AstraZeneca PLC
14 February 2020 7:00 GMT

Full-year and Q4 2019 results
A year of significant innovation for patients; accelerating the strategic transition

AstraZeneca delivered a year of strong revenue growth, supported by the launch of new medicines[1] and further good progress on its pipeline, with several approvals and data readouts. These trends are set to continue in 2020, accompanied by growth in earnings and cash. In maintaining its focus on patients and science, the Company remains on track to deliver its strategic ambitions.

Full-year Product Sales growth of 12% (15% at CER[2]) to $23,565m included fourth-quarter Product Sales of $6,250m (+8%, +9% at CER). All three therapy areas and every sales region grew at CER in the quarter and over the full year. Highlights for the year included:

- Sales of new medicines increased by 59% (62% at CER) to $9,906m, including new-medicine growth in Emerging Markets of 75% (84% at CER) to $1,865m. New medicines represented 42% of total Product Sales (FY 2018: 30%)

- Sales growth across the therapy areas: Oncology +44% (+47% at CER) to $8,667m, New CVRM[3] +9% (+12% at CER) to $4,376m and Respiratory +10% (+13% at CER) to $5,391m

- For the first time, around half of Product Sales in the year were within the specialty-care[4] setting

- Sales growth across regions: total Emerging Markets sales increased by 18% (24% at CER) to $8,165m, with China sales growth of 29% (35% at CER); China sales in the quarter increased by 25% (28% at CER) to $1,189m. US sales increased by 13% in the year to $7,747m; Europe sales declined by 2% in the year (up by 2% at CER) to $4,350m; Japan sales increased by 27% (26% at CER) to $2,548m

	FY 2019			Q4 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Product Sales	23,565	12	15	6,250	8	9
Collaboration Revenue	819	(21)	(20)	414	(36)	(36)
Total Revenue	24,384	10	13	6,664	4	5
Reported[5] Operating Profit	2,924	(14)	(16)	577	(46)	(56)
Core[6] Operating Profit	6,436	13	13	1,545	(29)	(33)
Reported EPS[7]	$1.03	(40)	(44)	$0.24	(71)	(78)
Core EPS	$3.50	1	-	$0.89	(44)	(46)

Pascal Soriot, Chief Executive Officer, commenting on the results said:
"In the first full year of our return to growth, we made good progress in line with our strategy. Results from our new medicines and Emerging Markets accompanied positive news for patients, most recently including regulatory approvals of *Enhertu* in breast cancer and *Calquence* in leukaemia. Our collaborations also progressed at pace, including that with Daiichi Sankyo, while there were several regulatory approvals for new medicines in China at the end of the year, such as *Lynparza* in first-line ovarian cancer.

Driven by a strong team, 2020 is anticipated to be another year of progress for AstraZeneca. We are becoming a better-balanced business, both regionally and through our medicines. This transition is a further step towards improving operating leverage and cash generation. As we accelerate our commitments to achieving our long-term climate-change and decarbonisation targets, we will maintain our focus on executing a strategy centred on science and patients."

Guidance
The Company provides guidance for FY 2020 at CER; Company guidance is on:
- Total Revenue, comprising Product Sales and Collaboration Revenue
- Core EPS

Prior guidance was on Product Sales and Core EPS. The change to guiding on Total Revenue and Core EPS reflects the changing nature and growing strategic impact of Collaboration Revenue, which will primarily comprise potential income from existing collaborations as follows:

- A share of gross profits derived from sales of *Enhertu* (trastuzumab deruxtecan) in several markets, where those sales are recorded by Daiichi Sankyo Company, Limited (Daiichi Sankyo)
- A share of gross profits derived from sales of roxadustat in China, recorded by FibroGen Inc. (FibroGen)[8]
- Milestone revenue from the MSD[9] collaboration on *Lynparza* and selumetinib
- Smaller amounts of milestone and royalty revenue from other marketed and pipeline medicines

All guidance assumes an unfavourable impact from China lasting up to a few months as a result of the recent novel coronavirus (Covid-19) outbreak. The Company will monitor closely the development of the epidemic and anticipates providing an update at the time of the Q1 2020 results.

Depending on the impact of the Covid-19 epidemic, Total Revenue is expected to increase by a high single-digit to a low double-digit percentage and Core EPS is expected to increase by a mid- to high-teens percentage.

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 any 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.

Indications
The Company provides indications for FY 2020 at CER:

- The Company is focused on improving operating leverage

- A Core Tax Rate of 18-22%. Variations in the Core Tax Rate between quarters are anticipated to continue

- Capital Expenditure is expected to be broadly stable versus the prior year

Currency impact
If foreign-exchange rates for February to December 2020 were to remain at the average of rates seen in January 2020, it is anticipated that there would be a neutral impact on Total Revenue and a low single-digit adverse impact on Core EPS, versus the prior year. In addition, the Company's foreign-exchange rate sensitivity analysis is contained within the operating and financial review.

Financial summary

- Product Sales increased by 12% in the year (15% at CER) to $23,565m, driven by the performances of new medicines and Emerging Markets

- The Reported Gross Profit Margin increased by three percentage points in the year (two at CER) to 79%, partly reflecting the mix of sales; the Core Gross Profit Margin was stable at 80%. The performance came despite the impact of a provision regarding *Epanova* for inventory and supply-related costs of $115m, recorded in Reported and Core Cost of Sales

- Reported Operating Expense increased by 11% in the year (14% at CER) to $18,080m and represented 74% of Total Revenue (FY 2018: 74%); part of the rise reflected an increased level of intangible asset impairments. Core Operating Expense increased by 4% (7% at CER) to $14,748m and represented 60% of

Total Revenue (FY 2018: 64%); the increase was driven by investment in the launches of new medicines and in Emerging Markets

- The Reported Operating Profit Margin declined in the year by three percentage points (four at CER) to 12%; the Core Operating Profit Margin increased by one percentage point (stable at CER) to 26%

- Reported EPS of $1.03 in the year, based on a weighted-average number of shares of 1,301m, represented a decline of 40% (44% at CER); Core EPS increased by 1% (stable at CER) to $3.50

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

Commercial summary

Oncology
Sales increased by 44% in the year (47% at CER) to $8,667m, including:

Table 1: Select Oncology sales

	FY 2019			Q4 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Tagrisso	3,189	71	74	884	49	49
Imfinzi	1,469	n/m	n/m	424	62	62
Lynparza	1,198	85	89	351	68	69
Calquence	164	n/m	n/m	56	n/m	n/m

The strong Oncology performance continued to benefit from new medicines such as *Tagrisso, Lynparza* and *Imfinzi*. The full impact of recent regulatory approvals for *Calquence* and *Enhertu* is anticipated to favourably affect Total Revenue growth in 2020.

The performance from legacy Oncology medicines in the year included a decline in *Faslodex* sales of 13% (11% at CER) to $892m; the fall in the fourth quarter of 39% (38% at CER) led to sales of *Faslodex* of $166m. These declines reflected the 2019 launch of multiple generic *Faslodex* medicines in the US. *Iressa* sales also declined in the year by 18% (15% at CER) to $423m and in the quarter by 29% (28% at CER) to $80m; *Iressa* continued to be included on the China volume-based procurement programme in the year. The Company anticipates continued declines for both medicines.

Oncology sales increased in Emerging Markets by 45% (52% at CER) to $2,211m.

New CVRM
Sales increased by 9% in the year (12% at CER) to $4,376m, including:

Table 2: Select New CVRM sales

	FY 2019			Q4 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Farxiga	1,543	11	14	419	6	7
Brilinta	1,581	20	23	428	14	15
Bydureon	549	(6)	(5)	139	1	1

The Company anticipates reporting on roxadustat sales within Total Revenue in due course.

New CVRM sales increased in Emerging Markets by 33% in the year (41% at CER) to $1,133m.

Respiratory
Sales increased by 10% in the year (13% at CER) to $5,391m, including:

Table 3: Select Respiratory sales

	FY 2019			Q4 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Symbicort	2,495	(3)	-	712	12	13
Pulmicort	1,466	14	18	413	6	7
Fasenra	704	n/m	n/m	206	65	65

Respiratory sales increased in Emerging Markets by 21% (27% at CER) to $1,987m.

Emerging Markets
As the Company's largest region, at 35% of total Product Sales, Emerging Markets sales increased by 18% in the year (24% at CER) to $8,165m, including:

- A China sales increase of 29% (35% at CER) to $4,880m
- An ex-China sales increase of 6% (12% at CER) to $3,285m

Sustainability summary

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

- Access to healthcare: the Company announced that the Young Health Programme (YHP) will partner with UNICEF[10] to prevent non-communicable diseases among young people. AstraZeneca and UNICEF will collaborate on initiatives that will reach more than five million young people, train c.1,000 youth advocates, and potentially help to shape public policy around the world over the next six years

- Environmental protection: AstraZeneca recently unveiled an ambitious programme for zero-carbon emissions from its global operations by 2025 and a carbon-negative value chain by 2030. The strategy brings forward decarbonisation plans by more than a decade. In 2019, the Company was ranked 56th overall, as

one of the world's one hundred most sustainable companies by environmental research and media group, Corporate Knights, and second for biopharmaceutical companies

- Ethics and transparency: the Hampton-Alexander independent review body, which works to support improvements in women's representation at board level and in leadership roles two layers below the board, recently published its latest review. In the reviews FTSE 100 ranking, AstraZeneca moved up from seventh place in 2018 to sixth in 2019 for women represented in the top-three layers of management

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

Notes
These notes refer to pages one to five.

