month period to 30 September 2019 (the year to date or YTD 2019) and three-month period to 30 September 2019 (the quarter or Q3 2019) compared to the nine-month period to 30 September 2018 (YTD 2018) and three-month period to 30 September 2018 (Q3 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 dollar values and percentages may not agree to totals.

Table 1: Total Revenue

	YTD 2019			Q3 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Product Sales	17,315	13	17	6,132	16	18
Collaboration Revenue	405	3	6	274	n/m	n/m
Total Revenue	**17,720**	**13**	**17**	**6,406**	**20**	**22**

Table 2: Product Sales

	YTD 2019				Q3 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	6,393	37	50	54	2,334	38	46	48
BioPharmaceuticals	7,061	41	9	13	2,432	40	12	14
New CVRM	*3,207*	*19*	*11*	*14*	*1,113*	*18*	*8*	*11*
Respiratory	*3,854*	*22*	*9*	*13*	*1,319*	*22*	*15*	*18*
Other medicines	3,861	22	(16)	(12)	1,366	22	(9)	(7)
Total	**17,315**	**100**	**13**	**17**	**6,132**	**100**	**16**	**18**

Specialty-care medicines comprise all Oncology medicines, *Brilinta* and *Fasenra*. At 46% of Product Sales (YTD 2018: 35%), specialty-care medicine sales increased by 50% in the year to date (54% at CER) to $8,054m.

Table 3: Top-ten medicines by Product Sales

Medicine	Therapy area	YTD 2019				Q3 2019			
		$m	% of total	% change		$m	% of total	% change	
				Actual	CER			Actual	CER
Tagrisso	Oncology	2,305	13	82	86	891	15	76	78
Symbicort	Respiratory	1,783	10	(7)	(4)	613	10	(1)	1
Brilinta	CVRM	1,153	7	22	26	416	7	24	27
Nexium	Other medicines	1,130	7	(14)	(11)	374	6	(11)	(10)
Farxiga	CVRM	1,124	6	13	17	398	6	12	14
Pulmicort	Respiratory	1,053	6	17	23	337	6	28	31
Imfinzi	Oncology	1,045	6	n/m	n/m	412	7	n/m	n/m
Crestor	CVRM	982	6	(9)	(5)	337	6	(4)	(2)
Lynparza	Oncology	847	5	93	98	327	5	94	96
Faslodex	Oncology	726	4	(4)	(1)	205	3	(20)	(19)
Total		**12,149**	**70**	**22**	**26**	**4,311**	**70**	**24**	**26**

Table 4: Collaboration Revenue

	YTD 2019				Q3 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Initial Collaboration Revenue	-	-	-	-	-	-	-	-
Ongoing Collaboration Revenue	405	100	45	49	274	100	n/m	n/m
Royalties	*45*	*11*	*17*	*23*	*13*	*5*	*(27)*	*(25)*
Milestones/other	*360*	*89*	*49*	*53*	*261*	*95*	*n/m*	*n/m*
Total	**405**	**100**	**3**	**6**	**274**	**100**	**n/m**	**n/m**

YTD 2019 Ongoing Collaboration Revenue included $260m of *Lynparza* milestone receipts as part of a collaboration with MSD[22]. Of this, $200m was received in the quarter.

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

Product Sales

The performance of new and legacy medicines is shown below, with a geographical split shown in Notes 7 & 8.

Table 5: YTD 2019 therapy area and medicine performance

Therapy area	Medicine	YTD 2019			
		$m	% of total	% change	
				Actual	CER
Oncology	*Tagrisso*	2,305	13	82	86
	Imfinzi	1,045	6	n/m	n/m
	Lynparza	847	5	93	98
	Iressa	343	2	(16)	(11)
	Calquence	108	1	n/m	n/m
	Legacy:				
	Faslodex	726	4	(4)	(1)
	Zoladex	617	4	8	15
	Arimidex	174	1	5	10
	Casodex	157	1	2	6
	Others	68	-	(26)	(24)
	Total Oncology	**6,393**	**37**	**50**	**54**
BioPharmaceuticals: CVRM	*Farxiga*	1,124	6	13	17
	Brilinta	1,153	7	22	26
	Bydureon	410	2	(8)	(7)
	Onglyza	396	2	-	4
	Byetta	83	-	(12)	(10)
	Other diabetes	36	-	33	35
	Lokelma	6	-	n/m	n/m
	Legacy:				
	Crestor	982	6	(9)	(5)
	Seloken/Toprol-XL	570	3	3	10
	Atacand	161	1	(20)	(16)
	Others	199	1	(13)	(9)
	BioPharmaceuticals: total CVRM	**5,121**	**30**	**3**	**7**

Therapy area	Medicine	YTD 2019			
		$m	% of total	% change	
				Actual	CER
BioPharmaceuticals: Respiratory	*Symbicort*	1,783	10	(7)	(4)
	Pulmicort	1,053	6	17	23
	Fasenra	498	3	n/m	n/m
	Daliresp/Daxas	157	1	16	17
	Duaklir	55	-	(24)	(20)
	Tudorza/Eklira	50	-	(45)	(42)
	Bevespi	30	-	32	32
	Breztri	1	-	n/m	n/m
	Others	226	1	(3)	2
	BioPharmaceuticals: total Respiratory	**3,854**	**22**	**9**	**13**
Other medicines	*Nexium*	1,130	7	(14)	(11)
	Synagis	295	2	(29)	(29)
	Losec/Prilosec	217	1	3	8
	Seroquel XR/IR	151	1	(51)	(49)
	Movantik/Moventig	72	-	(15)	(15)
	Others	83	-	(54)	(48)
	Total other medicines	**1,948**	**11**	**(22)**	**(20)**
	Total Product Sales	**17,315**	**100**	**13**	**17**

Table 6: Q3 2019 therapy area and medicine performance

Therapy area	Medicine	Q3 2019			
		$m	% of total	% change	
				Actual	CER
Oncology	*Tagrisso*	891	15	76	78
	Imfinzi	412	7	n/m	n/m
	Lynparza	327	5	94	96
	Iressa	91	1	(31)	(29)
	Calquence	44	1	n/m	n/m
	Legacy:				
	Faslodex	205	3	(20)	(19)
	Zoladex	226	4	17	21
	Arimidex	63	1	15	17
	Casodex	52	1	3	5
	Others	20	-	(27)	(26)
	Total Oncology	**2,334**	**38**	**46**	**48**
BioPharmaceuticals: CVRM	*Farxiga*	398	6	12	14
	Brilinta	416	7	24	27
	Onglyza	127	2	(9)	(7)
	Bydureon	127	2	(16)	(16)
	Byetta	28	-	(19)	(18)
	Other diabetes	14	-	38	44
	Lokelma	4	-	n/m	n/m
	Legacy:				
	Crestor	337	6	(4)	(2)
	Seloken/Toprol-XL	177	3	(1)	3
	Atacand	55	1	(15)	(11)
	Others	65	1	(8)	(6)
	BioPharmaceuticals: total CVRM	**1,749**	**29**	**3**	**6**

Therapy area	Medicine	Q3 2019			
		$m	% of total	% change	
				Actual	CER
BioPharmaceuticals: Respiratory	*Symbicort*	613	10	(1)	1
	Pulmicort	337	6	28	31
	Fasenra	202	3	n/m	n/m
	Daliresp/Daxas	53	1	2	3
	Duaklir	18	-	(21)	(19)
	Tudorza/Eklira	17	-	(4)	-
	Bevespi	10	-	4	4
	Breztri	1	-	n/m	n/m
	Others	67	1	(5)	-
	BioPharmaceuticals: total Respiratory	**1,319**	**22**	**15**	**18**
Other medicines	*Nexium*	374	6	(11)	(10)
	Synagis	146	2	(11)	(11)
	Losec/Prilosec	73	1	10	13
	Seroquel XR/IR	82	1	5	6
	Movantik/Moventig	25	-	(22)	(23)
	Others	31	1	(55)	(59)
	Total other medicines	**731**	**12**	**(12)**	**(11)**
	Total Product Sales	**6,132**	**100**	**16**	**18**

Product Sales summary

Oncology

Product Sales of $6,393m in the year to date; an increase of 50% (54% at CER). Oncology Product Sales represented 37% of total Product Sales, up from 28% in the first nine months of 2018.

Oncology: lung cancer

Tagrisso

Tagrisso has been approved and launched in 87 countries, including the US, China, in Europe and Japan for the 2nd-line treatment of patients with Stage IV EGFR T790M[23]-mutated NSCLC. *Tagrisso* has also been approved in 78 countries, including the US, China, in Europe and Japan for the 1st-line treatment of patients with EGFRm NSCLC; a number of additional regulatory reviews are underway.

Product Sales in the year to date of $2,305m represented growth of 82% (86% 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 Emerging Markets.

Sales in the US increased by 57% in the year to date to $909m. 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 17% sequential quarterly increase in US sales of *Tagrisso* in Q3 2019, reflecting continued underlying demand growth; sales were, however, flattered in the quarter by the impact of gross-to-net and stocking adjustments.

In Emerging Markets, *Tagrisso* sales increased by 108% in the year to date (120% at CER) to $553m, with notable growth in China, after the medicine was added to the NRDL with effect from January 2019 in the 2nd-line setting; it also received 1st-line regulatory approval in China during the period.

Sales of *Tagrisso* in Japan increased by 145% in the year to date to $468m, reflecting the increasing use of *Tagrisso* as a 1st-line treatment; the medicine has reached a very high penetration rate in Japan. 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 $337m in the year to date represented an increase of 52% (61% at CER), driven by emerging use in the 1st-line setting as more countries granted reimbursement, as well as continued strong levels of demand in the 2nd-line setting.

Imfinzi

Imfinzi is approved in 53 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 11 countries, including the US.

Global Product Sales of *Imfinzi* increased by 182% in the year to date (184% at CER) to $1,045m, of which $759m were in the US, almost entirely for the treatment of unresectable, Stage III NSCLC; sales in the US increased by 118% in the year to date.

In Japan, sales of $149m (YTD 2018: $9m) reflected encouraging levels of demand, supported by higher CRT and treatment rates. Sales in Europe of $115m (YTD 2018: $9m) followed recent regulatory approvals and launches; additional regulatory and reimbursement decisions are expected in due course.

Iressa

Product Sales in the year to date of $343m; a decline of 16% (11% at CER).

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

Emerging Markets sales were stable in the year to date (up by 6% at CER) to $227m; *Iressa* entered the NRDL in China in 2017 and remains within the China centralised-procurement programme. Given the growing use of *Tagrisso*, sales of *Iressa* declined by 31% to $14m in the US and by 29% (24% at CER) to $61m in Europe. Japan sales amounted to $37m, reflecting a decline of 45%.

Oncology: *Lynparza*

By the end of the period, *Lynparza* was approved in 65 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 44 countries for the treatment of metastatic breast cancer.

Product Sales of *Lynparza* amounted to $847m in the year to date, an increase of 93% (98% at CER). The strong performance was geographically spread, with launches continuing in Emerging Markets and the Established Rest of World region (RoW). Ongoing MSD co-promotion efforts also contributed to sales.

US sales increased by 86% to $432m, 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 medicine in the US in the PARP-inhibitor class, as measured by total prescription volumes in both ovarian and breast cancer.

Sales in Europe increased by 52% (61% at CER) to $208m, driven by increasing levels of reimbursement and BRCA-testing rates, as well as the recent 1st-line ovarian- and breast-indication launches. The Company continues to implement a number of launches in the broad, 2nd-line, maintenance ovarian-cancer indication, regardless of BRCAm status.

Following the initial launch in April 2018, and the subsequent breast- and 1st-line ovarian-cancer launches in 2019, Japan sales of *Lynparza* amounted to $91m in the year to date, representing growth of 262% (263% at CER). Emerging Markets sales of $101m, up by 205% (227% at CER), 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 medicines

Calquence

Product Sales in the year to date of $108m; an increase of 185%. 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 year to date, with an increasing number of CLL patients now treated, following compendia inclusion in the National Comprehensive Cancer Network guidelines as Category 1 for relapsed/refractory CLL.

Legacy: *Faslodex*

Product Sales in the year to date of $726m; a decline of 4% (1% at CER).

Emerging Markets sales of *Faslodex* increased by 31% in the year to date (41% at CER) to $145m. US sales declined by 21% to $311m, reflecting the recent launch of multiple generic *Faslodex* medicines; in Q3 2019, *Faslodex* sales in the US declined by 55% to $60m. In Europe, where generic competitor medicines are also available, sales in the year to date declined by 2% (up by 4% at CER) to $168m, while in Japan, sales increased by 24% to $97m.

Legacy: *Zoladex*

Product Sales in the year to date of $617m; an increase of 8% (15% at CER).

Emerging Markets sales of *Zoladex* increased by 21% (30% at CER) year to date to $380m. Sales in Europe increased by 1% (7% at CER) to $100m. In the Established RoW region, sales declined by 13% (11% at CER) to $133m, driven by the effects of increased competition.

BioPharmaceuticals: CVRM
Total CVRM sales, which include *Crestor* and other legacy medicines, increased by 3% in the year to date (7% at CER) to $5,121m and represented 30% of total Product Sales (YTD 2018: 32%).

New CVRM sales increased by 11% in the year to date (14% at CER) to $3,207m, reflecting strong performances from *Farxiga* and *Brilinta*. New CVRM sales represented 19% of Product Sales in the year to date (YTD 2018: 19%).

CVRM: Diabetes

Farxiga
Product Sales of $1,124m in the year to date; an increase of 13% (17% at CER).

Emerging Markets sales increased by 40% (50% at CER) to $339m, fuelled by growth in ex-China Emerging Markets. US sales declined by 6% to $396m, impacted by changes in formulary access for competitor medicines. AstraZeneca was granted a label update in the US in Q4 2019 to reflect results from the DECLARE CVOT. The level of sales growth in the US in the year to date was, however, adversely impacted by gross-to-net adjustments; underlying demand remained strong.

Sales in Europe increased by 18% (26% at CER) to $273m. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales, increased by 32% (31% at CER) to $61m.

Onglyza
Product Sales of $396m in the year to date; a stable performance (growth of 4% at CER).

Sales in Emerging Markets increased by 8% (17% at CER) to $131m, driven by the performance in China. The performance was also supported in the US by favourable prior-year gross-to-net adjustments and improved realised price across the business mix; US sales of *Onglyza* increased by 7% in the year to date to $174m.

Europe sales declined by 22% (17% at CER) to $53m, 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 $410m in the year to date; a decline of 8% (7% at CER).

Sales were partly driven by the impact of production constraints in the first half for the new *Bydureon BCise* device and declining volumes for the dual-chamber pen. US sales of $340m declined by 5% in the year to date, while *Bydureon* sales in Europe declined by 19% (14% at CER) to $50m.