1. *Tagrisso*, *Imfinzi*, *Lynparza*, *Calquence*, *Farxiga*, *Brilinta*, *Lokelma*, *Fasenra*, *Bevespi* and *Breztri*. These new medicines are pillars in the main therapy areas and are important platforms for future growth. Over time, *Enhertu* and roxadustat will be added to this list.
2. 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.
3. New Cardiovascular (CV), Renal & Metabolism comprises Diabetes medicines, *Brilinta* and *Lokelma*. Over time, roxadustat will be added to this list.
4. Specialty-care medicines comprise all Oncology medicines, *Brilinta*, *Lokelma* and *Fasenra*.
5. 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. The UK is yet to announce its IFRS endorsement process and is anticipated to continue to follow the EU endorsement process for the foreseeable future.
6. Core financial measures. These are non-GAAP financial measures because, unlike Reported performance, they cannot be derived directly from the information in the Group's Financial Statements. See the operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
7. Earnings per share.
8. FibroGen and AstraZeneca are collaborating on the development and commercialisation of roxadustat in the US, China, and other global markets. FibroGen and Astellas Pharma Inc. (Astellas) are collaborating on the development and commercialisation of roxadustat in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East, and South Africa.
9. Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.
10. United Nations International Children's Emergency Fund.

Table 4: pipeline highlights

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

Regulatory approvals	- *Imfinzi* - unresectable[10], Stage III NSCLC[11] (CN) - *Lynparza* - ovarian cancer (1st line[12], BRCAm[13]) (SOLO-1) (CN) - *Lynparza* - pancreatic cancer (1st line, BRCAm) (US) - *Enhertu* - breast cancer (3rd line, HER2+[14]) (US) - *Calquence* - CLL[15] (US) - *Qtrilmet* - T2D[16] (EU) - *Lokelma* - hyperkalaemia (CN) - *Breztri* - COPD[17] (CN)
Regulatory submission acceptances and/or submissions	- *Imfinzi* - SCLC[18] (ED[19]): regulatory submission (JP), acceptance (EU), Priority Review (US) - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): regulatory submission (JP), acceptance (EU), Priority Review (US) - *Lynparza* - prostate cancer (2nd line): regulatory submission acceptance (EU), Priority Review (US) - *Calquence* - CLL: regulatory submission (JP), acceptance (EU) - selumetinib - NF1[20]: regulatory submission acceptance, Priority Review (US) - *Farxiga* - HF[21] CVOT[22]: regulatory submission (JP, CN), acceptance (EU), Priority Review (US) - *Brilinta* - CAD[23]/T2D CVOT: regulatory submission (JP, CN) - roxadustat - anaemia from CKD[24]: regulatory submission acceptance (US)[8] - *Symbicort* - mild asthma: regulatory submission (CN)
Major Phase III data readouts or other significant developments	- *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): met Phase III primary endpoint (PFS[25]) - *Imfinzi*, tremelimumab - HCC[26]: Orphan Drug Designation (US) - *Enhertu* - gastric cancer (3rd line, HER2+): met Phase II primary and key secondary (OS[27]) endpoints - *Brilinta* - stroke: met Phase III primary endpoint - *Epanova* - mixed dyslipidaemia: Phase III terminated as unlikely to meet primary endpoint - roxadustat - anaemia from CKD: met Phase III pooled safety objective - cotadutide - NASH[28]: Fast Track designation (US)

[10] An unresectable tumour is one that cannot be removed completely through surgery.
[11] Non-small cell lung cancer.
[12] The initial treatment of a cancer in the advanced, metastatic setting.
[13] Breast cancer susceptibility genes 1/2 mutation.
[14] Human epidermal growth factor receptor 2 positive.
[15] Chronic lymphocytic leukaemia.
[16] Type-2 diabetes.
[17] Chronic obstructive pulmonary disease.
[18] Small cell lung cancer.
[19] Extensive-disease stage.
[20] Neurofibromatosis type 1.
[21] Heart failure.
[22] CV outcomes trial.
[23] Coronary artery disease.
[24] Chronic kidney disease.
[25] Progression-free survival.
[26] Hepatocellular carcinoma (liver cancer).
[27] Overall survival.
[28] Non-alcoholic steatohepatitis (non-alcoholic fatty liver disease).

Table 5: 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
H1 2020	- *Imfinzi* - SCLC (ED): regulatory decision (US) - *Imfinzi* +/- treme - bladder cancer (1st line) (DANUBE): data readout, regulatory submission - *Imfinzi* +/- treme - head & neck cancer (1st line): data readout, regulatory submission - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): regulatory decision (US) - *Lynparza* - breast cancer (BRCAm): regulatory decision (CN) - *Lynparza* - prostate cancer (2nd line): regulatory decision (US) - *Lynparza* + cediranib - ovarian cancer (2nd line): data readout - *Enhertu* - breast cancer (3rd line, HER2+): regulatory decision (JP) - *Enhertu* - gastric cancer (3rd line, HER2+): regulatory submission - selumetinib - NF1: regulatory decision (US) - selumetinib - NF1: regulatory submission (EU) - *Forxiga* - T2D CVOT: regulatory decision (CN) - *Farxiga* - HF CVOT: regulatory decision (US) - *Brilinta* - stroke (THALES): regulatory submission - *Lokelma* - hyperkalaemia: regulatory decision (JP) - *Symbicort* - mild asthma: regulatory submission (EU) - *Bevespi* - COPD: regulatory decision (CN)
H2 2020	- *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-2): data readout - *Imfinzi* - SCLC (ED): regulatory decision (EU, JP) - *Imfinzi* - SCLC (ED): regulatory submission (CN) - *Imfinzi* +/- treme - HCC (1st line): data readout - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): regulatory decision (EU) - *Lynparza* - ovarian cancer (3rd line, BRCAm): regulatory submission (US) - *Lynparza* - pancreatic cancer (1st line, BRCAm): regulatory decision (EU) - *Lynparza* - prostate cancer (2nd line): regulatory decision (EU) - *Enhertu* - breast cancer (3rd line, HER2+): regulatory submission (EU) - *Calquence* - CLL: regulatory decision (EU) - *Forxiga* - HF CVOT: regulatory decision (EU, JP, CN) - *Brilinta*/*Brilique* - CAD/T2D CVOT: regulatory decision (US, EU) - roxadustat - anaemia from CKD: regulatory decision (US) - *Symbicort* - mild asthma: regulatory decision (CN) - *Fasenra* - nasal polyposis: data readout - PT010 - COPD: regulatory decision (US, EU) - PT027 - asthma: data readout - tezepelumab - severe asthma: data readout - anifrolumab - lupus (SLE[29]): regulatory submission

[29] Systemic lupus erythematosus.

Timing	News flow
2021	- *Imfinzi* - adjuvant NSCLC: data readout, regulatory submission - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-2): regulatory submission - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): data readout (OS), regulatory submission - *Imfinzi* +/- treme - SCLC (LD[30]): data readout - *Imfinzi* +/- treme - HCC (1st line): regulatory submission - *Imfinzi* - HCC (locoregional): data readout, regulatory submission - *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 - *Enhertu* - breast cancer (3rd line, HER2+) (Phase III): data readout, regulatory submission - *Enhertu* - breast cancer (2nd line, HER2+): data readout - *Enhertu* - breast cancer (HER2-low): data readout - *Calquence* - CLL: regulatory decision (JP) - *Farxiga* - chronic kidney disease: data readout, regulatory submission - roxadustat - anaemia from myelodysplastic syndrome[31]: data readout - *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 first quarter financial results on 29 April 2020.

AstraZeneca
AstraZeneca (LSE/STO/NYSE: AZN) 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. Based in Cambridge, UK, 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.

Contacts
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

[30] Limited-disease stage.
[31] A group of disorders in which the bone marrow fails to produce healthy blood cells.

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Operating and financial review

All narrative on growth and results in this section is based on actual exchange rates, and financial figures are in US$ millions ($m), unless stated otherwise. The performance shown in this announcement covers the year to 31 December 2019 (the year or FY 2019) and three-month period to 31 December 2019 (the quarter or Q4 2019) compared to the year to 31 December 2018 (FY 2018) and three-month period to 31 December 2018 (Q4 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 Group 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 Group 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 Consolidated Financial Information 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 6: Total Revenue

	FY 2019			Q4 2019		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Product Sales	23,565	12	15	6,250	8	9
Collaboration Revenue	819	(21)	(20)	414	(36)	(36)
Total Revenue	**24,384**	**10**	**13**	**6,664**	**4**	**5**

Table 7: Product Sales

	FY 2019				Q4 2019			
	$m	% of total	% change		$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	8,667	37	44	47	2,274	36	29	29
BioPharmaceuticals	9,767	41	10	13	2,705	43	10	11
New CVRM	*4,376*	*19*	*9*	*12*	*1,168*	*19*	*6*	*7*
Respiratory	*5,391*	*23*	*10*	*13*	*1,537*	*25*	*13*	*14*
Other medicines	5,131	22	(16)	(13)	1,271	20	(17)	(16)
Total	**23,565**	**100**	**12**	**15**	**6,250**	**100**	**8**	**9**

Specialty-care medicines comprise all Oncology medicines, *Brilinta*, *Lokelma* and *Fasenra*. At 47% of Product Sales (FY 2018: 36%), specialty-care medicine sales increased by 43% in the year (47% at CER) to $10,966m.

Table 8: Top-ten medicines by Product Sales

Medicine	Therapy Area	FY 2019				Q4 2019		
		$m	% of total	% change		$m	% change	
				Actual	CER		Actual	CER
Tagrisso	Oncology	3,189	14	71	74	884	49	49
Symbicort	Respiratory	2,495	11	(3)	-	712	12	13
Brilinta	CVRM	1,581	7	20	23	428	14	15
Farxiga	CVRM	1,543	7	11	14	419	6	7
Nexium	Other medicines	1,483	6	(13)	(11)	353	(10)	(10)
Imfinzi	Oncology	1,469	6	n/m	n/m	424	62	62
Pulmicort	Respiratory	1,466	6	14	18	413	6	7
Crestor	CVRM	1,278	5	(11)	(8)	296	(16)	(15)
Lynparza	Oncology	1,198	5	85	89	351	68	69
Faslodex	Oncology	892	4	(13)	(11)	166	(39)	(38)
Total		**16,594**	**70**	**20**	**23**	**4,446**	**15**	**16**

Table 9: Collaboration Revenue

	FY 2019				Q4 2019		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Initial Collaboration Revenue	-	-	-	-	-	-	-
Ongoing Collaboration Revenue	819	100	(21)	(20)	414	(36)	(36)
Royalties	*62*	*8*	*29*	*34*	*18*	*59*	*63*
Milestones/other: Lynparza	*610*	*74*	*(23)*	*(20)*	*350*	*(44)*	*(43)*
Milestones/other: nirsevimab[32]	*34*	*4*	*n/m*	*n/m*	*-*	*n/m*	*n/m*
Other Milestones/other	*113*	*14*	*(19)*	*(18)*	*46*	*n/m*	*n/m*
Total	**819**	**100**	**(21)**	**(20)**	**414**	**(36)**	**(36)**

Royalties included those associated with *Nexium* (over-the-counter format), *Zoladex*, *Tudorza*/*Eklira* and *Duaklir*. *Lynparza* milestone and other receipts in Q4 2019, as part of a collaboration with MSD, comprised sales-milestone income of $250m and a final option-based receipt of $100m.

Product Sales

The performance of the Company's medicines is shown below, with a geographical split shown in Notes 7 & 8.

Table 10: Therapy area and medicine performance

Therapy area	Medicine	FY 2019				Q4 2019		
		$m	% of total	% change		$m	% change	
				Actual	CER		Actual	CER
Oncology	*Tagrisso*	3,189	14	71	74	884	49	49
	Imfinzi	1,469	6	n/m	n/m	424	62	62
	Lynparza	1,198	5	85	89	351	68	69
	Calquence	164	1	n/m	n/m	56	n/m	n/m
	Faslodex[33]	892	4	(13)	(11)	166	(39)	(38)
	Zoladex[33]	813	3	8	13	196	8	9
	Iressa[33]	423	2	(18)	(15)	80	(29)	(28)
	Arimidex[33]	225	1	6	11	51	10	11
	Casodex[33]	200	1	-	3	43	(6)	(5)
	Others	94	-	(18)	(17)	26	15	12
	Total Oncology	**8,667**	**37**	**44**	**47**	**2,274**	**29**	**29**

[32] Formerly MEDI8897.
[33] Legacy medicine.

Therapy area	Medicine	FY 2019				Q4 2019		
		$m	% of total	% change		$m	% change	
				Actual	CER		Actual	CER
BioPharmaceuticals: CVRM	*Farxiga*	1,543	7	11	14	419	6	7
	Brilinta	1,581	7	20	23	428	14	15
	Bydureon	549	2	(6)	(5)	139	1	1
	Onglyza	527	2	(3)	-	131	(11)	(10)
	Byetta	110	-	(13)	(11)	27	(16)	(15)
	Other diabetes	52	-	33	35	16	35	36
	Lokelma	14	-	n/m	n/m	8	n/m	n/m
	Crestor[33]	1,278	5	(11)	(8)	296	(16)	(15)
	Seloken/Toprol-XL[33]	760	3	7	12	190	18	20
	Atacand[33]	221	1	(15)	(11)	60	3	5
	Others	271	1	(9)	(6)	72	1	4
	BioPharmaceuticals: total CVRM	**6,906**	**29**	**3**	**6**	**1,785**	**2**	**4**
BioPharmaceuticals: Respiratory	*Symbicort*	2,495	11	(3)	-	712	12	13
	Pulmicort	1,466	6	14	18	413	6	7
	Fasenra	704	3	n/m	n/m	206	65	65
	Daliresp/Daxas	215	1	14	15	58	8	8
	Duaklir	77	-	(19)	(15)	22	(2)	-
	Bevespi	42	-	26	26	12	12	12
	Breztri	2	-	n/m	n/m	1	n/m	n/m
	Others	390	2	(13)	(9)	114	(9)	(7)
	BioPharmaceuticals: total Respiratory	**5,391**	**23**	**10**	**13**	**1,537**	**13**	**14**
Other medicines	*Nexium*	1,483	6	(13)	(11)	353	(10)	(10)
	Synagis	358	2	(46)	(46)	63	(75)	(75)
	Losec/Prilosec	263	1	(3)	1	46	(24)	(23)
	Seroquel XR/IR	191	1	(47)	(46)	40	(27)	(27)
	Others	306	1	(23)	(20)	151	12	14
	Total other medicines	**2,601**	**11**	**(24)**	**(21)**	**653**	**(27)**	**(27)**
	Total Product Sales	**23,565**	**100**	**12**	**15**	**6,250**	**8**	**9**

Product Sales summary

Oncology

Product Sales of $8,667m in the year; an increase of 44% (47% at CER). Oncology Product Sales represented 37% of total Product Sales, up from 29% in 2018.

Tagrisso

Tagrisso has been approved in 80 countries, including the US, China, in Europe and Japan for the 1st-line treatment of patients with epidermal growth factor receptor (EGFR)-mutated (EGFRm) NSCLC; to date, reimbursement has been granted in 18 countries, with further reimbursement decisions anticipated throughout 2020, as well as additional regulatory decisions in new countries. The regulatory decisions regarding the 1st-line setting followed *Tagrisso*'s approval and launch in 87 countries, including the US, China, in Europe and Japan for the 2nd-line treatment of patients with Stage IV EGFR T790M[34]-mutated NSCLC.

Product Sales in the year of $3,189m represented growth of 71% (74% at CER), partly driven by the aforementioned regulatory approvals and reimbursements in the 1st-line setting; continued growth was also delivered in the 2nd-line setting, for example, within Europe and Emerging Markets. Sales in the US increased by 46% in the year to $1,268m. Q4 2019 sales in the US, however, grew sequentially by only 2% reflecting an increase in inventory movements in Q3 2019 and adverse gross-to-net adjustments[35] in the fourth quarter. Demand continued and *Tagrisso* is established as the standard of care (SoC) in the 1st-line setting, following regulatory approval in 2018.

In Emerging Markets, *Tagrisso* sales increased by 120% in the year (130% at CER) to $762m, with notable growth in China, following the admission to the China National Drug Reimbursement List (NRDL) in the 2nd line setting, which took place at the start of the year. Sales of *Tagrisso* in Japan increased by 100% in the year (97% at CER) to $633m; in the final quarter, however, sales were adversely impacted by a 15% mandated price reduction that took effect from 1 November 2019. In Europe, sales of $474m in the year represented an increase of 51% (59% 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 61 countries, including the US, China, 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 15 countries, including the US.

Global Product Sales of *Imfinzi* increased by 132% in the year (133% at CER) to $1,469m, of which $1,041m were in the US, almost entirely for the treatment of unresectable, Stage III NSCLC; sales in the US increased by 85% in the year. In Japan, sales of $211m (FY 2018: $35m) reflected encouraging levels of demand, supported by higher CRT and treatment rates. Sales in Europe of $179m (FY 2018: $27m) followed recent regulatory approvals and launches.

Lynparza

By the end of the year, *Lynparza* was approved in 73 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 58 countries for the treatment of metastatic breast cancer and, in the US, for the treatment of pancreatic cancer.

Product Sales of *Lynparza* amounted to $1,198m in the year, an increase of 85% (89% 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.

[34] Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.
[35] Gross-to-net adjustments reflect the timing difference between forecast net Product Sales, based on accrued rebates, discounts and other adjustments, and recognised net Product Sales.

US sales increased by 81% to $626m, driven by the launch in the 1st-line BRCAm ovarian cancer setting at the end of 2018. *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 51% (59% at CER) to $287m, driven by increasing levels of reimbursement and BRCA-testing rates, as well as the recent 1st-line ovarian- and breast-indication launches.

Japan sales of *Lynparza* amounted to $130m in the year, representing growth of 170% (167% at CER). Emerging Markets sales of $133m, up by 161% (177% 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); *Lynparza* was recently admitted to the China NRDL for the same indication, with effect from January 2020.

Calquence
Product Sales in the year of $164m; an increase of 164%, with most sales in the US. *Calquence* was recently approved by the US FDA for the treatment of CLL and small lymphocytic lymphoma (SLL) in November 2019.

Legacy: *Iressa*
Product Sales in the year of $423m; a decline of 18% (15% at CER).

Emerging Markets sales were stable in the year (up by 4% at CER) at $286m; *Iressa* continued to be included on the China volume-based procurement programme. Given the growing use of *Tagrisso*, sales of *Iressa* in the US declined by 33% to $17m and by 36% (32% at CER) to $70m in Europe. Japan sales amounted to $44m, reflecting a decline of 50%.