CVRM: other medicines

Brilinta
Product Sales of $1,153m in the year to date; an increase of 22% (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 50% (59% at CER) to $348m. US sales of *Brilinta*, at $500m, represented an increase of 22%, 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 increased by 2% in the year to date (9% at CER) to $262m.

Lokelma
Product Sales of $6m in the year to date, predominantly in the US, where *Lokelma* was recently launched.

Lokelma is approved in the US and in the 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 $982m in the year to date; a decline of 9% (5% at CER).

Sales in Emerging Markets declined by 2% (up by 4% at CER) to $621m; the CER growth came despite the impact from the aforementioned '4+7' pilot tender scheme in China. US sales declined by 31% to $88m, underlining the ongoing effect of generic *Crestor* medicines. In Europe, sales declined by 30% (25% at CER) to $112m, reflecting a similar impact that began in Europe in 2017.

In Japan, where AstraZeneca collaborates with Shionogi Co. Ltd, sales increased by 3% to $126m. 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 $3,854m in the year to date; an increase of 9% (13% at CER). Respiratory represented 22% of total Product Sales (YTD 2018: 23%).

Symbicort
Product Sales in the year to date of $1,783m; a decline of 7% (4% 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 10% (18% at CER) to $401m in the year to date. In contrast, US sales declined by 11% to $585m, 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 year to date (8% at CER) to $508m, 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 13% in the year to date (14% at CER) to $131m (Q3 2019: $64m, +26%, +22% at CER); partly reflecting the destocking by Astellas Pharma Co. Ltd (Astellas) following the termination of the co-promotion agreement earlier in the year. 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 was to be terminated on 30 July 2019. Since the termination, the Company has solely distributed and promoted the medicine in Japan.

Pulmicort
Product Sales in the year to date of $1,053m; an increase of 17% (23% at CER).

Emerging Markets, where sales increased by 23% in the year to date (29% at CER) to $845m, represented 80% of global sales of *Pulmicort*. China, comprising the overwhelming majority of *Pulmicort* sales in Emerging Markets, delivered a particularly strong double-digit performance, strengthened by higher levels of demand and underpinned by the impact of AstraZeneca's support in China for over 17,000 nebulisation centres.

Sales in the US increased by 10% to $89m due to favourable managed-market rebates and sales in Europe declined by 12% (6% at CER) to $60m reflecting the legacy status of the medicine.

Fasenra
Fasenra has been approved in 50 countries, including the US, in the EU and Japan as an add-on maintenance treatment for patients with severe asthma and with an eosinophilic phenotype. The medicine is currently reimbursed in 32 countries, with early-access programmes in an additional 11 countries. At the end of the period, *Fasenra* led the medicine class for the treatment of severe eosinophilic asthma by new-patient share in a number of key markets. Product Sales of $498m in the year to date represented an increase of 189% (193% at CER).

Sales in the US increased by 166% in the year to date to $343m. In Europe and Japan, AstraZeneca was granted regulatory approval in 2018 on a similar basis to that in the US. In Europe, sales of $81m in the year to date represented an increase of 378% (406% at CER). Sales in Japan increased by 138% to $62m in the year to date, following the medicine's launch in 2018.

Daliresp/Daxas
Product Sales in the year to date of $157m; an increase of 16% (17% at CER).

US sales, representing 85% of the global total, increased by 21% to $134m in the year to date, 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 year to date of $55m; a decline of 24% (20% at CER).

In the first nine months of the year, the overwhelming majority of sales were in Europe, where sales declined by 24% (20% at CER) to $53m; the decline was predominately a result of an adverse 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) became responsible for the commercialisation of *Duaklir* in the US, with AstraZeneca continuing to manufacture and supply the medicine. Circassia communicated making the medicine available to patients in the US in due course.

Bevespi
Product Sales in the year to date of $30m; an increase of 32%.

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

In June 2019, *Bevespi* received the first approval by the Japanese Ministry of Health, Labour and Welfare as a fixed-dose, long-acting dual bronchodilator in a pressurised metered-dose inhaler (pMDI) to relieve symptoms in patients with COPD.

Breztri
Product Sales in the year to date of $1m.

In June 2019, *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 was the first approval by the Japanese Ministry of Health, Labour and Welfare of a triple-combination therapy in a pressurised metered-dose inhaler (pMDI).

Other medicines (outside the main therapy areas)

Product Sales of $1,948m in the year to date; a decline of 22% (20% at CER), partly reflecting the H1 2019 divestment of US rights to *Synagis* and the H2 2018 divestment of the prescription medicine rights to *Nexium* in Europe.

Other Product Sales represented 11% of total Product Sales, down from 16% in the first nine months of 2018.

Nexium
Product Sales in the year to date of $1,130m; a decline of 14% (11% at CER).

Emerging Markets sales of *Nexium* increased by 10% (16% at CER) to $574m. In Europe, sales declined by 73% (71% at CER) to $49m, reflecting the aforementioned divestment. Sales in the US declined by 30% to $175m, reflecting its 2015 loss of exclusivity and, in Japan, where AstraZeneca collaborates with Daiichi Sankyo Company, Limited (Daiichi Sankyo), sales declined by 6% (5% at CER) to $291m.

Regional Product Sales

Table 7: Regional Product Sales

Global Sales	YTD 2019				Q3 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Emerging Markets	6,074	35	19	26	2,123	35	25	29
China	*3,691*	*21*	*30*	*37*	*1,283*	*21*	*35*	*40*
Ex-China	*2,382*	*14*	*5*	*12*	*839*	*14*	*12*	*15*
US	5,688	33	18	18	2,025	33	17	17
Europe	3,168	18	(4)	2	1,139	19	1	4
Established RoW	2,385	14	17	19	845	14	21	19
Japan	*1,830*	*11*	*29*	*29*	*657*	*11*	*31*	*27*
Canada	*345*	*2*	*(4)*	*(1)*	*120*	*2*	*5*	*5*
Other Established RoW	*211*	*1*	*(18)*	*(12)*	*69*	*1*	*(16)*	*(11)*
Total	**17,315**	**100**	**13**	**17**	**6,132**	**100**	**16**	**18**

Table 8: Regional Product Sales, Emerging Markets
Product Sales of $6,074m in the year to date; an increase of 19% (26% at CER).

Emerging Markets	YTD 2019				Q3 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	1,665	27	42	51	617	29	45	49
BioPharmaceuticals	3,644	60	16	23	1,240	58	20	24
CVRM	*2,225*	*37*	*11*	*18*	*777*	*37*	*16*	*19*
Respiratory	*1,419*	*23*	*24*	*31*	*463*	*22*	*28*	*32*
Other medicines	765	13	(4)	1	266	13	10	19
Total Emerging Markets	**6,074**	**100**	**19**	**26**	**2,123**	**100**	**25**	**29**

New medicines represented 22% of Emerging Markets sales (YTD 2018: 15%). Notable performances included:

— *Tagrisso* ($553m, +108%, +120% at CER)
— *Lynparza* ($101m, +205%, +227% at CER)
— *Brilinta* ($348m, +50%, +59% at CER)
— *Farxiga* ($339m, +40%, +50% at CER)

The performance was also underpinned by the strong sales of a number of other medicines, including:

— *Zoladex* ($380m, +21%, +30% at CER)
— *Pulmicort* ($845m, +23%, +29% at CER)
— *Symbicort* ($401m, +10%, +18% at CER)

Ex-China Emerging Markets sales increased by 5% in the year to date (12% at CER) to $2,382m and new medicines represented 28% of sales (YTD 2018: 21%). In Q3 2019, ex-China Emerging Markets sales delivered impressive growth, increasing by 12% (15% at CER) to $839m, with new medicines representing 31% of sales (Q3 2018: 22%). The performance was supported by encouraging levels of growth in (ex-China) Asia Pacific, Middle East and Africa, Brazil and Russia.

China sales comprised 61% of Emerging Markets sales, increasing by 30% in the year to date (37% at CER) to $3,691m. New medicines, primarily driven by *Tagrisso* and *Lynparza* in Oncology and *Brilinta* and *Farxiga* in New CVRM, delivered particularly encouraging sales growth. New medicines represented 19% of China sales (YTD 2018: 9%). This performance was augmented by strong sales from *Pulmicort*, *Nexium* and *Symbicort*.

During the period, the Chinese National Healthcare Security Administration published the preliminary 2019 NRDL update. The list included one additional AstraZeneca medicine, namely *Kombiglyze* for Diabetes. As a further result of the update, respiratory medicines, including *Symbicort* for asthma and COPD and *Nexium* for acid reflux, had reimbursement restrictions removed. The updated final list is anticipated to be published in Q4 2019, after the conclusion of reimbursement discussions. Since the year 2000, AstraZeneca has had more than 40 medicines added to the NRDL and, from 2012, 15 of the Company's medicines have been admitted to the National Essential Drug List.

Table 9: Regional Product Sales, US
Product Sales of $5,688m; an increase of 18% in the year to date.

US	YTD 2019			Q3 2019		
	$m	% of total	% change	$m	% of total	% change
Oncology	2,538	45	57	917	45	40
BioPharmaceuticals	2,805	49	7	964	48	4
CVRM	*1,622*	*29*	*1*	*537*	*27*	*(6)*
Respiratory	*1,183*	*21*	*15*	*427*	*21*	*20*
Other medicines	345	6	(41)	144	7	(6)
Total US	**5,688**	**100**	**18**	**2,025**	**100**	**17**

New medicines represented 61% of US Product Sales (YTD 2018: 45%). The performance reflected, in particular, the success of the new Oncology medicines ($2,208m, +84%), including *Tagrisso*, *Imfinzi* and *Lynparza* in Oncology, *Brilinta* in New CVRM, plus the compelling performance of *Fasenra* in Respiratory.

Table 10: Regional Product Sales, Europe
Product Sales in the year to date of $3,168m; a decline of 4% (up by 2% at CER).

Europe	YTD 2019				Q3 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	1,027	32	34	42	377	33	44	51
BioPharmaceuticals	1,677	53	(10)	(4)	550	49	(6)	(0)
CVRM	*858*	*27*	*(8)*	*(3)*	*292*	*26*	*(3)*	*2*
Respiratory	*819*	*26*	*(11)*	*(6)*	*258*	*23*	*(8)*	*(3)*
Other medicines	465	15	(30)	(28)	213	19	(26)	(29)
Total Europe	**3,168**	**100**	**(4)**	**2**	**1,139**	**100**	**1**	**4**

The performance in Europe partly reflected adverse continued pricing pressures, the impact of the aforementioned divestment of the prescription medicine rights to *Nexium* in H2 2018 and declining sales of *Crestor*. New medicines, however, represented 40% of Product Sales (YTD 2018: 27%) and the Europe sales performance continued to improve through 2019. Oncology delivered particularly compelling growth in the year to date, with the following medicines representing 64% of Oncology sales in Europe:

- *Tagrisso* ($337m, +52% +61% at CER)
- *Lynparza* ($208m, +52%, +61% at CER)
- *Imfinzi* ($115m, YTD 2018: $9m)

This strong performance was also supported by the successes of *Brilinta* and *Forxiga* in New CVRM and *Fasenra* in Respiratory.

Table 11: Regional Product Sales, Established RoW
Product Sales in the year to date of $2,385m; an increase of 17% (19% at CER).

Established RoW	YTD 2019				Q3 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	1,163	49	66	67	423	50	67	63
BioPharmaceuticals	849	36	(3)	(1)	314	37	6	6
CVRM	*416*	*17*	*(2)*	*1*	*143*	*17*	*(4)*	*(3)*
Respiratory	*433*	*18*	*(4)*	*(2)*	*171*	*20*	*17*	*16*
Other medicines	373	16	(19)	(16)	108	13	(27)	(31)
Total Established RoW	**2,385**	**100**	**17**	**19**	**845**	**100**	**21**	**19**

New medicines represented 42% of Established RoW sales (YTD 2018: 20%). The performance during the year to date reflected, in particular, the successes of *Tagrisso* and *Imfinzi* in Oncology, *Forxiga* in New CVRM and *Fasenra* in Respiratory.

Japan sales, comprising 77% of total Established RoW sales, increased by 29% in the year to date to $1,830m. New medicines represented 45% of Japan sales (YTD 2018: 21%), 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. Overall, in the year to date, Oncology sales in Japan increased by 69% to $1,057m and represented 58% of Japan sales. This performance was also supported a number of other ongoing successes, including:

— *Farxiga* ($61m, +32%, +31% at CER)
— *Fasenra* ($62m, +138%, +138% at CER)

Financial performance

Table 12: YTD 2019 Reported Profit and Loss

	Reported			
	YTD 2019 $m	YTD 2018 $m	% change Actual	% change CER
Product Sales	17,315	15,281	13	17
Collaboration Revenue	405	392	3	6
Total Revenue	17,720	15,673	13	17
Cost of Sales	(3,543)	(3,299)	7	12
Gross Profit	14,177	12,374	15	18
Gross Profit Margin[24]	*79.5%*	*78.4%*	*+1*	*+1*
Distribution Expense	(247)	(238)	4	10
% Total Revenue	*1.4%*	*1.5%*	-	-
R&D Expense	(3,968)	(3,920)	1	5
% Total Revenue	*22.4%*	*25.0%*	*+3*	*+3*
SG&A Expense	(8,656)	(7,431)	16	20
% Total Revenue	*48.9%*	*47.4%*	*-1*	*-1*
Other Operating Income & Expense	1,041	1,525	(32)	(31)
% Total Revenue	*5.9%*	*9.7%*	*-4*	*-4*
Operating Profit	2,347	2,310	2	3
Operating Profit Margin	*13.2%*	*14.7%*	*-1*	*-2*
Net Finance Expense	(948)	(970)	(2)	6
Joint Ventures and Associates	(91)	(77)	18	21
Profit Before Tax	1,308	1,263	4	(1)
Taxation	(358)	(222)	61	54
Tax Rate	27%	18%		
Profit After Tax	950	1,041	(9)	(13)
EPS	$0.79	$0.88	(11)	(15)

[24] Gross Profit Margin, as a percentage of Product Sales, reflects Gross Profit derived from Product Sales, divided by Product Sales.