Legacy: *Faslodex*
Product Sales in the year of $892m; a decline of 13% (11% at CER).

Emerging Markets sales of *Faslodex* increased by 29% in the year (36% at CER) to $198m. US sales declined by 39% to $328m, reflecting the launch of multiple generic *Faslodex* medicines; in Q4 2019, *Faslodex* sales in the US declined by 88% to $17m. In Europe, where generic competitor medicines are established, sales in the year increased by 3% (9% at CER) to $229m, while in Japan, sales increased by 20% (19% at CER) to $131m.

Legacy: *Zoladex*
Product Sales in the year of $813m; an increase of 8% (13% at CER).

Emerging Markets sales of *Zoladex* increased by 20% (28% at CER) in the year to $492m. Sales in Europe increased by 2% (7% at CER) to $135m. In the Established RoW region, sales declined by 11% (10% at CER) to $179m, driven by the effects of increased competition.

Further in prostate cancer, the agreement between AstraZeneca and Janssen Pharmaceutical K. K. in Japan for the co-promotion of abiraterone acetate, announced in 2013, recently ceased; sales of abiraterone acetate recorded by AstraZeneca amounted to $36m in the year.

BioPharmaceuticals: CVRM

Total CVRM sales, which include *Crestor* and other legacy medicines, increased by 3% in the year (6% at CER) to $6,906m and represented 29% of total Product Sales (FY 2018: 32%).

New CVRM sales increased by 9% in the year (12% at CER) to $4,376m, reflecting strong performances from *Farxiga* and *Brilinta*. New CVRM sales represented 19% of Product Sales in the year (FY 2018: 19%).

Farxiga
Product Sales of $1,543m in the year; an increase of 11% (14% at CER).

Emerging Markets sales increased by 40% (48% at CER) to $471m, reflecting growth in the sodium-glucose transport protein 2 (SGLT-2) class at the expense of the dipeptidyl-peptidase 4 class; there was also a further improvement in levels of access. *Farxiga* was admitted to the China NRDL with effect from the start of 2020.

US sales declined by 9% to $537m, impacted by changes in formulary access for competitor medicines at the beginning of the year. The level of sales growth in the US in the year was also adversely affected by the impact on price from increased levels of competition, the mix of sales and managed markets. There were favourable movements in the share of new-to-brand prescriptions in the second half, however, a result of a label update in the US to reflect results from the DECLARE CVOT. US sales increased sequentially by 12% from Q3 2019 to Q4 2019.

Sales in Europe increased by 18% (25% at CER) to $373m, partly reflecting growth in the SGLT-2 class and an acceleration on new-to-brand prescriptions following the aforementioned DECLARE label update. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales, increased by 16% (14% at CER) to $87m.

Onglyza
Product Sales of $527m in the year; a decline of 3% (stable at CER).

Sales in Emerging Markets increased by 3% (9% at CER) to $176m, driven by the performance in China. Growth in the US was supported by improved pricing; US sales of *Onglyza* increased by 3% in the year to $230m. The US performance in FY 2018 was adversely impacted by the effect of gross-to-net adjustments, resulting in a favourable comparison for FY 2019. There was also a benefit from the mix of sales and managed markets, offsetting declining class-driven volumes. Europe sales declined by 22% (17% at CER) to $70m, 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 $549m in the year; a decline of 6% (5% at CER).

Sales were impacted by production constraints in the first half of the year for the new *Bydureon BCise* device and declining volumes for the dual-chamber pen; these constraints were resolved in the second half of the year. US sales of $459m represented a decline of 3% in the year, resulting from the pricing impact of managed markets and the transition to the *BCise* device. *Bydureon* sales in Europe fell by 19% (14% at CER) to $66m.

Brilinta
Product Sales of $1,581m in the year; an increase of 20% (23% 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 42% (49% at CER) to $462m. US sales of *Brilinta*, at $710m, represented an increase of 21%, 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 1% in the year (7% at CER) to $351m, driven by performances in Spain, Italy and the UK.

Lokelma
Product Sales of $14m in the year (FY 2018: $nil), predominantly in the US, reflecting the recent launch of the medicine. *Lokelma* represented strong levels of new-to-brand prescriptions by market share at the end of the period in the US. It is also approved in China and in the EU for the treatment of hyperkalaemia; launches in several markets are expected soon.

Legacy: *Crestor*
Product Sales of $1,278m in the year; a decline of 11% (8% at CER).

Sales in Emerging Markets declined by 4% (stable at CER) to $806m. The performance was adversely impacted in the final quarter by the effect of volume-based procurement in China; sales of *Crestor* in Emerging Markets declined by 12% in the quarter (10% at CER) to $185m. US sales declined by 39% to $104m, reflecting the

ongoing effect of competition from generic *Crestor* medicines. In Europe, sales declined by 27% (23% at CER) to $148m, reflecting a similar impact. In Japan, where AstraZeneca collaborates with Shionogi Co. Ltd, sales increased by 3% (2% at CER) to $171m. 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 $5,391m in the year; an increase of 10% (13% at CER). Respiratory represented 23% of total Product Sales (FY 2018: 23%).

Symbicort
Product Sales in the year of $2,495m; a decline of 3% (stable at CER).

Symbicort continued its global market-volume leadership within the inhaled corticosteroid (ICS) / long-acting beta agonist (LABA) class and became market-value leader. Emerging Markets sales increased by 11% in the year (17% at CER) to $547m, reflecting particularly strong performances in China, Latin America and Asia Pacific. In contrast, however, volume growth in the US was offset by the impact of continued pricing pressure and managed-market rebates; US sales declined by 4% to $829m. This contrasted with US sales of *Symbicort* in Q4 2019, where sales increased by 18% to $244m, partly driven by a comparison with one-off unfavourable adjustments in Q4 2018. Building on this performance, AstraZeneca entered an agreement in January 2020 with Prasco, LLC to distribute an authorised-generic version of *Symbicort* in the US.

In Europe, sales declined by 12% in the year (7% at CER) to $678m, driven by price competition and government pricing interventions. In Japan, sales increased by 9% in the year (7% at CER) to $226m, supported by the impact of AstraZeneca regaining full rights, following termination earlier in the year of the Astellas co-promotion agreement.

Pulmicort
Product Sales in the year of $1,466m; an increase of 14% (18% at CER).

Emerging Markets, where sales increased by 20% in the year (24% at CER) to $1,190m, represented 81% of global sales of *Pulmicort*. The performance in China was strengthened by higher levels of demand and was underpinned by the impact of AstraZeneca's support in China for over 17,500 nebulisation centres. Sales in the US declined by 5% to $110m and sales in Europe declined by 10% (4% at CER) to $81m reflecting the legacy status of the medicine.

Fasenra
Fasenra has been approved in 53 countries, including the US, in the EU and Japan for the treatment of severe, uncontrolled eosinophilic asthma, with further regulatory reviews ongoing; *Fasenra* has achieved reimbursement in 36 countries.

Product Sales in the year of $704m, an increase of 137% (139% at CER).

Sales in the US increased by 121% in the year to $482m. In patients with severe, uncontrolled asthma, *Fasenra* ended the year as the leading novel biologic medicine, as measured by new-to-brand prescriptions.

In Europe, sales of $118m in the year represented an increase of 268% (287% at CER). Sales in Japan increased by 91% (89% at CER) to $86m in the year, following the medicine's launch in 2018. In its approved indication and among new patients, *Fasenra* obtained the leading market share of all biologics in the top-five European countries and in Japan.

Daliresp/Daxas
Product Sales in the year of $215m; an increase of 14% (15% at CER).

US sales, representing 86% of the global total, increased by 19% to $184m in the year, driven by favourable affordability-programme changes and inventory movements.

Duaklir
Product Sales in the year of $77m; a decline of 19% (15% at CER).

In 2019, the overwhelming majority of sales were in Europe, where sales declined by 22% (17% at CER) to $71m, mainly a result of an adverse performance in Germany. 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.

Bevespi
Product Sales in the year of $42m; an increase of 26%.

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.

Breztri
Product Sales in the year of $2m (FY 2018: $nil), entirely in Japan.

In December 2019, *Breztri* received regulatory approval in China as a triple-combination therapy for the treatment of COPD. It also received regulatory approval in Japan earlier in the year.

Other medicines (outside the three main therapy areas)

Product Sales of $2,601m in the year; a decline of 24% (21% at CER). Other Product Sales represented 11% of total Product Sales, down from 16% in FY 2018 and 21% in FY 2017.

Nexium
Product Sales in the year of $1,483m; a decline of 13% (11% at CER).

Emerging Markets sales of *Nexium* increased by 8% (14% at CER) to $748m. In Europe, sales declined by 73% (72% at CER) to $63m, following divestment of prescription medicine rights in 2018. Sales in the US declined by 29% to $218m, reflecting its 2015 loss of exclusivity and, in Japan, where AstraZeneca collaborates with Daiichi Sankyo, sales declined by 1% (2% at CER) to $401m.