Table 13: Q3 2019 Reported Profit and Loss

	Reported			
	Q3 2019	Q3 2018	% change	
	$m	$m	Actual	CER
Product Sales	6,132	5,266	16	18
Collaboration Revenue	274	74	n/m	n/m
Total Revenue	6,406	5,340	20	22
Cost of Sales	(1,351)	(1,153)	17	23
Gross Profit	5,055	4,187	21	22
Gross Profit Margin	*78.0%*	*78.1%*	-	*-1*
Distribution Expense	(88)	(73)	20	25
% Total Revenue	*1.4%*	*1.4%*	-	-
R&D Expense	(1,346)	(1,279)	5	8
% Total Revenue	*21.0%*	*24.0%*	*+3*	*+3*
SG&A Expense	(3,199)	(2,423)	32	34
% Total Revenue	*49.9%*	*45.4%*	*-5*	*-4*
Other Operating Income & Expense	335	439	(24)	(23)
% Total Revenue	*5.2%*	*8.2%*	*-3*	*-3*
Operating Profit	757	851	(11)	(13)
Operating Profit Margin	*11.8%*	*15.9%*	*-4*	*-5*
Net Finance Expense	(316)	(330)	(4)	2
Joint Ventures and Associates	(32)	(44)	(27)	(21)
Profit Before Tax	409	477	(14)	(21)
Taxation	(129)	(71)	81	65
Tax Rate	32%	15%		
Profit After Tax	280	406	(31)	(36)
EPS	$0.23	$0.34	(33)	(38)

Table 14: YTD 2019 reconciliation of Reported Profit Before Tax to EBITDA[25]

	YTD 2019 $m	YTD 2018 $m	% change Actual	% change CER
Reported Profit Before Tax	1,308	1,263	4	(1)
Net Finance Expense	948	970	(2)	6
Joint Ventures and Associates	91	77	18	21
Depreciation, Amortisation and Impairment	2,119	2,091	1	5
EBITDA	4,466	4,401	1	4

Table 15: Q3 2019 reconciliation of Reported Profit Before Tax to EBITDA

	Q3 2019 $m	Q3 2018 $m	% change Actual	% change CER
Reported Profit Before Tax	409	477	(14)	(21)
Net Finance Expense	316	330	(4)	2
Joint Ventures and Associates	32	44	(27)	(21)
Depreciation, Amortisation and Impairment	716	698	2	5
EBITDA	1,473	1,549	(5)	(5)

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

Table 16: YTD 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	14,177	122	69	-	-	14,368	14	18
Gross Profit Margin[28]	*79.5%*					*80.6%*	*+1*	*+1*
Distribution Expense	(247)	-	-	-	-	(247)	4	10
R&D Expense	(3,968)	82	60	-	-	(3,826)	1	4
SG&A Expense	(8,656)	147	1,009	294	742	(6,464)	4	8
Other Operating Income & Expense	1,041	-	3	-	16	1,060	(7)	(6)
Operating Profit	2,347	351	1,141	294	758	4,891	41	42
Operating Profit Margin	*13.2%*					*27.6%*	*+5*	*+5*
Net Finance Expense	(948)	-	-	216	153	(579)	3	13
Taxation	(358)	(74)	(240)	(106)	(136)	(914)	68	68
EPS	$0.79	$0.22	$0.69	$0.31	$0.60	$2.61	39	38

[26] Other adjustments include fair-value adjustments relating to contingent consideration on business combinations 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.
[28] Movements in Gross Profit Margin are expressed in percentage points.

Table 17: Q3 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	5,055	70	18	-	-	5,143	21	22
Gross Profit Margin[28]	*78.0%*					*79.4%*	*-*	*-1*
Distribution Expense	(88)	-	-	-	-	(88)	20	25
R&D Expense	(1,346)	18	7	-	-	(1,321)	6	9
SG&A Expense	(3,199)	37	327	96	533	(2,206)	7	9
Other Operating Income & Expense	335	-	1	-	16	352	(20)	(19)
Operating Profit	757	125	353	96	549	1,880	43	41
Operating Profit Margin	*11.8%*					*29.3%*	*+5*	*+4*
Net Finance Expense	(316)	-	-	72	52	(192)	(1)	5
Taxation	(129)	(27)	(75)	(35)	(116)	(382)	80	75
EPS	$0.23	$0.08	$0.20	$0.10	$0.38	$0.99	40	36

Profit and loss summary

a) Gross Profit

Reported Gross Profit increased by 15% in the year to date (18% at CER) to $14,177m; Core Gross Profit increased by 14% (18% at CER) to $14,368m, reflecting the growth in Product Sales. The calculation of Reported and Core Gross Profit Margin excludes the impact of Collaboration Revenue and any associated costs, thereby reflecting the underlying performance of Product Sales. The Reported Gross Profit Margin increased by one percentage point in the year to date to 80%, partly reflecting the mix of Product Sales; the Core Gross Profit Margin increased by one percentage point to 81%.

b) Operating Expense

Reported Operating Expense increased by 11% in the year to date (15% at CER) to $12,871m and represented 73% of Total Revenue (YTD 2018: 74%). Core Operating Expense increased by 3% (6% at CER) to $10,537m and represented 59% of Total Revenue (YTD 2018: 65%), demonstrating a significant improvement in operating leverage.

Reported R&D Expense increased by 1% in the year to date (5% at CER) to $3,968m. Core R&D Expense increased by 1% (4% at CER) to $3,826m, partly a result of investment in the development of the potential new oncology medicine, trastuzumab deruxtecan.

Reported SG&A Expense increased by 16% in the year to date (20% at CER) to $8,656m; Core SG&A Expense increased by 4% (8% at CER) to $6,464m, primarily a result of 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 Expense partly reflected fair-value adjustments arising on acquisition-related liabilities recognised in 2019, as well as an increase in legal provisions.

c) 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 32% in the year to date (31% at CER) to $1,041m and included:

- $515m, reflecting an agreement to sell US rights to *Synagis* to Swedish Orphan Biovitrum AB (publ) (Sobi)
- $243m, as part of an agreement to divest the global commercial rights, excluding China, Japan, the US and Mexico, for *Losec* and associated brands to Cheplapharm Arzneimittel GmbH (Cheplapharm)

Core Other Operating Income and Expense declined by 7% in the year to date (6% at CER) to $1,060m.

d) Operating Profit

Reported Operating Profit increased by 2% in the year to date (3% at CER) to $2,347m, with the growth in Product Sales offset by the aforementioned increase in Reported SG&A Expense and the decline in Other Operating Income & Expense; the Reported Operating Profit Margin declined by one percentage point (two at CER) to 13%. Core Operating Profit increased by 41% (42% at CER) to $4,891m; the Core Operating Profit Margin increased by five percentage points to 28%, demonstrating a significant improvement in operating leverage.

e) Net Finance Expense

Reported Net Finance Expense declined by 2% in the year to date (up by 6% at CER) to $948m. 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 in respect of the Bristol-Myers Squibb global Diabetes alliance profit-participation liability. Excluding the discount unwind on acquisition-related liabilities, Core Net Finance Expense increased by 3% (13% at CER) to $579m.

f) Profit Before Tax

Reported Profit Before Tax increased by 4% in the year to date (a decline of 1% at CER) to $1,308m, reflecting the growth in Product Sales offset by the aforementioned increase in Reported SG&A Expense and the decline in Other Operating Income & Expense. Core Profit Before Tax increased by 49% (48% at CER) to $4,221m, partly a result of the growth in Product Sales ahead of the growth of Core Operating Expense.

g) Taxation

The Reported Tax Rate for the year to date was 27% and the Core Tax Rate was 22% (YTD 2018: 18% and 19%, respectively). 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. Taxation paid for the year to date was $965m, representing 74% of Reported Profit Before Tax (YTD 2018: $406m, 32%); the increase primarily reflected the phasing of tax payments between periods and included refunds in FY 2018, following agreement of prior-year liabilities.

h) EPS

Reported EPS of $0.79 in the year to date, based on a weighted-average number of shares of 1,297m, represented a decline of 11% (15% at CER); Core EPS increased by 39% (38% at CER) to $2.61. The difference between the Reported and Core year-on-year performance partly reflected the impact of a favourable $346m legal settlement in YTD 2018 that was recognised as income in Reported Other Operating Income and Expense. It was also a result of an increase in legal provisions and revaluation movements on acquisition-related liabilities in 2019.

In 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.

Table 18: Cash Flow

	YTD 2019 $m	YTD 2018 $m	Change $m
Reported Operating Profit	2,347	2,310	37
Depreciation, Amortisation and Impairment	2,119	2,091	28
Increase in Working Capital and Short-Term Provisions	(812)	(1,741)	929
Gains on Disposal of Intangible Assets	(833)	(975)	142
Non-Cash and Other Movements	313	(428)	741
Interest Paid	(575)	(457)	(118)
Taxation Paid	(965)	(406)	(559)
Net Cash Inflow from Operating Activities	**1,594**	**394**	**1,200**
Net Cash Inflow before Financing Activities	879	430	449
Net Cash Outflow from Financing Activities	(1,771)	(312)	(1,459)

A Net Cash Inflow from Operating Activities of $1,594m in the year to date compared to an inflow of $394m in YTD 2018, reflecting an underlying improvement in business performance combined with favourable working-capital movements. The improvement in the movement of Working Capital and Short-Term Provisions centred on the release of various provisions and accruals within Trade and Other Payables, including the impact of a number of legal settlements. The favourable performance was partly offset by an increase in Taxation Paid, at $965m (YTD 2018: $406m); the increase reflected the aforementioned phasing of tax payments between periods and included refunds in FY 2018, following agreement of prior-year liabilities.

Net Cash Inflows before Financing Activities of $879m compared with an inflow of $430m in YTD 2018. The movement in Net Cash Inflow from Operating Activities was more than offset by changes in the Purchase of Intangible Assets, namely:

- The first of two $675m upfront payments to Daiichi Sankyo as part of the agreement on trastuzumab deruxtecan
- The impact of a final true-up net payment of $413m to MSD, based on 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 period, 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 $337m in the year to date (YTD 2018: $247m).

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.

i) Capital expenditure

Capital expenditure amounted to $659m in the year to date, compared to $728m in YTD 2018. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK. AstraZeneca is targeting an initial occupation date of late 2020, with an overall full completion of the building expected in late 2021. The Company expects associated capital expenditure of c.$1,270m (c.£980m, translated at average exchange rates in the first half of the year), the majority of which was paid in prior periods. The Company has made significant progress on its transition to Cambridge; as of the end of September 2019, c.3,000 colleagues were based in the city.

The Company anticipates of a broadly stable level of total capital expenditure in FY 2019 (FY 2018: $1,043m).

Table 19: Debt and capital structure

	At 30 Sep 2019 $m	At 31 Dec 2018 $m	At 30 Sep 2018 $m
Cash and Cash Equivalents	3,967	4,831	3,420
Other Investments	909	895	860
Cash and Investments	**4,876**	**5,726**	**4,280**
Overdrafts and Short-Term Borrowings	(228)	(755)	(1,092)
Leases[29]	(712)	-	-
Current Instalments of Loans	-	(999)	(1,399)
Loans Due After One Year	(17,218)	(17,359)	(18,422)
Interest-Bearing Loans and Borrowings (Gross Debt)	**(18,158)**	**(19,113)**	**(20,913)**
Net Derivatives	(16)	384	448
Net Debt	**(13,298)**	**(13,003)**	**(16,185)**

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.

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

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 20: 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)[30]	
Currency	**Primary Relevance**	**FY 2018[31]**	**YTD 2019[32]**	**% change**	**Product Sales**	**Core Operating Profit**
CNY	Product Sales	6.62	6.87	(4)	221	126
EUR	Product Sales	0.85	0.89	(5)	145	66
JPY	Product Sales	110.45	109.07	1	114	74
Other[33]					216	105
GBP	Operating Expense	0.75	0.79	(5)	26	(72)
SEK	Operating Expense	8.69	9.40	(8)	4	(73)

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

Corporate and business development

a) Divestment of rights for *Losec*

In September 2019, the Company agreed to sell the global commercial rights, excluding China, Japan, the US and Mexico, for *Losec* (omeprazole) and associated medicines to Cheplapharm. The divestment included medicines containing omeprazole marketed by AstraZeneca or its collaborators under the brand names *Acimax*, *Antra*, *Mepral*, *Mopral*, *Omepral* and *Zoltum.*

Losec is a proton pump inhibitor discovered and developed by AstraZeneca, which helps to reduce the amount of acid produced by the stomach in patients with gastrointestinal reflux conditions and ulcers. It has a number of approved indications and is commonly prescribed for patients with gastro oesophageal reflux disease.

Cheplapharm paid AstraZeneca $243m on completion of the agreement in the quarter and will also pay sales-contingent milestones of up to $33m across 2021 and 2022. Income arising from the upfront payment was reported in the Company's financial statements within Other Operating Income and Expense. In 2018, *Losec* sales in the countries covered by the agreement were $98m.

b) Amended collaboration agreement with Ironwood for *Linzess* in China

In September 2019, AstraZeneca amended its collaboration agreement with Ironwood Pharmaceuticals, Inc. (Ironwood) in mainland China, China Hong Kong and China Macau for *Linzess* (linaclotide), a first-in-class new treatment for patients with irritable bowel syndrome with constipation. The amended agreement gave AstraZeneca sole responsibility for developing, manufacturing and commercialising *Linzess* in the above markets.

AstraZeneca will pay Ironwood three non-contingent payments, totalling $35m, between 2021 and 2024. In addition, Ironwood could receive up to $90m in milestone payments, contingent on the achievement of certain sales targets. Ironwood will also be eligible for royalties beginning in the mid-single-digit percent, based on the annual net sales of *Linzess* in the above markets, where Ironwood will no longer jointly funds the development and commercialisation of *Linzess* or share in the profit from sales.

Sustainability

AstraZeneca's sustainability ambition has three priority areas[34], aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

Recent developments and progress against the Company's priorities are reported below:

a) Access to healthcare

During the period, the Company celebrated the fifth anniversary of its HHA programme. HHA is committed to tackling hypertension and the increasing burden of CV disease, with a presence across East and West Africa. By the end of August 2019, HHA had conducted over 12 million blood-pressure screenings and identified over two million elevated readings since launch in 2014, working with collaborators across Kenya, Ethiopia, Tanzania and Ghana.

In September 2019, the Company launched its Young Health Programme (YHP) in the Republic of the Union of Myanmar with global collaborator, Plan International UK, a children's charity that strives to advance children's rights and equality for girls. In the US, the Company enhanced its existing country-wide programme by announcing a charitable collaboration with Learning Undefeated, a non-profit organisation that provides life-changing science, technology, engineering and mathematics (STEM) education opportunities for underserved communities. The US programme introduces a new model for YHP, combining a focus on STEM with elements of disease-prevention education. The intention is to make STEM education engaging, accessible and exciting for middle-school students while, at the same time, incorporating important disease prevention and health-promotion lessons and experiments. The addition of the two new programmes brought the total number of active global plans to 19.

The YHP selected and provided sponsorships to 25 young people to attend the One Young World 2019 Summit in London, UK in October 2019. The summit brought together delegates from more than 190 countries to highlight and discuss some of the most severe issues facing the next generation and build connections that work towards solutions. The YHP delegation consisted of young leaders in their own right, actively leading efforts to improve the health and wellbeing of young people in their home countries.

During the period, the YHP and Plan International UK held a series of workshops with young people in three countries on three continents: Kenya, India and Brazil, to solicit their ideas and opinions on adolescent health and universal health coverage. Their feedback informed the development of a Manifesto on Adolescent Health that AstraZeneca and Plan International UK shared with the UN General Assembly and the first high-level meeting on universal health coverage in September 2019. This vital work formed part of the Company's advocacy work within the YHP and was an important way to include young voices in global-health discourse.

b) Environmental protection

During the period, the Company held a stakeholder workshop in Nairobi, Kenya to discuss policy, education and research needs to address concerns relating to pharmaceuticals in the environment, arising from increasing patient access to medicines in emerging economies where there is inadequate environmental infrastructure and different water use and re-use patterns. The workshop brought together key international experts and opinion leaders.

In Emerging Markets, AstraZeneca goes above and beyond local guidelines and conducts research to ensure adherence to the same high standards of behaviour as in more tightly-regulated locations.

[34] 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'.

In September 2019, the Company participated in side-meetings alongside the United Nations General Assembly focused on climate action and access to healthcare. Since June 2018, AstraZeneca has been contributing to the UN Global Compact's Health Is Everyone's Business initiative. In September 2019, Pam Cheng, AstraZeneca Executive Vice President Operations & IT, spoke at the launch event for their Business Leadership Brief for Healthy Planet, Healthy People, linking health and the environment and the need to act on climate change. The brief included AstraZeneca's best-practice examples taken from United Nations Global Compact, Health Case Study.

In September 2019, the Company also participated in Climate Week, taking part in events such as The Climate Group's 'Step Up: The Business Case for Greater Government Ambition' panel, as the first pharmaceutical-company member of the global EV100 initiative[35]. The Company is also 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 by 2025 for its global operations.

c) Ethics and transparency

During the period, the Company expanded the Bioethics information available on its website. Bioethics refers in the broadest sense to the range of ethical issues that arise from the study and practice of biological and medical science. The Global Standard: Bioethics sets out the fundamental policy principles and practices that apply to each of the subject-matter areas. The Company worked with the Slave-Free Alliance (SFA) on a risk-gap analysis which showed positive management engagement and drive, significant global efforts to drive risk awareness amongst employees, as well as robust third-party risk management and whistleblowing platforms. The SFA also identified opportunities to provide further public information, and to action site audits focused on this risk area. Ongoing external benchmarking is planned in due course.

During the period, the Company launched an employee campaign, 'Speak Up - Your Voice Matters' using internal social-media channels. The campaign encouraged honest and open dialogue, and included interactive scenario videos, senior-leader reflections and guides for manager in support of a healthy business culture, where people feel able to make their voices heard.

In September 2019, recognising transparency as a foundation of trust with AstraZeneca stakeholders, the Company launched a 'Transparency Map'. This is an interactive tool designed to increase transparency around data on sourcing and suppliers, site environmental and wellbeing programmes, intellectual property and healthcare-professional payment-disclosure practices, and access to healthcare programmes. At present, no other pharmaceutical company has disclosed this level of information in this easily accessible way.

d) Other developments

In September 2019, the Company was recognised for its sustainability efforts in the DJSI, achieving fourth position overall in the pharmaceutical industry. The DJSI is the longest-running, global sustainability-benchmark system and is an in-depth analysis of companies' economic, social and environmental performance. AstraZeneca maintained its 2018 overall score and achieved a perfect score of 100 in the areas of environmental reporting, labour-practice indicators, social reporting and health-outcome contribution. This marked the 18th time the Company has been included in the DJSI.

In September 2019, the Company was again named as a member of the FTSE4Good Index Series, ranking in the 94th percentile of the healthcare industry, with perfect scores in climate change, anti-corruption, corporate governance and customer responsibility. Since its inception in 2001, the FTSE4Good Index Series has only included companies that reflect strong Environmental, Social and Governance (ESG) risk-management practices, as measured by an overall ESG rating.

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.

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

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 21: Update from the late-stage pipeline

Regulatory approvals	5	- *Tagrisso* - NSCLC (1st line, EGFRm): regulatory approval (CN) - *Farxiga*/*Forxiga* - T2D CVOT: regulatory approval (US, EU) - roxadustat - anaemia of CKD, NDD: regulatory approval (CN) - *Fasenra Pen* - severe eosinophilic asthma; auto-injector and self-administration: regulatory approval (US)
Regulatory submissions and/or acceptances	6	- *Lynparza* - pancreatic cancer (BRCAm): regulatory submission acceptance (US, EU) - *Calquence* - CLL: regulatory submission under review (US) - trastuzumab deruxtecan - advanced/refractory, metastatic breast cancer (HER2-positive): regulatory submission acceptance (US, JP); Priority Review designation (US) - *Brilinta*/*Brilique* - CAD/T2D CVOT: regulatory submission acceptance (US, EU)
Major Phase III data readouts or other major developments	13	- *Tagrisso* - NSCLC (1st line, EGFRm): met Phase III key secondary endpoint (OS) - *Imfinzi* + treme - NSCLC (1st line) (NEPTUNE trial): did not meet Phase III primary endpoint - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): met Phase III primary endpoint - *Lynparza* - prostate cancer (2nd line, castration-resistant): met Phase III primary endpoint - *Calquence* - CLL: Breakthrough Therapy Designation (US) - *Farxiga* - HF CVOT: met Phase III primary endpoint; Fast Track designation (US) - *Farxiga* - CKD: Fast Track designation (US) - *Qtrilmet* - T2D: positive opinion (EU) - PT010 - COPD (ETHOS): met Phase III primary endpoint - PT010 - COPD: complete response letter (US) - *Fasenra* - eosinophilic oesophagitis: Orphan Drug Designation (US) - anifrolumab - SLE (TULIP 2): met Phase III primary endpoint

New molecular entities and major lifecycle medicines in Phase III trials or under regulatory review	16	**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[36] - savolitinib - NSCLC[36] **CVRM** - roxadustat - anaemia of CKD **Respiratory (and immunology)** - *Fasenra* - multiple indications - *Breztri* - COPD - PT027 - asthma - tezepelumab - severe asthma - nirsevimab - lower respiratory tract infection - anifrolumab - lupus
Total projects in clinical pipeline	144	

[36] 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*[37] are already benefitting patients. An extensive pipeline of 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 European Society of Medical Oncology congress (ESMO 2019), the Company presented over 60 abstracts spanning multiple tumour types, including seven oral presentations, with five Presidential presentations and five late-breaking abstracts. Highlights included late-breaking results from the Phase III *Lynparza* PAOLA-1 trial in 1st-line advanced ovarian cancer, and results of the Phase III *Lynparza* PROfound trial in metastatic, castrate-resistant prostate cancer (mCRPC), where both trials met their primary endpoint. Positive OS data from the *Tagrisso* Phase III FLAURA trial in 1st-line EGFRm NSCLC were also presented.

The Company presented further evidence of its progress at the 2019 International Association for the Study of Lung Cancer World Congress on Lung Cancer (WCLC) in Barcelona, Spain where Phase III *Imfinzi* CASPIAN SCLC data were presented in the Presidential Symposium.

Oncology: lung cancer

a) *Tagrisso*

Tagrisso has now received approval in 78 countries, including in the US, Japan, China and in the EU, for the 1st-line treatment of patients with Stage IV EGFRm NSCLC. Regulatory approvals have been achieved in 87 countries, including the US, in the EU, Japan and in China for the 2nd-line treatment of patients with EGFR T790M-mutated NSCLC.

In September 2019, AstraZeneca announced that it had received marketing authorisation from the China NMPA for *Tagrisso* as a 1st-line treatment for adults with locally-advanced or metastatic NSCLC whose tumours have the genetic mutations of EGFR exon 19 deletions or exon 21 (L858R) substitutions. The approval followed the priority-review pathway and was based on results from the Phase III FLAURA trial.

During the period, AstraZeneca announced positive OS results from the Phase III FLAURA trial, a randomised, double-blind, multi-centre trial of *Tagrisso* in previously-untreated patients with locally-advanced or metastatic NSCLC whose tumours have EGFR mutations. *Tagrisso* showed a statistically significant and clinically meaningful improvement in OS, a key secondary endpoint for *Tagrisso* versus gefitinib or erlotinib, both of which were previous SoC treatments in this setting (HR[38] 0.799 [95% CI[39], 0.641-0.997], p=0.0462). *Tagrisso* delivered a median OS of 38.6 months, versus 31.8 months for the comparator arm. At three years, 28% of patients in the *Tagrisso* arm and only 9% of patients in the comparator arm remained on treatment. *Tagrisso* also showed a statistically significant and clinically meaningful 52% reduction in the risk of central nervous system (CNS) disease progression, increasing the time patients with CNS metastases lived without CNS-disease progression or death (HR 0.48 [95% CI, 0.26-0.86], p=0.014).

[37] Licensed to Innate Pharma in the US and EU for hairy cell leukaemia.
[38] Hazard ratio.
[39] Confidence interval.

Table 22: Key ongoing *Tagrisso* trials in lung cancer

Trial	Population	Design	Timeline	Status
Phase III ADAURA	Adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD[40] Q4 2015 LPCD[41] Q1 2019 First data anticipated 2021+[42]	Recruitment completed
Phase III LAURA	Locally-advanced, unresectable EGFRm NSCLC	Placebo or *Tagrisso*	FPCD Q3 2018 First data anticipated 2021+	Recruitment ongoing
Phase III FLAURA2	1st-line EGFRm NSCLC	*Tagrisso* or *Tagrisso* + platinum-based chemotherapy doublet	FPCD Q3 2019 First data anticipated 2021+	Recruitment ongoing
Phase II SAVANNAH	EGFRm, MET+ locally-advanced or metastatic NSCLC patients who have progressed on *Tagrisso*	*Tagrisso* + savolitinib	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase II ORCHARD	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 2021+	Recruitment ongoing

b) *Imfinzi*

During the period, the Company presented detailed results from the Phase III CASPIAN trial of *Imfinzi* in patients with previously-untreated extensive-stage SCLC at the aforementioned Presidential Symposium of the International Association for the Study of Lung Cancer WCLC 2019 in Barcelona, Spain. *Imfinzi*, in combination with four cycles of SoC chemotherapy (etoposide, with either cisplatin or carboplatin), demonstrated a statistically significant and clinically meaningful improvement in OS versus SoC consisting of up to six cycles of chemotherapy and optional prophylactic cranial irradiation. The risk of death was reduced by 27% (equal to a HR of 0.73), with median OS of 13.0 months for *Imfinzi* plus chemotherapy, versus 10.3 months for SoC.

Results showed a prolonged OS benefit, with an estimated 33.9% of patients alive at 18 months following treatment with *Imfinzi* plus chemotherapy, versus 24.7% of patients following SoC. Across all efficacy endpoints, benefits were observed in patients treated with *Imfinzi* plus chemotherapy versus SoC. Results showed a significantly higher PFS rate at 12 months (17.5% versus 4.7%), a 10.3% increase in confirmed objective response rate (ORR) (67.9% versus 57.6%), and improved duration of response at 12 months (22.7% versus 6.3%).

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

This trial also includes a third arm containing tremelimumab, an anti-CTLA4 antibody and potential new medicine, with *Imfinzi* and chemotherapy. The trial will continue to the final analysis of OS for the combination of dual immune checkpoint blockade with chemotherapy.

During the period, AstraZeneca announced final OS results from the Phase III NEPTUNE trial, a randomised, open-label, multi-centre, global trial of *Imfinzi* in combination with tremelimumab versus SoC platinum-based chemotherapy in previously-untreated Stage IV (metastatic) NSCLC patients. The trial was performed in an 'all-comers' population, and the primary-analysis population was patients with a high tumour mutational burden (TMB). TMB is a measurement of the number of mutations within the genome (DNA) of a tumour, and tumours with high levels of TMB may be more visible to the immune system. In the primary analysis population of patients whose blood TMB was 20 or more mutations per megabase (mut/Mb), the combination of *Imfinzi* and tremelimumab did not meet the primary endpoint of improving OS, compared to SoC chemotherapy. The safety and tolerability profile for the combination of *Imfinzi* and tremelimumab was consistent with previous trials.

Trial timelines throughout the *Imfinzi* programme have been updated and optimised to reflect event rates and an effort to optimise the trials to focus on *Imfinzi* as a monotherapy based on learnings from previous trials.

Table 23: Key ongoing *Imfinzi* trials in lung cancer

Trial	Population	Design	Timeline	Status
Phase III AEGEAN	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
Phase III ADJUVANT BR.31[43]	Stage Ib-IIIa NSCLC	Placebo or *Imfinzi*	FPCD Q1 2015 First data anticipated 2021	Recruitment ongoing
Phase III PACIFIC-2	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
Phase III PACIFIC-4	Unresectable, Stage I-II NSCLC	Stereotactic body radiation therapy followed by placebo or *Imfinzi*	FPCD Q2 2019 First data anticipated 2021+	Recruitment ongoing
Phase III PACIFIC-5	Unresectable, Stage III NSCLC (predominantly Asia)	Concurrent or sequential CRT, followed by placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated 2021	Recruitment ongoing
Phase III ADRIATIC	Limited-disease stage SCLC	Concurrent CRT, followed by placebo or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing

[43] Conducted by the Canadian Cancer Trials Group.