Regional Product Sales

Table 11: Regional Product Sales

	FY 2019				Q4 2019		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Emerging Markets	8,165	35	18	24	2,091	18	20
China	*4,880*	*21*	*29*	*35*	*1,189*	*25*	*28*
Ex-China	*3,285*	*14*	*6*	*12*	*902*	*10*	*11*
US	7,747	33	13	13	2,059	1	1
Europe	4,350	18	(2)	2	1,182	1	4
Established RoW	3,303	14	17	18	918	16	13
Japan	*2,548*	*11*	*27*	*26*	*719*	*22*	*17*
Canada	*470*	*2*	*(4)*	*(1)*	*126*	*(4)*	*(3)*
Other Established RoW	*285*	*1*	*(13)*	*(4)*	*73*	*5*	*10*

	FY 2019				Q4 2019		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Total	**23,565**	**100**	**12**	**15**	**6,250**	**8**	**9**

Table 12: Emerging Markets Product Sales

	FY 2019				Q4 2019		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Oncology	2,211	27	45	52	546	54	57
BioPharmaceuticals	3,120	38	25	31	865	18	20
New CVRM	*1,133*	*14*	*33*	*41*	*297*	*25*	*27*
Respiratory	*1,987*	*24*	*21*	*27*	*568*	*14*	*16*
Other medicines	2,834	35	(1)	4	680	1	2
Total	**8,165**	**100**	**18**	**24**	**2,091**	**18**	**20**

Table 13: Notable new-medicine performances in Emerging Markets

Product Sales	FY 2019 $m	% change	
		Actual	CER
Tagrisso	762	n/m	n/m
Lynparza	133	n/m	n/m
Farxiga	471	40	48
Brilinta	462	42	49

New medicines represented 23% of Emerging Markets sales (FY 2018: 15%). Sales of specialty-care medicines increased by 44% (52% at CER) to $2,678m and comprised 33% of Emerging Markets sales in the year (FY 2018: 27%).

Table 14: Notable other performances in Emerging Markets

Product Sales	FY 2019 $m	% change	
		Actual	CER
Zoladex	492	20	28
Pulmicort	1,190	20	24
Symbicort	547	11	17

China sales comprised 60% of Emerging Markets sales in the year, increasing by 29% (35% at CER) to $4,880m. China sales in the quarter increased by 25% (28% at CER) to $1,189m, when the performance was adversely impacted by the effect of volume-based procurement in China. New-medicine sales, primarily driven by *Tagrisso* and *Lynparza* in Oncology and *Brilinta* and *Farxiga* in New CVRM, delivered particularly encouraging growth and represented 19% of China sales (FY 2018: 11%). This performance was augmented by strong sales of *Zoladex*, *Pulmicort*, *Nexium* and *Symbicort*.

In early 2019, *Tagrisso* benefitted from being added to the 2018 NRDL by the China National Healthcare Security Administration (NHSA) as a treatment for patients with Stage IV EGFR T790M-mutated NSCLC. Furthermore, the NHSA published the preliminary 2019 NRDL in the second half of 2019, which included one additional AstraZeneca medicine, namely *Kombiglyze* for Diabetes. Respiratory medicines *Symbicort* for asthma and COPD and *Nexium* for acid reflux also benefitted as reimbursement restrictions were removed. In December 2019, the NHSA published the final 2019 NRDL, which was updated to include a further three AstraZeneca medicines: *Lynparza* in ovarian cancer, *Forxiga* in T2D and roxadustat in anaemia from CKD; *Faslodex*, however, was removed from the list. Since 2012, 15 of the Company's medicines have also been admitted to China's Essential Drugs List[36].

Ex-China Emerging Markets sales increased by 6% in the year (12% at CER) to $3,284m. New medicines represented 29% of Product Sales in the year (FY 2018: 21%), increasing by 45% (53% at CER). The performance was underpinned by strong levels of growth at CER in the following regions:

Table 15: Ex-China Emerging Markets

Product Sales	FY 2019 % change	
	Actual	CER
Russia	35	40
Brazil	(2)	7
Ex-Brazil Latin America	3	16
Ex-China Asia Pacific	8	10
Middle East and Africa	3	8

Financial performance

Table 16: Reported Profit and Loss

	FY 2019 $m	FY 2018 $m	% change Actual	% change CER	Q4 2019 $m	Q4 2018 $m	% change Actual	% change CER
Product Sales	23,565	21,049	12	15	6,250	5,768	8	9
Collaboration Revenue	819	1,041	(21)	(20)	414	649	(36)	(36)
Total Revenue	24,384	22,090	10	13	6,664	6,417	4	5
Cost of Sales	(4,921)	(4,936)	-	5	(1,378)	(1,637)	(16)	(10)
Gross Profit	19,463	17,154	13	16	5,286	4,780	11	10
Gross Profit Margin[37]	*79.1%*	*76.6%*	*3*	*2*	*78.0%*	*71.6%*	*6*	*5*

[36] Used to decide which medicines to stock at hospitals and clinics and also to define reimbursement under China's public healthcare system.
[37] 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.

	FY 2019 $m	FY 2018 $m	% change Actual	% change CER	Q4 2019 $m	Q4 2018 $m	% change Actual	% change CER
Distribution Expense	(339)	(331)	2	7	(92)	(93)	(2)	-
% Total Revenue	*1.4%*	*1.5%*	-	-	*1.4%*	*1.5%*	-	-
R&D Expense	(6,059)	(5,932)	2	5	(2,091)	(2,012)	4	5
% Total Revenue	*24.8%*	*26.9%*	*2*	*2*	*31.4%*	*31.4%*	-	-
SG&A Expense	(11,682)	(10,031)	16	20	(3,026)	(2,600)	16	18
% Total Revenue	*47.9%*	*45.4%*	*(2)*	*(3)*	*45.4%*	*40.5%*	*(5)*	*(5)*
Total Operating Expenses	(18,080)	(16,294)	11	14	(5,209)	(4,705)	11	12
% Total Revenue	*74.1%*	*73.8%*	-	-	*78.2%*	*73.3%*	*(5)*	*(5)*
Other Operating Income & Expense	1,541	2,527	(39)	(38)	500	1,002	(50)	(50)
% Total Revenue	*6.3%*	*11.4%*	*(5)*	*(5)*	*7.5%*	*15.6%*	*(8)*	*(8)*
Operating Profit	2,924	3,387	(14)	(16)	577	1,077	(46)	(56)
Operating Profit Margin	*12.0%*	*15.3%*	*(3)*	*(4)*	*8.7%*	*16.8%*	*(8)*	*(10)*
Net Finance Expense	(1,260)	(1,281)	(2)	4	(312)	(311)	-	(1)
Joint Ventures and Associates	(116)	(113)	3	5	(25)	(36)	(30)	(30)
Profit Before Tax	1,548	1,993	(22)	(29)	240	730	(67)	(79)
Taxation	(321)	57	n/m	n/m	37	279	(87)	(81)
Tax Rate	21%	-3%			-15%	-38%		
Profit After Tax	1,227	2,050	(40)	(45)	277	1,009	(72)	(80)
EPS	1.03	1.70	(40)	(44)	0.24	0.82	(71)	(78)

Table 17: Reconciliation of Reported Profit Before Tax to EBITDA[38]

	FY 2019 $m	FY 2018 $m	% change Actual	% change CER	Q4 2019 $m	Q4 2018 $m	% change Actual	% change CER
Reported Profit Before Tax	1,548	1,993	(22)	(29)	240	730	(67)	(79)
Net Finance Expense	1,260	1,281	(2)	4	312	311	-	(1)
Joint Ventures and Associates	116	113	3	5	25	36	(30)	(30)
Depreciation, Amortisation and Impairment	3,762	3,753	-	3	1,643	1,662	(1)	-
EBITDA	6,686	7,140	(6)	(6)	2,220	2,739	(19)	(22)

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

Table 18: FY 2019 reconciliation of Reported to Core financial measures

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other[39]	Core[40]	Core % change	
	$m	$m	$m	$m	$m	$m	Actual	CER
Gross Profit	19,463	73	87	-	-	19,623	10	13
Gross Profit Margin	*79.1%*					*79.8%*	-	-
Distribution Expense	(339)	-	-	-	-	(339)	2	7
R&D Expense	(6,059)	101	638	-	-	(5,320)	1	4
SG&A Expense	(11,682)	173	1,771	(126)	775	(9,089)	5	8
Total Operating Expenses	(18,080)	274	2,409	(126)	775	(14,748)	4	7
Other Operating Income & Expense	1,541	-	1	-	19	1,561	(27)	(26)
Operating Profit	2,924	347	2,497	(126)	794	6,436	13	13
Operating Profit Margin	*12.0%*					*26.4%*	*+1*	-
Net Finance Expense	(1,260)	-	-	287	208	(765)	4	10
Taxation	(321)	(66)	(519)	(54)	(149)	(1,109)	n/m	n/m
EPS	$1.03	$0.22	$1.52	$0.08	$0.65	$3.50	1	-

[39] 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).
[40] Each of the measures in the Core column in the above table are non-GAAP financial measures. See the operating and financial review for related definitions.

Table 19: Q4 2019 reconciliation of Reported to Core financial measures

	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other[39]	Core[40]	Core % change	
	$m	$m	$m	$m	$m	$m	Actual	CER
Gross Profit	5,286	(49)	18	-	-	5,255	1	1
Gross Profit Margin	*78.0%*					*77.5%*	*-1*	*-2*
Distribution Expense	(92)	-	-	-	-	(92)	(2)	-
R&D Expense	(2,091)	19	578	-	-	(1,494)	2	4
SG&A Expense	(3,026)	26	762	(420)	33	(2,625)	8	9
Total Operating Expenses	(5,209)	45	1,340	(420)	33	(4,211)	5	7
Other Operating Income & Expense	500	-	(2)	-	3	501	(50)	(50)
Operating Profit	577	(4)	1,356	(420)	36	1,545	(29)	(33)
Operating Profit Margin	*8.7%*					*23.2%*	*-11*	*-12*
Net Finance Expense	(312)	-	-	71	55	(186)	6	-
Taxation	37	8	(279)	52	(13)	(195)	n/m	n/m
EPS	$0.24	-	$0.83	($0.23)	$0.05	$0.89	(44)	(46)

Profit and Loss summary

a) Gross Profit

The increase in Reported and Core Gross Profit for the year was a reflection of the growth in Product Sales. Reported Gross Profit was adversely impacted in the prior year by the recognition of costs associated with the closure of two biologic-medicine manufacturing sites in Colorado, US. A partial reversal of these costs was recorded in the quarter.

Following the recommendation from an independent Data Monitoring Committee, AstraZeneca recently decided to terminate the Phase III STRENGTH trial for *Epanova* (omega-3 carboxylic acids), due to its low likelihood of demonstrating a benefit to patients with mixed dyslipidaemia who are at increased risk of CV disease. This was considered to be an adjusting event after the reporting period, resulting in a provision for inventory and supply-related costs of $115m, recorded in Reported and Core Cost of Sales in FY 2019.

b) Operating Expense

Reported Operating Expense in the year represented 74% of Total Revenue (FY 2018: 74%), Core Operating Expense represented 60% of Total Revenue (FY 2018: 64%).

Reported and Core R&D Expense increased partly a result of investment in the development of *Enhertu*. Reported and Core SG&A Expense grew primarily because 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 and intangible asset impairments; the latter included impairments of *Bydureon*, *Qtern* and *Tudorza*/*Eklira*.

The aforementioned STRENGTH-trial termination also resulted in a full impairment of the *Epanova* intangible asset of $533m, recorded in Reported R&D Expense in FY 2019.

c) Other Operating Income and Expense[41]

Reported and Core Other Operating Income and Expense in the year included:

- $515m, reflecting an agreement to sell US rights to *Synagis* to Swedish Orphan Biovitrum AB (publ) (Sobi)
- $243m, reflecting 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)
- $213m, reflecting agreements to sell its commercial rights to *Seroquel* and *Seroquel XR* in the US, Canada, Europe and Russia to Cheplapharm
- $181m, reflecting an agreement to sell the commercial rights to *Arimidex* and *Casodex* in a number of European, African and other countries to Juvisé Pharmaceuticals

In January 2020, the Company announced that it had agreed to divest the global commercial rights to a number of established hypertension medicines, including *Inderal*, *Tenormin* and *Zestril* to Atnahs Pharma. Atnahs Pharma will make an upfront payment of $350m to AstraZeneca. AstraZeneca may also receive future sales-contingent payments of up to $40m between 2020 and 2022. Income arising from the upfront and future payments will be reported in AstraZeneca's financial statements within Other Operating Income and Expense. The divestment is expected to complete in the first quarter of 2020.

d) Net Finance Expense

Reported and Core Net Finance Expense increased at CER in the year, partly reflecting an adverse movement in loan interest, as well as the effect of the adoption of IFRS 16 (see Note 1). There was also a discount unwind in respect of the profit-participation financial liability in relation to the aforementioned FY 2019 divestment of the US rights to participate in the future cash flows from the US profits or losses for nirsevimab, impacting Reported and Core Finance Expense.

e) Taxation

The Reported Tax Rate for the year was 21% and the Core Tax Rate was 20% (FY 2018: (3)% and 11% respectively). These tax rates were higher than the UK Corporation Tax Rate due to the impact of the geographical mix of profits.

f) EPS

Reported EPS of $1.03 in the year, based on a weighted-average number of shares of 1,301m, represented a decline of 40% (44% at CER); Core EPS increased by 1% (stable at CER) to $3.50. The difference between the Reported and Core performance partly reflected the impact of a favourable $346m legal settlement in FY 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, as well as an increase in intangible asset impairments.

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 $3.5bn, net of transaction costs of $22m.

[41] 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.

g) Dividend per share

The Board reaffirms its commitment to the progressive dividend policy; a second interim dividend of $1.90 per share (146.4 pence, 18.32 SEK) has been declared, taking the unchanged full-year dividend per share to $2.80 (218.3 pence, 26.81 SEK). Dividend payments are normally paid as follows:

- First interim dividend - announced with half-year and second-quarter results and paid in September
- Second interim dividend - 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.

Table 20: Cash Flow

	FY 2019 $m	FY 2018 $m	Change $m
Reported Operating Profit	2,924	3,387	(463)
Depreciation, Amortisation and Impairment	3,762	3,753	9
Increase in Working Capital and Short-Term Provisions	(346)	(639)	293
Gains on Disposal of Intangible Assets	(1,243)	(1,885)	642
Non-Cash and Other Movements	(236)	(785)	549
Interest Paid	(774)	(676)	(98)
Taxation Paid	(1,118)	(537)	(581)
Net Cash Inflow from Operating Activities	**2,969**	**2,618**	**351**
Net Cash Inflow before Financing Activities	2,312	3,581	(1,269)
Net Cash Outflow from Financing Activities	(1,765)	(2,044)	279

The increase in Net Cash Inflows from Operating Activities in the year primarily reflected an underlying improvement in business performance, combined with favourable working-capital movements and the impact of the adoption of IFRS 16 (Leases) on 1 January 2019. The positive cash performance was partly offset by an increase in Taxation Paid, which represented 72% of Reported Profit Before Tax (FY 2018: 27%); the increase in the amount paid primarily reflected the phasing of tax payments between periods and the impact of refunds in FY 2018, following agreement of prior-period liabilities. The adoption of IFRS 16 resulted in a presentational change within the cash-flow statement, whereby cash outflows of $186m are now presented as financing, instead of operating.

The decline in Net Cash Inflows before Financing Activities primarily reflected the Purchase of Intangible Assets, which included:

- The first of two $675m upfront payments to Daiichi Sankyo as part of the agreement on *Enhertu*
- 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

Payments from Pfizer, Inc. totalling $250m were received in the year, 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 an agreement with Luye Pharma Group Ltd, relating to the rights to *Seroquel* and *Seroquel XR* in the UK, China and other international markets, announced in June 2018, AstraZeneca received a deferred consideration payment of $240m in the quarter, also recorded within Disposal of Intangible Assets. Other business-development transactions are referred to in the section Other Operating Income and Expense above.

The cash payment of contingent consideration, in respect of the former Bristol-Myers Squibb Company share of the global diabetes alliance, amounted to $454m in the year (FY 2018: $349m).

As part of the total consideration received in respect of the aforementioned agreement to sell US rights to *Synagis*, $821m was received and included in Disposal of Intangible Assets and $150m was related to the rights to participate in the future cash flows from the US profits or losses for nirsevimab. This was recognised as a financial liability as the Company did not fully transfer the risks and rewards of the underlying cash flows arising from nirsevimab to Sobi; this was recorded in Other Payables, within Non-current Liabilities. The associated cash flow was presented within Investing Activities as AstraZeneca received the payment in exchange for agreeing to transfer future cashflows relating to an intangible asset.

In October 2019, Circassia announced the launch of *Duaklir* in the US, upon which the Company made a $91m milestone payment to Almirall, S.A. (Almirall). Following the announcement in December 2019 that *Enhertu* had been approved in the US for patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting, AstraZeneca accrued a first milestone payment to Daiichi Sankyo for $125m; this amount was capitalised upon approval.

In April 2019, the Company completed a placing of new Ordinary Shares 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 as to strengthen AstraZeneca's balance sheet. The proceeds from the placing were recorded in the second quarter, supporting a reduced level of Net Debt.

h) Capital expenditure

Capital expenditure amounted to $979m in the year, compared to $1,043m in FY 2018. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK. The Company continues to expect total associated capital expenditure for the project of c.$1.3bn (c.£1bn, translated at average exchange rates for the year).

The Company anticipates a broadly stable level of total capital expenditure in FY 2020 (FY 2019: $979m).

Table 21: Debt and capital structure

	At 31 Dec 2019 $m	At 31 Dec 2018 $m
Cash and Cash Equivalents	5,369	4,831
Other Investments	911	895
Cash and Investments	**6,280**	**5,726**
Overdrafts and Short-Term Borrowings	(225)	(755)
Lease Liabilities[42]	(675)	-
Current Instalments of Loans	(1,597)	(999)
Loans Due After One Year	(15,730)	(17,359)

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

	At 31 Dec 2019 $m	At 31 Dec 2018 $m
Interest-Bearing Loans and Borrowings (Gross Debt)	**(18,227)**	**(19,113)**
Net Derivatives	43	384
Net Debt	**(11,904)**	**(13,003)**

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

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

Table 22: 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)[43]	
Currency	**Primary Relevance**	**FY 2019[44]**	**YTD 2020[45]**	**% change**	**Product Sales**	**Core Operating Profit**
CNY	Product Sales	6.92	6.93	-	288	190
EUR	Product Sales	0.89	0.90	(1)	171	68
JPY	Product Sales	108.98	109.38	-	139	98
Other[46]					231	123
GBP	Operating Expense	0.78	0.77	2	27	(93)
SEK	Operating Expense	9.46	9.47	-	5	(51)

[43] Based on best prevailing assumptions around currency profiles.
[44] Based on average daily spot rates in FY 2019.
[45] Based on average daily spot rates from 1 January 2020 to 31 January 2020.
[46] Other currencies include AUD, BRL, CAD, KRW and RUB.