Trial	Population	Design	Timeline	Status
Phase III PEARL	Stage IV, 1st-line NSCLC (Asia)	SoC chemotherapy or *Imfinzi*	FPCD Q1 2017 LPCD Q1 2019 First data anticipated 2021	Recruitment completed
Phase III POSEIDON	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q2 2017 LPCD Q3 2018 First data anticipated Q4 2019	Recruitment completed
Phase III CASPIAN	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

***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 11 countries.

Table 24: Key *Imfinzi* trials in tumour types other than lung cancer

Trial	Population	Design	Timeline	Status
Phase III POTOMAC	Non-muscle invasive bladder cancer	SoC BCG[44] or SoC BCG + *Imfinzi*	FPCD Q3 2018 First data anticipated 2021+	Recruitment ongoing
Phase III NIAGARA	Muscle-invasive bladder cancer	Neo-adjuvant cisplatin and gemcitabine SoC chemotherapy or SoC + *Imfinzi*, followed by adjuvant placebo or *Imfinzi*	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III EMERALD-1	Locoregional hepatocellular carcinoma (liver cancer)	TACE[45] followed by placebo or TACE + *Imfinzi*, followed by *Imfinzi* +	FPCD Q1 2019 First data	Recruitment ongoing

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

Trial	Population	Design	Timeline	Status
		bevacizumab or TACE + *Imfinzi* followed by *Imfinzi*	anticipated 2021	
Phase III EMERALD-2	Locoregional hepatocellular carcinoma at high risk of recurrence after surgery or radiofrequency ablation	Adjuvant *Imfinzi* or *Imfinzi* + bevacizumab	FPCD Q2 2019 First data anticipated 2021+	Recruitment ongoing
Phase III CALLA	Locally-advanced cervical cancer	CRT or CRT + *Imfinzi*, followed by placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase III DANUBE	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 H1 2020	Recruitment completed
Phase III NILE	Stage IV, 1st-line cisplatin chemotherapy-eligible bladder cancer	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase III KESTREL	Stage IV, 1st-line HNSCC	SoC or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H1 2020	Recruitment completed
Phase III HIMALAYA	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 completed
Phase III TOPAZ-1	Stage IV, 1st-line biliary-tract cancer	Gemcitabine and cisplatin SoC chemotherapy or SoC + *Imfinzi*	FPCD Q2 2019 First data anticipated 2021	Recruitment ongoing

Oncology: *Lynparza* (multiple cancers)
During the period, the Company announced positive data and presented the detailed positive results at the aforementioned ESMO 2019 meeting from the Phase III PAOLA-1 trial in patients with advanced ovarian cancer. The trial, in the 1st-line maintenance setting, compared *Lynparza* added to SoC bevacizumab versus bevacizumab alone, in women with or without BRCA-gene mutations.

Investigator-assessed results showed that *Lynparza* added to bevacizumab reduced the risk of disease progression or death by 41% (equal to a HR of 0.59) and improved PFS to a median of 22.1 months, versus 16.6 months for those treated with bevacizumab alone. At two years since trial initiation, 46% of patients treated with *Lynparza* added to bevacizumab showed no disease progression, versus 28% of patients receiving bevacizumab alone.

The sensitivity analysis of blinded independent central review (BICR) of PFS was consistent and showed a similar improvement, with a median of 26.1 months for *Lynparza* added to bevacizumab, versus 18.3 months for bevacizumab alone. The safety and tolerability profiles of *Lynparza* and bevacizumab were consistent with that known from previous trials for each medicine, and with no detriment to quality of life.

AstraZeneca also announced and presented detailed positive results at ESMO 2019 from the Phase III PROfound trial of *Lynparza* in men with mCRPC who have a homologous recombination repair (HRR) gene mutation and have progressed on prior treatment with new hormonal anticancer treatments, e.g. enzalutamide and abiraterone. Results showed a statistically significant and clinically meaningful improvement with *Lynparza* in the primary endpoint of radiographic progression-free survival (rPFS), improving the time men with BRCA1/2- or ATM-mutated mCRPC lived without disease progression or death to a median of 7.4 months versus 3.6 months for those treated with abiraterone or enzalutamide. *Lynparza* reduced the risk of disease progression or death by 66% (equal to a HR of 0.34) for these patients.

The trial also met the key secondary endpoint of rPFS in the overall HRR-mutated (HRRm) population, where *Lynparza* reduced the risk of disease progression or death by 51% (equal to a HR of 0.49) and improved rPFS to a median of 5.8 months, versus 3.5 months for abiraterone or enzalutamide.

During the period, the Company received submission acceptances from the US FDA and the European Medicines Agency (EMA) for supplemental New Drug Applications (sNDA) for the use of *Lynparza* tablets in BRCAm pancreatic cancer. A regulatory decision in the US is anticipated in Q4 2019, while the Company anticipates an EMA decision in H2 2020.

Table 25: Key *Lynparza* trials

Trial	Population	Design	Timeline	Status
Phase III OlympiA	Adjuvant BRCAm breast cancer	SoC placebo or *Lynparza*	FPCD Q2 2014 LPCD Q2 2019 First data anticipated 2021	Recruitment completed
Phase III PROfound	Metastatic castration-resistant 2nd-line+ HRRm prostate cancer	SoC (abiraterone or enzalutamide) or *Lynparza*	FPCD Q2 2017 LPCD Q4 2018	Primary endpoint met
Phase III PAOLA-1[46]	Stage IV, 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + *Lynparza* maintenance	FPCD Q2 2015 LPCD Q2 2018	Primary endpoint met
Phase III GY004[47]	Recurrent platinum-sensitive ovarian cancer	SoC chemotherapy or cediranib or cediranib + *Lynparza*	FPCD Q1 2016 First data anticipated H1 2020	Recruitment ongoing
Phase II/III GY005[47]	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 2021+	Recruitment ongoing (Phase III component)
Phase III DuO-O	Stage IV, 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + *Imfinzi* +/- *Lynparza* maintenance	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase II MEDIOLA	Advanced, 2nd-line gBRCAm[48] ovarian cancer Stage IV, 1st to 3rd-line gBRCAm, HER2-negative breast	*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

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

Trial	Population	Design	Timeline	Status
	cancer Stage IV, 2nd-line SCLC Stage IV, 2nd-line gastric cancer			cohorts presented in 2017 and 2018
Phase II LYNK-002	HRRm advanced solid tumours	*Lynparza*	FPCD Q1 2019	Recruitment ongoing
Phase II VIOLETTE	Stage IV, advanced, triple-negative breast cancer: -HRRm[49] (BRCA) -HRRm (non-BRCA) -Non-HRRm	*Lynparza* *Lynparza* + ATR (AZD6738)	FPCD Q2 2018 First data anticipated 2021	Recruitment ongoing
Phase III PROpel	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + *Lynparza*	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase II BAYOU	Stage IV, 1st-line cis-platinum chemotherapy-ineligible urothelial bladder cancer	*Imfinzi* or *Imfinzi* + *Lynparza*	FPCD Q1 2018 First data anticipated H1 2020	Recruitment ongoing
Phase II ORION	Stage IV, 1st-line NSCLC	SoC chemotherapy + *Imfinzi*, followed by *Imfinzi* or *Imfinzi* + *Lynparza* maintenance	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing

Trastuzumab deruxtecan (breast and other cancers)
During the period, the Company announced that the US FDA had accepted for review the Biologics License Application for [fam-] trastuzumab deruxtecan and granted Priority Review designation, with a Prescription Drug User Fee Act (PDUFA) date set for the second quarter of 2020.

Table 26: Key trastuzumab deruxtecan trials

Trial	Population	Design	Timeline	Status
Phase II DESTINY-Breast01	Stage IV, HER2-positive (IHC 3+) breast cancer post trastuzumab emtansine	Trastuzumab deruxtecan	FPCD Q3 2017 LPCD Q3 2018	Data read out Q2 2019 Breakthrough Therapy Designation (US) status awarded

[49] Homologous recombination repair mutated.

Trial	Population	Design	Timeline	Status
Phase III DESTINY-Breast02	Stage IV, HER2-positive (IHC 3+) breast cancer post trastuzumab emtansine	SoC or trastuzumab deruxtecan	FPCD Q3 2018 First data anticipated 2021	Recruitment ongoing
Phase III DESTINY-Breast03	Stage IV, HER2-positive (IHC 3+) breast cancer	Trastuzumab emtansine or trastuzumab deruxtecan	FPCD Q3 2018 First data anticipated 2021	Recruitment ongoing
Phase III DESTINY-Breast04	Stage IV, HER2-low (IHC 1+/2+) breast cancer	SoC or trastuzumab deruxtecan	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase II DESTINY-Gastric01	Stage IV, HER2-positive (IHC 3+) gastric cancer	SoC or trastuzumab deruxtecan	FPCD Q4 2017 LPCD Q2 2019 First data anticipated H1 2020	Recruitment completed

***Calquence* (blood cancers)**
During the period, AstraZeneca received regulatory approval for *Calquence* in relapsed/refractory MCL in Chile, Singapore, Canada and India and announced that the US FDA had granted Breakthrough Therapy Designation for *Calquence* as a monotherapy treatment for adult patients with CLL, one of the most common types of leukaemia in adults. The agency granted the designation based on positive results from the interim analyses of the ELEVATE-TN and ASCEND Phase III clinical trials. Together, the trials showed that *Calquence*, alone or in combination, significantly increased the time patients lived without disease progression or death, with safety and tolerability that was consistent with its established profile. The Company also submitted for review to the US FDA the sNDA for the use of *Calquence* in 1st-line and relapsed/refractory CLL.

During the period, *Calquence* was also assigned Category 1 status as a preferred regimen in the treatment of relapsed/refractory CLL within the US NCCN guidelines.

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)
During the period, the US FDA granted approval for *Farxiga* to include positive CV outcomes and renal data from the Phase III DECLARE-TIMI 58 trial in adults with T2D. The trial enrolled a majority of patients with no existing CV disease. In this trial, *Farxiga* achieved a statistically significant reduction in the composite endpoint of hospitalisation for HF or CV death versus placebo, one of the two primary efficacy endpoints. There were also fewer major adverse CV events observed with *Farxiga* for the other primary efficacy endpoint; this did not, however, reach statistical significance. Similarly, the European Commission (EC) approved a similar update to the marketing authorisation for *Forxiga*.

The Company also announced positive results from the landmark Phase III DAPA-HF trial, which showed that *Farxiga* met the primary composite endpoint with a statistically significant and clinically meaningful reduction of CV death or worsening of HF (defined as hospitalisation or an urgent HF visit), compared to placebo. The trial

was conducted in patients with reduced ejection fraction on SoC treatment, including those with and without T2D. The safety profile of *Farxiga* in the DAPA-HF trial was consistent with the well-established safety profile of the medicine.

Detailed results of the DAPA-HF trial were presented at the recent European Society of Cardiology (ESC) Congress in Paris, France, showing that *Farxiga* reduced the composite of CV death or worsening of HF by 26% ($p<0.0001$). Each of the individual components of the composite endpoint was statistically significant, with a 30% decline ($p<0.0001$) in the risk of experiencing a first episode of worsening HF and an 18% decline ($p=0.0294$) in the risk of dying from CV causes. The effect of *Farxiga* on the primary composite endpoint was generally consistent across the key subgroups examined.

In September 2019, the Company announced that the US FDA had granted Fast Track designation for the development of *Farxiga* to reduce the risk of CV death, or the worsening of HF, in adults with HF with reduced ejection fraction or preserved ejection fraction. This followed the announcement in August 2019 that the US FDA had granted Fast Track designation for *Farxiga* to delay the progression of renal failure and prevent CV and renal deaths in patients with CKD.

b) *Qtrilmet* (T2D)

During the period, the Company announced that it had received a positive Committee for Medicinal Products for Human Use (CHMP) opinion for *Qtrilmet* (metformin, *Forxiga* and *Onglyza*) modified-release tablets for marketing authorisation in the European Union for the treatment of adults with T2D. The CHMP is the EMA committee responsible for human medicines. The committee recommended the marketing authorisation for *Qtrilmet* to improve glycaemic control when metformin with or without sulphonyl urea and either *Onglyza* and *Forxiga* does not provide adequate glycaemic control, or when T2D patients are already being treated with metformin, *Onglyza* and *Forxiga*. *Qtrilmet* is approved in the US under the name *Qternmet XR* as an adjunct to diet and exercise to improve glycaemic control in adults with T2D.

c) *Brilinta* (CV disease)

At the aforementioned ESC meeting, AstraZeneca also presented detailed data from the positive Phase III THEMIS trial, which showed that *Brilinta* reduced the risk of CV events in patients with CAD and T2D. In the trial, *Brilinta* plus aspirin reduced the relative risk for the composite of CV death, heart attack or stroke by 10%, compared with aspirin alone; this was a statistically significant reduction. The overall THEMIS trial population consisted of patients with CAD and T2D with no prior heart attack or stroke. Additionally, in a clinically meaningful and prespecified sub-analysis of patients who had previously undergone a percutaneous coronary intervention (PCI), a procedure to open a blocked or narrowed coronary artery, a 15% relative-risk reduction was observed for *Brilinta* plus aspirin for the composite of CV death, heart attack, or stroke, compared with aspirin alone. The safety profile for *Brilinta* was consistent with the known profile of the medicine, with an increased risk of bleeding events observed in both THEMIS and the THEMIS-PCI sub-analysis.

During the period, the Company received submission acceptances from both the US FDA (PDUFA date in Q2 2019) and the EMA to include THEMIS data in the label for *Brilinta.*

Table 27: Key large CVRM trials
Major CVRM outcomes trials are highlighted in the following table:

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Farxiga					
Phase III DECLARE	c.17,000[50] patients with T2D	Arm 1: *Farxiga* 10mg QD[51] + SoC QD Arm 2: placebo + SoC for T2D	Superiority for MACE[52] or superiority for the composite endpoint of CV death or hHF[53]	FPCD Q2 2013	Primary safety endpoint met One of two primary efficacy endpoints met
Phase III DAPA-HF	c.4,500 patients with HF and reduced ejection fraction, with and without T2D	Arm 1: *Farxiga* 10mg or 5 mg QD + SoC Arm 2: placebo + SoC	Time to first occurrence of CV death or hHF or an urgent HF visit	FPCD Q1 2017 LPCD Q3 2018	Data read out Q3 2019 Primary endpoint met Fast Track designation (US)
Phase III DELIVER	c.4,700 patients with HF and preserved ejection fraction, with and without T2D	Arm 1: *Farxiga* 10mg QD Arm 2: placebo	Time to first occurrence of CV death or worsening HF	FPCD Q3 2018 First data anticipated 2021+	Recruitment ongoing Fast Track designation (US)
Phase III DAPA-CKD	c.4,000 patients with CKD, with and without T2D	Arm 1: *Farxiga* 10mg or 5mg QD Arm 2: placebo	Time to first occurrence of ≥ 50% sustained decline in eGFR or reaching ESRD[54] or CV death or renal death	FPCD Q1 2017 LPCD Q1 2019 First data anticipated 2021	Recruitment completed Fast Track designation (US)
Brilinta					
Phase III THEMIS	c.19,000 patients with T2D and CAD without a history of MI[55] or stroke	Arm 1: *Brilinta* 60mg BID[56] Arm 2: placebo BID on a background of acetylsalicylic acid if not contra-indicated or not tolerated	Composite of CV death, non-fatal MI and non-fatal stroke	FPCD Q1 2014 LPCD Q2 2016	Primary endpoint met

[50] Included c.10,000 patients who had no prior index event and c.7,000 patients who had suffered an index event.
[51] *Quaque die*, or once a day.
[52] Major adverse cardiac events.
[53] Hospitalisation for heart failure.
[54] End-stage renal disease.
[55] Myocardial infarction.
[56] *Bis in die*, or twice a day.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III THALES	c.11,000 patients with acute ischaemic stroke or transient ischaemic attack	Arm 1: *Brilinta* 90mg BID Arm 2: placebo BID on a background of acetylsalicylic acid if not contra-indicated or not tolerated	Prevention of the composite of subsequent stroke and death at 30 days	FPCD Q1 2018 First data anticipated H1 2020	Recruitment ongoing
Epanova					
Phase III STRENGTH	c.13,000 patients with mixed dyslipidaemia/ hypertriglyceride-aemia	Arm 1: *Epanova* 4g QD + statin Arm 2: placebo (corn oil) + statin	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	Recruitment completed

d) Roxadustat (anaemia)

In August 2019, AstraZeneca announced that its partner FibroGen (China) Medical Technology Development Co., Ltd. (FibroGen China) received marketing authorisation for roxadustat in China for the treatment of anaemia caused by CKD in NDD patients. The approval, granted by the China NMPA, was primarily supported by a Phase III trial in NDD-CKD patients with anaemia, in which roxadustat demonstrated a statistically significant improvement in haemoglobin levels from baseline, averaged over weeks seven to nine of treatment, with a mean change of 1.9g/dL, compared to 0.4g/dL with placebo. These data were published in *The New England Journal of Medicine* in July 2019.

This followed the approval of roxadustat in China in December 2018 for anaemia caused by CKD in patients on dialysis. AstraZeneca and FibroGen China expect to launch roxadustat in China in due course; the Company and FibroGen, Inc. (FibroGen) anticipate a US FDA regulatory submission in the final quarter of 2019.

In September 2019, FibroGen and Astellas announced the Japanese approval of roxadustat for the treatment of dialysis patients with anaemia caused by CKD. The medicine will be marketed in Japan as Evrenzo by FibroGen and Astellas. AstraZeneca does not participate in the agreement between FibroGen and Astellas.

In October 2019, FibroGen announced that the results from the AstraZeneca-sponsored Phase III trials, OLYMPUS and ROCKIES, will be presented at the American Society of Nephrology Kidney Week in November 2019 in Washington D.C., US. In addition, FibroGen also confirmed that the pooled efficacy and safety results from the global Phase III programme will be presented at a late-breaker session at the meeting. The accepted abstracts on the individual Phase III roxadustat trials are available here.

Respiratory (and immunology)

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
- 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*, *Fasenra* and *Breztri* are already benefitting patients, with regulatory reviews for *Symbicort* as an anti-inflammatory reliever in mild asthma, and additional reviews for *Breztri* in COPD underway. The capability in inhalation technology spans both pMDI and dry-powder inhalers to serve patient needs.

During the period, AstraZeneca attended the European Respiratory Society International Congress in Madrid, Spain. The breadth and depth of the Company's science was reflected in the 65 abstracts accepted, including

17 oral presentations. The data presented at the congress primarily focused on *Symbicort* in mild to moderate asthma, and *Breztri* and *Fasenra* in COPD.

a) *Symbicort* (asthma)
During the period, *Symbicort Turbuhaler* was approved in Canada, Chile and Singapore as an anti-inflammatory reliever in mild, persistent asthma. The expanded indication in mild asthma was approved in Australia, New Zealand, Brazil and Russia earlier this year. In July 2019, the regulatory submission in the EU for *Symbicort Turbuhaler* in mild asthma was withdrawn and a new submission is anticipated during H1 2020.

b) PT010 (COPD)
During the period, AstraZeneca announced positive results from the Phase III ETHOS trial for triple-combination therapy PT010, in patients with moderate to very severe COPD. At the standard, and at half of the budesonide dose, PT010 (budesonide/glycopyrronium/formoterol fumarate 320/14.4/9.6mcg and 160/14.4/9.6mcg, respectively) met its primary endpoint, demonstrating a statistically significant reduction in the rate of moderate or severe exacerbations, compared with dual-combination therapies *Bevespi Aerosphere* (glycopyrronium/formoterol fumarate 14.4/9.6mcg) and PT009 (budesonide/formoterol fumarate 320/9.6mcg).

In the trial, all combination therapies were administered in a pMDI using the innovative *Aerosphere* delivery technology. The safety and tolerability of PT010 were consistent with the known profiles of the dual comparators. The ETHOS trial results will be presented at a forthcoming medical meeting.

In October 2019, AstraZeneca announced that the US FDA had issued a complete response letter regarding the New Drug Application (NDA) for PT010. The application previously submitted to the US FDA by the Company included data from only one Phase III trial, KRONOS. AstraZeneca will work closely with the agency regarding next steps, including submitting for review the aforementioned ETHOS trial, which was not completed at the time the NDA was submitted.

PT010 is under regulatory review in the EU and in China, where it has been granted priority-review status by the China NMPA. PT010 has received regulatory approval in Japan, under the name *Breztri Aerosphere*.

c) *Fasenra* (severe eosinophilic asthma and eosinophilic oesophagitis)
During the period, AstraZeneca announced that the US FDA had approved the self-administration of *Fasenra* in a pre-filled, single-use auto-injector (the *Fasenra Pen*). *Fasenra* self-administration and the *Fasenra Pen* were also approved in the EU.

In August 2019, the US FDA granted Orphan Drug Designation to *Fasenra* for the treatment of eosinophilic oesophagitis (EoE), a rare, chronic, inflammatory disease that occurs when eosinophils, a type of white blood cell, accumulate in the oesophagus, causing injury and inflammation. The US FDA grants Orphan Drug Designation status to medicines and potential new medicines intended for the treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 patients in the US.

Table 28: Key *Fasenra* trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase IIIb ANDHI	Severe eosinophilic asthma on SoC	*Fasenra* 30mg Q8W[57] SC[58] Placebo SC 24-week trial	Annual asthma exacerbation rate	FPCD Q3 2017 LPCD Q1 2019 Data anticipated Q4 2019	Recruitment completed

[57] *Quaque* eight weeks, or every eight weeks.
[58] Subcutaneous.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase IIIb PONENTE	Asthmatics (aged 18 years or older) receiving high-dose ICS plus LABA and chronic OCS[59] with or without additional asthma controller(s)	*Fasenra* 30mg Q8W SC 38-week trial	Reduction of OCS dose	FPCD Q3 2018 LPCD Q3 2019 Data anticipated H2 2020	Recruitment completed
Phase III MELTEMI	Asthmatic adults (aged 18-75 years) on ICS plus LABA2 agonist	*Fasenra* 30mg Q4W SC *Fasenra* 30mg Q8W SC	Safety and tolerability	FPCD Q2 2016 LPCD Q1 2017 Data anticipated H2 2020	Recruitment completed
Phase III OSTRO	Patients (aged 18-75 years) with severe bilateral nasal polyposis; symptomatic, despite SoC	*Fasenra* 30mg Q8W SC Placebo SC 56-week trial	Nasal-polyposis burden and reported nasal blockage	FPCD Q1 2018 LPCD Q2 2019 Data anticipated H2 2020	Recruitment completed
Phase III MIRACLE	Severe eosinophilic asthma (aged 12-75 years) despite background controller medication, medium dose and high dose ICS plus LABA ± chronic OCS (CN)	*Fasenra* 30mg Q8W SC Placebo SC 56-week trial	Annual asthma-exacerbation rate	FPCD Q3 2017 Data anticipated 2021+	Recruitment ongoing
Phase III RESOLUTE	Patients with moderate to very severe COPD with a history of frequent COPD exacerbations and elevated peripheral blood eosinophils	*Fasenra* 100mg Q8W SC Placebo SC 56-week trial	Annualised rate of moderate or severe COPD exacerbations	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing

[59] Oral corticosteroid.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III MANDARA	EGPA	*Fasenra* 30mg Q4W Mepolizumab 3x100mg Q4W 52-week trial with open-label extension	Proportion of patients who achieve remission, defined as a score[60] =0 and an OCS dose ≤4 mg/day at weeks 36 and 48	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)
Phase III NATRON	HES	*Fasenra* 30mg Q4W Placebo SC 24-week trial with open-label extension	Time to HES worsening flare or any cytotoxic and/or immuno-suppressive therapy increase or hospitalisation	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)
Phase III MESSINA	Eosinophilic oesophagitis	*Fasenra* 30mg SC Q4W Placebo SC 24-week trial with open-label extension	Proportion of patients with a histologic response Changes from baseline in dysphagia PRO[61]	Data anticipated 2021+	Initiating Orphan Drug Designation (US)

[60] Birmingham Vasculitis Activity Score.
[61] Patient-reported outcomes.

d) Anifrolumab (lupus)

In August 2019, AstraZeneca announced that the Phase III TULIP 2 trial for anifrolumab, a potential new medicine for the treatment of SLE, met its primary endpoint, achieving a statistically significant and clinically meaningful reduction in disease activity versus placebo, with both arms receiving SoC. The reduction was measured using the British Isles Lupus Assessment Group based Composite Lupus Assessment (BICLA) at week 52. The BICLA requires improvement in all organs with disease activity at baseline, with no new flares.

TULIP 2 was the second Phase III trial designed to assess the efficacy and safety of anifrolumab as a treatment for adults with moderate-to-severe SLE. The positive BICLA response in TULIP 2 was consistent with a positive pre-specified analysis of the previous Phase III TULIP 1 trial, which did not meet its primary endpoint of SLE Responder Index 4 (SRI4). Data from TULIP 1 and TULIP 2 will be presented in November 2019 at the American College of Rheumatology Annual Meeting in Atlanta, US.

Table 29: Key anifrolumab trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase II MUSE	Moderate to severely-active SLE patients on background SoC	300mg i.v.[62] anifrolumab Q4W 1,000mg i.v. anifrolumab Q4W Placebo i.v. Q4W 52-week trial	Response in SLE responder index, with sustained reduction of OCSs at six months	FPCD Q1 2012 LPCD Q1 2014	Data read out Q2 2015 Primary endpoint met Fast Track designation (US)
Phase III TULIP 1	Moderate to severely-active SLE patients on background SoC	300mg i.v. anifrolumab Q4W 150mg i.v. anifrolumab Q4W Placebo i.v. Q4W 52-week trial	Response in SLE responder index at week 52	FPCD Q3 2015 LPCD Q3 2017	Data read out Q3 2018 Primary endpoint not met Fast Track designation (US)
Phase III TULIP 2	Moderate to severely-active SLE patients on background SoC	300mg i.v. anifrolumab Q4W Placebo i.v. Q4W 52-week trial	Response in BICLA at week 52	FPCD Q3 2015 LPCD Q3 2017	Data read out Q3 2019 Primary endpoint met Fast Track designation (US)
Phase III TULIP LTE[63]	Moderate to severely active SLE patients on background SoC who have completed a	300mg i.v. anifrolumab Q4W Placebo i.v. Q4W	Long-term safety	FPCD Q2 2016 LPCD Q4 2018	Recruitment completed Fast Track designation (US)

[62] Intravenous.
[63] Long-term extension.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
	Phase III anifrolumab trial	152-week trial		Data anticipated 2021+	
Phase II NCT02962960	SLE patients with high interferon type I status and active skin manifestations	150mg SC every other week 300mg SC every other week Placebo SC every other week 52-week trial	PK[64]/PD[65], safety, tolerability	FPCD Q1 2017 LPCD Q4 2017	Trial completed Data read out Q1 2018
Phase II TULIP-LN1	Patients with active, proliferative LN[66]	900 mg i.v. Q4W for 12 weeks, then 300mg i.v. anifrolumab Q4W for 36 weeks 300mg i.v. anifrolumab Q4W Placebo i.v. Q4W 52-week trial	Response in proteinuria at week 52	FPCD Q4 2015 LPCD Q4 2018 Data anticipated 2021	Recruitment completed

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.

[64] Pharmacokinetics (the movement of medicines through the body).
[65] Pharmacodynamics (the body's biological response to medicines).
[66] Lupus nephritis.

Condensed consolidated statement of comprehensive income - YTD 2019

For the **nine months** ended 30 September	**2019 $m**	**2018 $m**
Product Sales	17,315	15,281
Collaboration Revenue	405	392
Total Revenue	17,720	15,673
Cost of sales	(3,543)	(3,299)
Gross Profit	14,177	12,374
Distribution costs	(247)	(238)
Research and development expense	(3,968)	(3,920)
Selling, general and administrative costs	(8,656)	(7,431)
Other operating income and expense	1,041	1,525
Operating profit	2,347	2,310
Finance income	133	112
Finance expense	(1,081)	(1,082)
Share of after-tax losses in associates and joint ventures	(91)	(77)
Profit before tax	1,308	1,263
Taxation	(358)	(222)
Profit for the period	950	1,041
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(151)	138
Net (losses)/gains on equity investments measured at fair value through other comprehensive income	(136)	159
Fair-value movements related to own credit risk on bonds designated as fair-value through profit or loss	(1)	3
Tax on items that will not be reclassified to profit or loss	21	(65)
	(267)	235
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(385)	(351)
Foreign exchange arising on designating borrowings in net investment hedges	(491)	(449)
Fair-value movements on cash flow hedges	(156)	5
Fair-value movements on cash flow hedges transferred to profit or loss	109	72
Fair-value movements on derivatives designated in net investment hedges	35	7
Costs of hedging	(35)	(36)
Tax on items that may be reclassified subsequently to profit or loss	62	39
	(861)	(713)
Other comprehensive loss for the period, net of tax	(1,128)	(478)
Total comprehensive (loss)/income for the period	(178)	563
Profit attributable to:		
Owners of the Parent	1,022	1,121
Non-controlling interests	(72)	(80)
	950	1,041
Total comprehensive income attributable to:		
Owners of the Parent	(107)	644
Non-controlling interests	(71)	(81)
	(178)	563
Basic earnings per $0.25 Ordinary Share	$0.79	$0.88
Diluted earnings per $0.25 Ordinary Share	$0.79	$0.88
Weighted average number of Ordinary Shares in issue (millions)	1,297	1,267
Diluted weighted average number of Ordinary Shares in issue (millions)	1,297	1,267