Sustainability

AstraZeneca's sustainability ambition has three priority areas[47], 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

By the end of December 2019, AstraZeneca's Healthy Heart Africa (HHA) programme, working with collaborators across Kenya, Ethiopia, Tanzania and Ghana, had conducted over 13.5 million blood-pressure screenings and identified over 2.4 million elevated readings since its launch in 2015. In November 2019, the Company extended the programme and launched Healthy Heart Asia in India. The launch was conducted in collaboration with the Ganga Godavari Cancer Screening Programme, AstraZeneca India's sustainability partner.

In January 2020, AstraZeneca announced that the YHP would partner with UNICEF to prevent non-communicable diseases among young people. The Company will support UNICEF with a $12.5m grant to support programming which will reach more than five million young people, train approximately 1,000 youth advocates, and potentially help to shape public policy around the world over the next six years. In October 2019, AstraZeneca announced plans to extend the funding for the YHP for a further five years, with a pledge of $35m to help to educate young people on the steps that they can take to reduce the risk of non-communicable diseases.

b) Environmental protection

In January 2020, during the World Economic Forum Annual Meeting in Davos, Switzerland, AstraZeneca announced an ambitious programme for zero-carbon emissions from its global operations by 2025. The Company also announced its commitment to ensuring that its entire value chain is carbon-negative by 2030, bringing forward decarbonisation plans by more than a decade. The 'Ambition Zero Carbon' strategy will accelerate the Company's existing science-based targets, doubling energy productivity and using renewable energy for both power and heat, as well as switching to 100% electric-vehicle fleet five years ahead of schedule.

In addition, the Company also announced plans to invest up to $1bn to help achieve these goals and to develop the next-generation respiratory inhalers with near-zero Global Warming Potential propellants. Also included in the plan is 'AZ Forest', a 50-million tree-reforestation initiative that will be rolled out over the next five years.

The Company was recently commended by the global environmental impact non-profit organisation, CDP, achieving a place on both the 'A List' for Climate Change and the 'A List' for Water Security, based on data submitted by the Company in 2019. A double 'A List' status was achieved for the fourth consecutive year. AstraZeneca is one of a small number of high-performing companies out of thousands that were scored, and fewer than ten companies worldwide appeared on both 'A Lists' in the last four years.

c) Ethics and transparency

During the period, the Workforce Disclosure Initiative[48] released its 2019 scorecard, underpinned by 138 institutional-investor signatories. The Company participated for the second year, indicating its willingness to work towards increasing the amount of workforce data disclosed.

In January 2020, the Company was included, for the second consecutive year, in the Bloomberg 2020 Gender-Equality Index. This year, the index recognised 325 companies which work to advance women in the workplace through measurement and transparency.

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[47] 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'.

[48] An investor effort designed to help companies enhance their workforce reporting.

During the period, the Hampton-Alexander independent review body, which works to increase the number of women on FTSE 350 boards on a voluntary business-led basis, published its latest review. It has a dual focus on improving women's representation at board level and in leadership roles two layers below board level and covers 23,000 leadership roles across all sectors of British business.

In the FTSE 100 ranking, AstraZeneca moved up from seventh place in 2018 to sixth in 2019 for women represented in the top three layers of leadership. With women representing 40% of leaders at this level, the Company was the highest-ranked pharmaceutical company. Having moved from five to four women Board members since 2018, however, AstraZeneca dropped from 12th place to 39th place in 2019, as this particular metric is sensitive to individual appointments.

d) Other developments

During the period, AstraZeneca was ranked 56th overall by Corporate Knights[49], out of more than 7,000 companies, as one of the world's one hundred most sustainable companies, and second among biopharmaceutical companies.

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. The 2019 Sustainability Report will be availability in due course.

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[49] Corporate Knights Inc. includes the sustainable-business magazine Corporate Knights and a research division that produces rankings and financial-product ratings based on corporate-sustainability performance.

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 23: Update from the late-stage pipeline

New molecular entities and major lifecycle events for medicines in Phase III trials or under regulatory review	17	**Oncology** - *Tagrisso* - NSCLC - *Imfinzi* - multiple cancers - *Lynparza* - multiple cancers - *Enhertu* - breast and other cancers - capivasertib - breast cancer - *Calquence* - blood cancers - tremelimumab - multiple cancers - selumetinib - NF1[50] - savolitinib - NSCLC[50] **CV, Renal & Metabolism** - roxadustat - anaemia from CKD **Respiratory (and immunology)** - *Fasenra* - multiple indications - *Breztri* - COPD - PT027 - asthma - tezepelumab - severe asthma - nirsevimab - lower respiratory tract infection - anifrolumab - lupus - brazikumab[51] - inflammatory bowel disease
Total projects in clinical pipeline	144	

[50] Phase II trial data, with potential for registration.
[51] Subject to regulatory approvals associated with AbbVie Inc.'s (AbbVie) proposed acquisition of Allergan plc (Allergan).

Oncology

At the 2019 American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, US, the Company presented over 30 abstracts including seven oral presentations. Highlights included the first presentation of data from the pivotal Phase III ELEVATE TN trial, evaluating the long-term efficacy and safety of *Calquence* in combination with obinutuzumab and *Calquence* monotherapy versus obinutuzumab combined with chlorambucil chemotherapy in previously untreated CLL.

At the 2019 San Antonio Breast Cancer Symposium (SABCS), US, AstraZeneca presented over 30 abstracts, including three oral presentations and two spotlight poster discussions. Highlights included the *Enhertu* DESTINY-Breast01 Phase II trial data in HER2-positive breast cancer.

Oncology: lung cancer

a) *Tagrisso*

Table 24: Key *Tagrisso* trials in lung cancer

Trial	Population	Design	Timeline	Status
Phase III ADAURA	Adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD[52] Q4 2015 LPCD[53] Q1 2019 First data anticipated 2021+[54]	Recruitment completed
Phase III LAURA	Locally advanced, unresectable EGFRm NSCLC	Placebo or *Tagrisso*	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III FLAURA2	1st-line EGFRm NSCLC	*Tagrisso* or *Tagrisso* + platinum-based chemotherapy doublet	FPCD Q4 2019 First data anticipated 2021+	Recruitment ongoing

b) *Imfinzi*

In December 2019, AstraZeneca announced that it has received marketing authorisation from the China NMPA for *Imfinzi* for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following concurrent CRT. The approval of *Imfinzi* was based on results from the primary analysis of PFS, supported by OS data from the Phase III PACIFIC trial.

In November 2019, the Company announced that the US Food and Drug Administration (FDA) had accepted a supplemental Biologics License Application and awarded Priority Review status for *Imfinzi* for the treatment of patients with previously untreated ED SCLC, based on results from the Phase III CASPIAN trial. A Prescription Drug User Fee Act (PDUFA) date is set for the first quarter of 2020. The Company also recently made regulatory submissions for *Imfinzi* in Japan and received a regulatory submission acceptance in the EU for previously untreated ED SCLC. The submissions were based on the flat dose of 1,500mg of *Imfinzi*, with four cycles of chemotherapy once every three weeks.

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

During the period, *Imfinzi* was assigned Category 1 status for the treatment of ED SCLC patients within the US National Comprehensive Cancer Network guidelines.

During the period, the Company announced positive PFS results for *Imfinzi* and tremelimumab, an anti-CTLA4 antibody, when added to chemotherapy, from the Phase III POSEIDON trial in previously-untreated Stage IV (metastatic) NSCLC. The trial met a primary endpoint by showing a statistically significant and clinically meaningful improvement in the final PFS analysis for *Imfinzi* and chemotherapy, and a key secondary endpoint for PFS of *Imfinzi* plus tremelimumab and chemotherapy. The safety and tolerability of *Imfinzi* was consistent with its known safety profile; the triple combination of *Imfinzi* plus tremelimumab and chemotherapy delivered a broadly similar safety profile. The trial will continue to assess the additional primary endpoint of OS, with data anticipated in 2021.

Table 25: Key *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[55]	Stage Ib-IIIa NSCLC	Placebo or *Imfinzi*	FPCD Q1 2015 LPCD Q4 2019 First data anticipated 2021	Recruitment completed
Phase III PACIFIC-2	Stage III unresected locally advanced NSCLC (concurrent CRT)	Placebo or *Imfinzi*	FPCD Q2 2018 LPCD Q3 2019 First data anticipated H2 2020	Recruitment completed
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
Phase III POSEIDON	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q2 2017 LPCD Q4 2018	PFS primary endpoint met
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

[55] Conducted by the Canadian Cancer Trials Group.

***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.

During the period, the Company announced that *Imfinzi* and tremelimumab had both been granted Orphan Drug Designation in the US for the treatment of HCC. *Imfinzi* has now received regulatory approval for the 2nd-line treatment of patients with locally advanced or metastatic urothelial carcinoma (bladder cancer) in 15 countries.

Table 26: 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[56] or SoC BCG + *Imfinzi*	FPCD Q4 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 HCC	TACE[57] followed by placebo or TACE + *Imfinzi*, followed by *Imfinzi* + bevacizumab or TACE + *Imfinzi* followed by *Imfinzi*	FPCD Q1 2019 First data anticipated 2021	Recruitment ongoing
Phase III EMERALD-2	Locoregional HCC 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	SoC chemotherapy or SoC + *Imfinzi* or	FPCD Q4 2018	Recruitment ongoing

[56] Bacillus Calmette-Guerin.
[57] Transarterial chemoembolisation.