Condensed consolidated statement of comprehensive income - Q3 2019

For the **quarter** ended 30 September	**2019 $m**	**2018 $m**
Product Sales	6,132	5,266
Collaboration Revenue	274	74
Total Revenue	6,406	5,340
Cost of sales	(1,351)	(1,153)
Gross Profit	5,055	4,187
Distribution costs	(88)	(73)
Research and development expense	(1,346)	(1,279)
Selling, general and administrative costs	(3,199)	(2,423)
Other operating income and expense	335	439
Operating profit	757	851
Finance income	37	34
Finance expense	(353)	(364)
Share of after-tax losses in associates and joint ventures	(32)	(44)
Profit before tax	**409**	**477**
Taxation	(129)	(71)
Profit for the period	280	406
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	96	(49)
Net (losses)/gains on equity investments measured at fair value through other comprehensive income	(82)	3
Fair-value movements related to own credit risk on bonds designated as fair value through profit or loss	1	5
Tax on items that will not be reclassified to profit or loss	4	2
	19	(39)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(299)	(67)
Foreign exchange arising on designating borrowings in net investment hedges	(305)	67
Fair-value movements on cash flow hedges	(113)	(14)
Fair-value movements on cash flow hedges transferred to profit or loss	95	3
Fair-value movements on derivatives designated in net investment hedges	44	11
Costs of hedging	(38)	(3)
Tax on items that may be reclassified subsequently to profit or loss	42	(16)
	(574)	(19)
Other comprehensive loss for the period, net of tax	(555)	(58)
Total comprehensive (loss)/income for the period	(275)	348
Profit attributable to:		
Owners of the Parent	299	431
Non-controlling interests	(19)	(25)
	280	406
Total comprehensive income attributable to:		
Owners of the Parent	(257)	374
Non-controlling interests	(18)	(26)
	(275)	348
Basic earnings per $0.25 Ordinary Share	$0.23	$0.34
Diluted earnings per $0.25 Ordinary Share	$0.23	$0.34
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,267
Diluted weighted average number of Ordinary Shares in issue (millions)	1,312	1,267

Condensed consolidated statement of financial position

	At 30 Sep 2019 $m	At 31 Dec 2018 $m	At 30 Sep 2018 $m
Assets			
Non-current assets			
Property, plant and equipment	7,317	7,421	7,591
Right-of-use assets	690	-	-
Goodwill	11,595	11,707	11,729
Intangible assets	21,454	21,959	24,418
Investments in associates and joint ventures	43	89	110
Other investments	1,293	833	1,124
Derivative financial instruments	56	157	449
Other receivables	384	515	708
Deferred tax assets	2,554	2,379	2,206
	45,386	45,060	48,335
Current assets			
Inventories	3,129	2,890	3,027
Trade and other receivables	5,279	5,574	5,509
Other investments	813	849	808
Derivative financial instruments	9	258	34
Intangible assets	95	-	-
Income tax receivable	228	207	310
Cash and cash equivalents	3,967	4,831	3,420
Assets held for sale	-	982	-
	13,520	15,591	13,108
Total assets	58,906	60,651	61,443
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(228)	(1,754)	(2,491)
Lease liabilities	(349)	-	-
Trade and other payables	(12,538)	(12,841)	(10,992)
Derivative financial instruments	(26)	(27)	(33)
Provisions	(401)	(506)	(508)
Income tax payable	(1,234)	(1,164)	(1,224)
	(14,776)	(16,292)	(15,248)
Non-current liabilities			
Interest-bearing loans and borrowings	(17,218)	(17,359)	(18,422)
Lease liabilities	(363)	-	-
Derivative financial instruments	(55)	(4)	(2)
Deferred tax liabilities	(2,595)	(3,286)	(3,685)
Retirement benefit obligations	(2,392)	(2,511)	(2,267)
Provisions	(990)	(385)	(393)
Other payables	(6,848)	(6,770)	(7,889)
	(30,461)	(30,315)	(32,658)
Total liabilities	(45,237)	(46,607)	(47,906)
Net assets	13,669	14,044	13,537
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	328	317	317
Share premium account	7,919	4,427	4,417
Other reserves	2,052	2,041	2,040
Retained earnings	1,865	5,683	5,162
	12,164	12,468	11,936
Non-controlling interests	1,505	1,576	1,601
Total equity	13,669	14,044	13,537

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	-	-	-	1,121	1,121	(80)	1,041
Other comprehensive loss	-	-	-	(477)	(477)	(1)	(478)
Transfer to other reserves	-	-	11	(11)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,542)	(3,542)	-	(3,542)
Issue of Ordinary Shares	-	24	-	-	24	-	24
Share-based payments change for the period	-	-	-	151	151	-	151
Settlement of share plan awards	-	-	-	(210)	(210)	-	(210)
Net movement	-	24	11	(3,059)	(3,024)	(81)	(3,105)
At 30 Sep 2018	**317**	**4,417**	**2,040**	**5,162**	**11,936**	**1,601**	**13,537**
At 1 Jan 2019	**317**	**4,427**	**2,041**	**5,683**	**12,468**	**1,576**	**14,044**
Adoption of new accounting standards[67]	-	-	-	54	54	-	54
Profit for the period	-	-	-	1,022	1,022	(72)	950
Other comprehensive loss	-	-	-	(1,129)	(1,129)	1	(1,128)
Transfer to other reserves	-	-	11	(11)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,583)	(3,583)	-	(3,583)
Issue of Ordinary Shares[68]	11	3,492	-	-	3,503	-	3,503
Share-based payments for the period	-	-	-	154	154	-	154
Settlement of share awards	-	-	-	(325)	(325)	-	(325)
Net movements	11	3,492	11	(3,818)	(304)	(71)	(375)
At 30 Sep 2019	**328**	**7,919**	**2,052**	**1,865**	**12,164**	**1,505**	**13,669**

[67] The Company adopted IFRIC 23 'Uncertainty over Income Tax Treatments' from 1 January 2019. See Note 1.
[68] 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 - YTD 2019

For the **nine months** ended 30 September	**2019** **$m**	**2018** **$m**
Cash flows from operating activities		
Profit before tax	1,308	1,263
Finance income and expense	948	970
Share of after-tax losses of associates and joint ventures	91	77
Depreciation, amortisation and impairment	2,119	2,091
Increase in working capital and short-term provisions	(812)	(1,741)
Gains on disposal of intangible assets	(833)	(975)
Fair value movements on contingent consideration arising from business combinations	(13)	(88)
Non-cash and other movements	326	(340)
Cash generated from operations	3,134	1,257
Interest paid	(575)	(457)
Tax paid	(965)	(406)
Net cash inflow from operating activities	1,594	394
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(487)	(247)
Purchase of property, plant and equipment	(659)	(728)
Disposal of property, plant and equipment	31	12
Purchase of intangible assets	(1,416)	(234)
Disposal of intangible assets	1,400	842
Movement in profit-participation liability[69]	150	-
Purchase of non-current asset investments	(6)	(46)
Disposal of non-current asset investments	18	24
Movement in short-term investments and fixed deposits	196	434
Payments to associates and joint ventures	(49)	(172)
Interest received	107	151
Net cash (outflow)/inflow from investing activities	(715)	36
Net cash inflow before financing activities	879	430
Cash flows from financing activities		
Proceeds from issue of share capital	3,503	24
Issue of loans	500	2,974
Repayment of loans	(1,500)	-
Dividends paid	(3,592)	(3,484)
Hedge contracts relating to dividend payments	4	(67)
Repayment of obligations under leases	(131)	-
Movement in short-term borrowings	(555)	241
Net cash outflow from financing activities	(1,771)	(312)
Net (decrease)/increase in cash and cash equivalents in the period	(892)	118
Cash and cash equivalents at the beginning of the period	4,671	3,172
Exchange rate effects	-	(28)
Cash and cash equivalents at the end of the period	3,779	3,262
Cash and cash equivalents consist of:		
Cash and cash equivalents	3,967	3,420
Overdrafts	(188)	(158)
	3,779	3,262

[69] 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.

Notes to the Interim Financial Statements

1 Basis of preparation and accounting policies

These unaudited condensed consolidated interim financial statements (Interim Financial Statements) for the nine months ended 30 September 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 nine months ended 30 September 2019 were approved by the Board of directors on 24 October 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 $131m 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 September 2019 the Group has $8.1bn in financial resources (cash balances of $4.0bn 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 $0.6bn 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 nine months ended 30 September 2019 is stated after charging restructuring costs of $351m ($271m for the nine months ended 30 September 2018). These have been charged to profit as follows:

	YTD 2019 $m	YTD 2018 $m	Q3 2019 $m	Q3 2018 $m
Cost of sales	122	77	70	22
Research and development expense	82	95	18	37
Selling, general and administrative costs	147	110	37	26
Other operating income and expense	-	(11)	-	(1)
Total	**351**	**271**	**125**	**84**

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[70] $m	Cash Flow $m	Non-cash & Other $m	Exchange Movements $m	At 30 Sep 2019 $m
Non-current instalments of loans	(17,359)	-	-	(15)	156	(17,218)
Non-current instalments of leases	-	(557)	-	189	5	(363)
Total long-term debt	**(17,359)**	**(557)**	**-**	**174**	**161**	**(17,581)**
Current instalments of loans	(999)	-	1,000	(1)	-	-
Current instalments of leases	-	(163)	149	(338)	3	(349)
Commercial paper	(211)	-	211	-	-	-
Bank collateral	(384)	-	347	-	-	(37)
Other short-term borrowings excluding overdrafts	-	-	(3)	-	-	(3)
Overdraft	(160)	-	(34)	-	6	(188)
Total current debt	**(1,754)**	**(163)**	**1,670**	**(339)**	**9**	**(577)**
Gross borrowings	**(19,113)**	**(720)**	**1,670**	**(165)**	**170**	**(18,158)**
Net derivative financial instruments	384	-	(214)	(186)	-	(16)
Net borrowings	**(18,729)**	**(720)**	**1,456**	**(351)**	**170**	**(18,174)**
Cash and cash equivalents	4,831	-	(858)	-	(6)	3,967
Other investments - current	849	-	14	(47)	(3)	813
Other investments - non-current	46	-	-	50	-	96
Cash and investments	**5,726**	**-**	**(844)**	**3**	**(9)**	**4,876**
Net debt	**(13,003)**	**(720)**	**612**	**(348)**	**161**	**(13,298)**

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

Other investments - non-current are included within the balance of $1,293m (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 Pharma put-option liability of $2,072m (31 December 2018: $1,838m) shown in non-current other payables.

[70] 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 $63m have been recognised in the nine months to 30 September 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 $2,106m of other investments, $2,635m held in money market funds, $336m of loans designated at fair value through profit or loss, $329m of loans designated in a fair value hedge relationship and ($16m) of derivatives as at 30 September 2019. The total fair value of interest-bearing loans and borrowings at 30 September 2019, which have a carrying value of $18,158m in the Condensed Consolidated Statement of Financial Position, was $20,614m. 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	(337)	(150)	(487)	(247)
Revaluations	-	(13)	(13)	38
Discount unwind	216	53	269	313
At 30 September	**3,862**	**1,013**	**4,875**	**5,638**

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 $3,862m (31 December 2018: $3,983m) would increase/decrease by $386m 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 and the Interim Financial Statements for the six months ended 30 June 2019 (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 AstraZeneca has made, and upon which the Company 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 third quarter of 2019 and to 24 October 2019

Patent litigation

Calquence
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*. In April 2018, AstraZeneca and Acerta Pharma filed a complaint in the District Court against Pharmacyclics and AbbVie, Inc. alleging that their medicine, ibrutinib, infringes a US patent owned by Acerta Pharma. In November 2018, Janssen Biotech, Inc. intervened as a defendant. In October 2019, the parties agreed to settle these proceedings. A provision has been taken.

Brilinta
Patent proceedings outside the US
As previously reported, in Canada, in October 2018, Taro Pharmaceuticals Inc. (Taro) challenged the patents listed on the Canadian Patent Register with reference to *Brilinta*. AstraZeneca commenced an infringement action against Taro in November 2018. The action was discontinued in September 2019 after Taro withdrew its challenge.

Symbicort
US patent proceedings
As previously disclosed in May 2019, AstraZeneca filed a Second Amended Complaint in the Abbreviated NDA (ANDA) litigation pending in the US District Court for the District of Delaware against Mylan Pharmaceuticals Inc. (Mylan) and 3M Company alleging infringement of US Patent No. 10,166,247 (the '247 patent). In October 2019, Mylan sent AstraZeneca a Paragraph IV notice relating to its ANDA in which Mylan asserts that its proposed generic product does not infringe the '247 patent and/or that the '247 patent is invalid and/or unenforceable.

In October 2019, the US District Court for the District of Delaware transferred the Delaware action with Mylan and 3M Company to the US District Court for the Northern District of West Virginia.

Product-liability litigation

***Farxiga* and *Xigduo* XR**
AstraZeneca has been named as a defendant in individual plaintiff lawsuits claiming physical injury, including Fournier's Gangrene and necrotising fasciitis, from treatment with *Farxiga* and/or *Xigduo* XR.

Nexium* and *Losec*/*Prilosec
Canada proceedings
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*. In August 2019, the third lawsuit, filed in Quebec, was dismissed.

Commercial litigation
Amplimmune
As previously disclosed, in June 2017, AstraZeneca was served with a lawsuit filed by the stockholders' agents for Amplimmune, Inc (Amplimmune) in Delaware State Court that alleges, among other things, breaches of

contractual obligations relating to a 2013 merger agreement between AstraZeneca and Amplimmune. The court will hold a summary judgment hearing on 13 November 2019, and trial is scheduled for February 2020.

Seroquel XR Antitrust Litigation
In the US, in August and September 2019, AstraZeneca was named in several related, putative class-action lawsuits brought in federal court in the Southern District of New York that were purportedly brought on behalf of classes of direct purchasers or end payors of *Seroquel XR* and that allege AstraZeneca and generic-medicine manufacturers violated antitrust laws when settling patent litigation related to *Seroquel XR*.

Taxation
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. The EC concluded that part of the UK measures was 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 Subsequent events

In October 2019, an amendment to the share purchase and option agreement (SPOA) with the sellers of Acerta Pharma (originally entered into in December 2015) came into effect, changing certain terms of the SPOA on both the timing and also reducing the maximum consideration that would be required to be made to acquire the remaining outstanding shares of Acerta Pharma if the options are exercised. The payments would be made in similar annual instalments commencing at the earliest from 2022 through to 2024, subject to the options being exercised. The changes to the terms have been reflected in the assumptions used to calculate the amortised cost of the option liability as at 30 September 2019 of $2,072m (30 June 2019: $2,057m, 31 December 2018: $1,838m).

In October 2019, AstraZeneca entered into settlement agreements with Pharmacyclics LLC (a company in the AbbVie Group) and Janssen Biotech, Inc resolving all patent litigation between the parties relating to *Calquence* and ibrutinib. A provision was established as at 30 September 2019.

AstraZeneca
What science can do

7 Product Sales analysis - YTD 2019

The table below provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals.

	World			Emerging Markets			US		Europe			Established RoW		
	YTD 2019 $m	Actual %	CER %	YTD 2019 $m	Actual %	CER %	YTD 2019 $m	Actual %	YTD 2019 $m	Actual %	CER %	YTD 2019 $m	Actual %	CER %
Oncology														
Tagrisso	2,305	82	86	553	n/m	n/m	909	57	337	52	61	506	n/m	n/m
Imfinzi	1,045	n/m	n/m	18	n/m	n/m	759	n/m	115	n/m	n/m	153	n/m	n/m
Lynparza	847	93	98	101	n/m	n/m	432	86	208	52	61	106	n/m	n/m
Iressa	343	(16)	(11)	227	-	6	14	(31)	61	(29)	(24)	42	(45)	(44)
Calquence	108	n/m	n/m	1	-	-	108	n/m	-	-	-	-	-	-
*Faslodex**	726	(4)	(1)	145	31	41	311	(21)	168	(2)	4	102	23	23
*Zoladex**	617	8	15	380	21	30	5	(16)	100	1	7	133	(13)	(11)
*Arimidex**	174	5	10	118	12	19	-	-	21	(7)	(1)	34	(7)	(6)
*Casodex**	157	2	6	99	10	17	-	(89)	12	(19)	(13)	46	(7)	(6)
Others	68	(26)	(24)	22	(9)	(5)	-	-	5	(4)	2	42	(34)	(34)
Total Oncology	**6,393**	**50**	**54**	**1,665**	**42**	**51**	**2,538**	**57**	**1,027**	**34**	**42**	**1,163**	**66**	**67**
BioPharmaceuticals: CVRM														
Farxiga	1,124	13	17	339	40	50	396	(6)	273	18	26	115	14	16
Brilinta	1,153	22	26	348	50	59	500	22	262	2	9	43	(4)	1
Bydureon	410	(8)	(7)	9	(2)	2	340	(5)	50	(19)	(14)	11	(29)	(25)
Onglyza	396	-	4	131	8	17	174	7	53	(22)	(17)	38	(15)	(12)
Byetta	83	(12)	(10)	8	33	49	52	(6)	14	(35)	(30)	9	(21)	(17)
Other diabetes	36	33	35	1	(36)	(34)	28	21	7	n/m	n/m	1	-	-
Lokelma	6	-	-	-	-	-	6	-	-	-	-	-	-	-
*Crestor**	982	(9)	(5)	621	(2)	4	88	(31)	112	(30)	(25)	162	-	1
*Seloken/Toprol-XL**	570	3	10	513	4	12	30	(9)	18	16	16	8	(15)	(11)
*Atacand**	161	(20)	(16)	117	3	10	8	(28)	22	(65)	(65)	14	(4)	2
Others	199	(13)	(9)	139	(11)	(7)	-	(96)	46	(16)	(12)	15	(23)	(21)
BioPharmaceuticals: total CVRM	**5,121**	**3**	**7**	**2,225**	**11**	**18**	**1,622**	**1**	**858**	**(8)**	**(3)**	**416**	**(2)**	**1**
BioPharmaceuticals: Respiratory														
Symbicort	1,783	(7)	(4)	401	10	18	585	(11)	508	(14)	(8)	289	(9)	(7)
Pulmicort	1,053	17	23	845	23	29	89	10	60	(12)	(6)	60	-	1
Fasenra	498	n/m	n/m	4	-	-	343	n/m	81	n/m	n/m	70	n/m	n/m
Daliresp/Daxas	157	16	17	3	(22)	(17)	134	21	19	(4)	2	1	-	3
Duaklir	55	(24)	(20)	1	(4)	-	-	-	53	(24)	(20)	1	(38)	(36)
Tudorza/Eklira	50	(45)	(42)	1	(5)	(3)	1	(98)	44	(18)	(13)	4	(44)	(42)
Bevespi	30	32	32	-	-	-	30	31	-	-	-	-	-	-
Breztri	1	-	-	-	-	-	-	-	-	-	-	1	-	-
Others	226	(3)	2	164	85	96	2	(58)	54	(49)	(47)	6	(82)	(81)
BioPharmaceuticals: total Respiratory	**3,854**	**9**	**13**	**1,419**	**24**	**31**	**1,183**	**15**	**819**	**(11)**	**(6)**	**433**	**(4)**	**(2)**
Other medicines														
Nexium	1,130	(14)	(11)	574	10	16	175	(30)	49	(73)	(71)	332	(8)	(7)
Synagis	295	(29)	(29)	-	-	-	36	(73)	258	(8)	(8)	-	-	-
Losec/Prilosec	217	3	8	145	11	17	7	38	45	(12)	(7)	20	(19)	(17)
Seroquel XR/IR	151	(51)	(49)	41	(61)	(60)	27	(71)	67	(17)	(13)	15	(34)	(33)
Movantik/Moventig	72	(15)	(15)	-	-	-	70	(14)	2	(11)	(12)	-	n/m	n/m
Others	83	(54)	(48)	4	(89)	(93)	29	23	44	(36)	(33)	5	(89)	(70)
Total other medicines	**1,948**	**(22)**	**(20)**	**765**	**(4)**	**1**	**345**	**(41)**	**465**	**(30)**	**(28)**	**373**	**(19)**	**(16)**
Total Product Sales	**17,315**	**13**	**17**	**6,074**	**19**	**26**	**5,688**	**18**	**3,168**	**(4)**	**2**	**2,385**	**17**	**19**

***Legacy medicines.**

8 Product Sales analysis - Q3 2019

The table below provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals.

	World			Emerging Markets			US		Europe			Established RoW		
	Q3 2019 $m	Actual %	CER %	Q3 2019 $m	Actual %	CER %	Q3 2019 $m	Actual %	Q3 2019 $m	Actual %	CER %	Q3 2019 $m	Actual %	CER %
Oncology														
Tagrisso	891	76	78	224	n/m	n/m	350	47	125	51	56	192	n/m	n/m
Imfinzi	412	n/m	n/m	6	n/m	n/m	286	68	55	n/m	n/m	65	n/m	n/m
Lynparza	327	94	96	42	n/m	n/m	170	n/m	77	54	60	38	92	92
Iressa	91	(31)	(29)	63	(19)	(17)	6	(4)	15	(39)	(34)	8	(67)	(69)
Calquence	44	n/m	n/m	1	-	-	44	(89)	-	-	-	-	-	-
Faslodex	205	(20)	(19)	49	23	25	60	(55)	58	9	14	38	27	24
Zoladex	226	17	21	145	31	36	1	(65)	35	11	19	46	(7)	(7)
Arimidex	63	15	17	46	32	32	-	-	6	(20)	(4)	10	(13)	(12)
Casodex	52	3	5	34	11	14	-	n/m	4	5	24	14	(8)	(13)
Others	20	(27)	(26)	6	(27)	(28)	-	-	2	(11)	4	13	(30)	(29)
Total Oncology	**2,334**	**46**	**48**	**617**	**45**	**49**	**917**	**40**	**377**	**44**	**51**	**423**	**67**	**63**
BioPharmaceuticals: CVRM														
Farxiga	398	12	14	133	56	59	126	(18)	95	21	26	43	17	18
Brilinta	416	24	27	131	56	61	179	18	91	7	12	15	2	3
Bydureon	127	(16)	(16)	2	(7)	(90)	106	(16)	16	(15)	(3)	3	(48)	(34)
Onglyza	127	(9)	(7)	44	10	18	54	(16)	17	(18)	(16)	12	(23)	(22)
Byetta	28	(19)	(18)	4	98	48	17	(28)	4	(27)	(11)	3	(10)	5
Other diabetes	14	38	44	1	(36)	(34)	11	34	3	n/m	n/m	-	-	-
Lokelma	4	-	-	-	-	-	4	-	-	-	-	-	-	-
Crestor	337	(4)	(2)	214	3	7	34	(11)	37	(23)	(22)	53	(12)	(15)
Seloken/Toprol-XL	177	(1)	3	164	-	3	4	(41)	5	37	38	3	16	29
Atacand	55	(15)	(11)	41	8	12	2	88	7	(67)	(67)	5	9	27
Others	65	(8)	(6)	44	(5)	(8)	-	-	16	(16)	(2)	6	(5)	-
BioPharmaceuticals: total CVRM	**1,749**	**3**	**6**	**777**	**16**	**19**	**537**	**(6)**	**292**	**(3)**	**2**	**143**	**(4)**	**(3)**
BioPharmaceuticals: Respiratory														
Symbicort	613	(1)	1	138	12	18	203	(6)	154	(13)	(10)	118	15	14
Pulmicort	337	28	31	269	31	35	33	50	16	(13)	(6)	20	10	8
Fasenra	202	n/m	n/m	3	-	-	135	n/m	36	n/m	n/m	28	84	80
Daliresp/Daxas	53	2	3	1	(63)	(57)	45	4	7	20	25	-	-	-
Duaklir	18	(21)	(19)	1	-	-	-	-	17	(26)	(20)	-	-	-
Tudorza/Eklira	17	(4)	-	2	95	97	1	n/m	13	(17)	(13)	1	(27)	(19)
Bevespi	10	4	4	-	-	-	10	1	-	-	-	-	-	-
Breztri	1	-	-	-	-	-	-	-	-	-	-	1	-	-
Others	67	(5)	-	49	76	80	1	(77)	15	(52)	(46)	2	(75)	(72)
BioPharmaceuticals: total Respiratory	**1,319**	**15**	**18**	**463**	**28**	**32**	**427**	**20**	**258**	**(8)**	**(3)**	**171**	**17**	**16**
Other medicines														
Nexium	374	(11)	(10)	205	13	18	56	(10)	17	(71)	(65)	96	(21)	(24)
Synagis	146	(11)	(11)	-	-	-	1	(83)	144	(7)	(7)	-	-	-
Losec/Prilosec	73	10	13	49	15	18	3	n/m	14	(9)	(3)	7	(8)	(2)
Seroquel XR/IR	82	5	6	17	32	27	40	15	20	(21)	(14)	4	(15)	(13)
Movantik/Moventig	25	(22)	(23)	-	n/m	n/m	25	(17)	-	n/m	n/m	-	n/m	n/m
Others	31	(55)	(59)	(6)	n/m	12	18	9	18	(46)	(81)	-	(99)	n/m
Total other medicines	**731**	**(12)**	**(11)**	**266**	**10**	**19**	**144**	**(6)**	**213**	**(26)**	**(29)**	**108**	**(27)**	**(31)**
Total Product Sales	**6,132**	**16**	**18**	**2,123**	**25**	**29**	**2,025**	**17**	**1,139**	**1**	**4**	**845**	**21**	**19**

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9 Sequential quarterly Product Sales - 2019

The table below provides an analysis of sequential quarterly Product Sales, with Actual and CER growth rates reflecting quarter-on-quarter growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals.

	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	891	14	13			
Imfinzi	295	13	13	338	15	15	412	22	22			
Lynparza	237	13	13	283	19	20	327	16	15			
Iressa	134	20	19	118	(12)	(13)	91	(23)	(22)			
Calquence	29	21	21	35	21	21	44	27	27			
Faslodex	254	(6)	(6)	267	5	5	205	(23)	(23)			
Zoladex	194	7	5	197	2	2	226	15	16			
Arimidex	51	11	9	60	18	20	63	5	5			
Casodex	48	4	4	57	19	17	52	(8)	(6)			
Others	20	(13)	(17)	28	40	42	20	(27)	(22)			
Total Oncology	**1,892**	**7**	**6**	**2,167**	**15**	**15**	**2,334**	**8**	**8**			
BioPharmaceuticals: CVRM												
Farxiga	349	(12)	(12)	377	8	9	398	5	5			
Brilinta	348	(7)	(8)	389	12	12	416	7	8			
Onglyza	153	3	3	116	(24)	(24)	127	9	11			
Bydureon	142	3	3	141	(1)	(1)	127	(10)	(10)			
Byetta	30	(6)	(6)	25	(17)	(17)	28	10	13			
Other diabetes	11	(8)	(17)	11	-	8	14	26	22			
Lokelma	-	-	-	2	-	-	4	n/m	n/m			
Crestor	335	(5)	(6)	310	(7)	(7)	337	9	9			
Seloken/Toprol-XL	225	41	39	168	(25)	(25)	177	6	8			
Atacand	50	(14)	(15)	56	12	14	55	(1)	(1)			
Others	71	(3)	(5)	63	(11)	(8)	65	4	2			
BioPharmaceuticals: total CVRM	**1,714**	**(2)**	**(3)**	**1,658**	**(3)**	**(3)**	**1,749**	**5**	**6**			
BioPharmaceuticals: Respiratory												
Symbicort	585	(8)	(8)	585	-	1	613	5	4			
Pulmicort	383	(2)	(2)	333	(13)	(13)	337	1	3			
Fasenra	129	3	2	167	29	30	202	21	21			
Daliresp/Daxas	48	(11)	(13)	56	17	19	53	(6)	(7)			
Tudorza/Eklira	20	5	-	13	(35)	(30)	17	33	37			
Duaklir	20	(9)	(9)	17	(15)	(14)	18	7	5			
Bevespi	10	-	-	10	-	-	10	4	8			
Breztri	-	-	-	-	-	-	1	n/m	n/m			
Others	88	(20)	(19)	71	(19)	(23)	67	(6)	(2)			
BioPharmaceuticals: total Respiratory	**1,283**	**(6)**	**(6)**	**1,252**	**(2)**	**(2)**	**1,319**	**5**	**6**			
Other medicines												
Nexium	363	(7)	3	393	8	9	374	(5)	(4)			
Losec/Prilosec	76	27	27	68	(11)	(11)	73	8	9			
Synagis	53	(79)	(90)	96	81	81	146	52	53			
Seroquel XR/IR	37	(34)	(32)	32	(14)	(13)	82	n/m	n/m			
Movantik/Moventig	25	-	-	22	(12)	(12)	25	13	13			
Others	22	(29)	(54)	30	36	50	31	4	(8)			
Total other medicines	**576**	**(35)**	**(41)**	**641**	**11**	**13**	**731**	**14**	**14**			
Total Product Sales	**5,465**	**(5)**	**(7)**	**5,718**	**5**	**5**	**6,132**	**7**	**8**			

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10 Sequential quarterly Product Sales - 2018

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

	Q1 2018	Actual	CER	Q2 2018	Actual	CER	Q3 2018	Actual	CER	Q4 2018	Actual	CER
	$m	%	%	$m	%	%	$m	%	%	$m	%	%
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
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
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	n/m	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**

11 Sequential quarterly Product Sales - 2017

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

	Q1 2017 $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
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: total 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
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	100	100
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	190	175
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 full year and fourth quarter 2019 results: 14 February 2020

Future dividends will normally be paid as follows:

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

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

The record date for the second interim dividend for 2019, payable on 30 March 2020, will be 28 February 2020. The ex-dividend date will be 27 February 2020. The record date for the first interim dividend for 2020, payable on 14 September 2020, will be 14 August 2020. The ex-dividend date will be 13 August 2020.

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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.