Trial	Population	Design	Timeline	Status
	chemotherapy-eligible bladder cancer	SoC + *Imfinzi* + treme	First data anticipated 2021+	
Phase III KESTREL	Stage IV, 1st-line head and neck squamous cell carcinoma	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 HCC	Sorafenib or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2017 LPCD Q4 2019 First data anticipated H2 2020	Recruitment Completed Orphan Drug Designation (US)
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)
In December 2019, AstraZeneca announced that it had received marketing authorisation from the China NMPA for *Lynparza* as a 1st-line maintenance treatment of adult patients with newly-diagnosed advanced BRCAm epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to 1st-line platinum-based chemotherapy. The approval in China was based on results from the Phase III SOLO-1 trial.

During the period, the Company announced that *Lynparza* had been approved in the US for the maintenance treatment of adult patients with germline (inherited) BRCAm metastatic pancreatic adenocarcinoma (pancreatic cancer) whose disease has not progressed for at least 16 weeks of a 1st-line platinum-based chemotherapy regimen. Patients will be selected for therapy based on a US FDA-approved companion diagnostic for *Lynparza*.

The approval followed the recommendation from the US FDA Oncologic Drugs Advisory Committee in December 2019 for *Lynparza* in this indication and was based on results from the pivotal Phase III POLO trial, published in *The New England Journal of Medicine* and presented at the 2019 American Society of Clinical Oncology Annual Meeting.

In January 2020, the Company announced that a supplemental New Drug Application (sNDA) for *Lynparza* in combination with bevacizumab has been accepted and granted Priority Review status in the US for the maintenance treatment of patients with advanced ovarian cancer who are in complete or partial response to 1st-line platinum-based chemotherapy with bevacizumab. The Company also made a regulatory submission for the same indication in Japan and achieved regulatory submission acceptance in the EU. During the same period, AstraZeneca also announced that an sNDA for *Lynparza* had been accepted and granted Priority Review status in the US for patients with metastatic castration-resistant prostate cancer and homologous recombination repair (HRR) gene mutations, who have progressed following prior treatment with a new hormonal agent.

At the 21st European Society of Gynaecological Oncology Congress in Athens, Greece, the Company presented further details from the Phase III PAOLA-1 trial of maintenance *Lynparza* with bevacizumab in patients with newly diagnosed, advanced ovarian cancer treated with platinum-based chemotherapy and bevacizumab as SoC. The updated data demonstrated that, in Stage III patients with primary debulking surgery and residual disease, patients who had received neoadjuvant chemotherapy and Stage IV patients, PFS was 22.0 months versus 16.6

months, with a hazard ratio of 0.65 (95% CI 0.51 - 0.82).

The Company continues to pursue the joint-venture agreement entered into in 2015 with Fujifilm Kyowa Kirin Biologics Co., Ltd. to develop biosimilar bevacizumab to enable the continued strategy of novel combinations with vascular endothelial growth factor inhibitors within the pipeline, commencing with *Lynparza* and other new medicines. The Phase III AVANA trial, which evaluated FKB238 (biosimilar bevacizumab) vs. Avastin (bevacizumab) in patients with advanced/recurrent non-squamous NSCLC, met the primary objective of efficacy equivalence on key clinical parameters.

Table 27: 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[58] prostate cancer	SoC (abiraterone or enzalutamide) or *Lynparza*	FPCD Q2 2017 LPCD Q4 2018	Primary endpoint met Priority Review (US)
Phase III PAOLA-1[59]	Advanced 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + *Lynparza* maintenance	FPCD Q2 2015 LPCD Q2 2018	Primary endpoint met Priority Review (US)
Phase III GY004[60]	Recurrent platinum-sensitive ovarian cancer	SoC chemotherapy or *Lynparza* or cediranib + *Lynparza*	FPCD Q1 2016 First data anticipated H1 2020	Recruitment ongoing
Phase II/III GY005[60]	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	Advanced 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + *Imfinzi* +/-	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing

[58] HRR mutated.
[59] Conducted by the ARCAGY/Groupe d'Investigateurs National des Etudes des Cancers Ovariens et du sein.
[60] Conducted by the National Cancer Institute (US).

Trial	Population	Design	Timeline	Status
		Lynparza maintenance		
Phase III PROpel	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + *Lynparza*	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing

***Enhertu* (breast and other cancers)**
In December 2019, AstraZeneca announced that the US FDA had approved *Enhertu* (fam-trastuzumab deruxtecan-nxki) for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting. This came under the Accelerated Approval programme, based on tumour-response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

High-level results from the positive registrational Phase II trial DESTINY-Gastric01 also showed that *Enhertu* had achieved a statistically significant and clinically meaningful improvement in the primary endpoint of objective response rate (ORR) and a key secondary endpoint of OS in patients with HER2-positive unresectable or metastatic gastric or gastroesophageal junction cancer that had progressed following two or more treatment regimens, including trastuzumab and chemotherapy. In addition to the planned discussion with the Japan Ministry of Health, Labour and Welfare, AstraZeneca and Daiichi Sankyo plan to discuss the data with other health authorities.

During the period, the Company presented detailed positive data from the global pivotal Phase II single-arm DESTINY-Breast01 trial at the aforementioned SABCS symposium; an accompanying article appeared in *The New England Journal of Medicine*. In the trial, *Enhertu* was investigated in patients with HER2-positive metastatic breast cancer who received two or more prior HER2-targeted regimens. The primary endpoint of ORR, confirmed by independent central review, was 60.9% with *Enhertu* monotherapy (5.4mg/kg). Patients had a median of six prior therapies for metastatic disease (a range of 2-27); patients achieved a disease control rate of 97.3%, with a median duration of response of 14.8 months and median PFS of 16.4 months. The median OS has not yet been reached, with an estimated survival rate of 86% at one year. The results were consistent across subgroups of patients.

Table 28: Key *Enhertu* trials

Trial	Population	Design	Timeline	Status
Phase II DESTINY-Breast01	Stage IV, HER2+ (IHC[61] 3+ and IHC 2+/ISH[62]+) breast cancer post trastuzumab emtansine	*Enhertu* (single arm)	FPCD Q4 2017 LPCD Q4 2018	Primary objective met Breakthrough Therapy Designation (US) Accelerated approval (US)
Phase III DESTINY-Breast02	Stage IV, HER2+ (IHC 3+ and IHC 2+/ISH+) breast cancer post trastuzumab emtansine	SoC chemotherapy or *Enhertu*	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing

[61] Immunohistochemistry.
[62] In situ hybridisation.

Trial	Population	Design	Timeline	Status
Phase III DESTINY-Breast03	Stage IV, HER2+ (IHC 3+ and IHC 2+/ISH+) breast cancer	Trastuzumab emtansine or *Enhertu*	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase III DESTINY-Breast04	Stage IV, HER2-low (IHC 1+/2+) breast cancer	SoC chemotherapy or *Enhertu*	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase II DESTINY-Gastric01	Stage IV, HER2+ (IHC 3+ and IHC 2+/ISH+) gastric cancer	SoC chemotherapy or *Enhertu*	FPCD Q4 2017 LPCD Q2 2019	Primary endpoint met

***Calquence* (blood cancers)**
In November 2019, AstraZeneca announced that the US FDA had approved *Calquence* for the treatment of adult patients with CLL or SLL. The approval was granted under the administration's Real-Time Oncology Review programme. Reflecting the newly established joint Project Orbis programme, approvals in Australia and Canada followed thereafter and, during the period, the Company also received regulatory submission acceptance in the EU for CLL and made a regulatory submission in Japan, for relapsed/refractory CLL.

The approvals were based on positive results from the interim analyses of two-Phase III clinical trials, namely ELEVATE TN in patients with previously untreated CLL, and ASCEND in patients with relapsed or refractory CLL. Together, the trials showed that *Calquence*, in combination with obinutuzumab or as a monotherapy, significantly reduced the relative risk of disease progression or death versus the comparator arms in both front-line and relapsed or refractory CLL. Across both trials, the safety and tolerability of *Calquence* were consistent with its established profile.

During the period, AstraZeneca presented results from the interim analysis of the ELEVATE TN trial at the aforementioned 2019 ASH meeting. The trial results demonstrated that *Calquence*, combined with obinutuzumab or as monotherapy, significantly improved PFS compared to chlorambucil plus obinutuzumab, a standard chemo-immunotherapy treatment, in patients with previously untreated CLL. At a median follow-up of 28.3 months, *Calquence*, in combination with obinutuzumab or as a monotherapy, significantly reduced the risk of disease progression or death by 90% and 80%, respectively, versus chlorambucil plus obinutuzumab.

Adverse events (AEs) led to treatment discontinuation in 11.2% of patients treated with *Calquence* in combination with obinutuzumab and 8.9% of patients treated with *Calquence* monotherapy versus 14.1% of patients treated with chlorambucil plus obinutuzumab. With over two years of follow-up, 79% of patients in both the *Calquence*-containing arms remain on *Calquence* as a monotherapy. In the *Calquence* combination arm (n=178), the most common AEs of any grade (≥30%) included headache (39.9%), diarrhoea (38.8%) and neutropenia (31.5%). In the *Calquence* monotherapy arm (n=179), the most common AEs of any grade (≥30%) included headache (36.9%) and diarrhoea (34.6%). In the chlorambucil plus obinutuzumab arm (n=169), the most common AEs of any grade (≥30%) included neutropenia (45.0%), infusion-related reaction (39.6%) and nausea.

Selumetinib (NF1)
In November 2019, the Company announced that the US FDA had accepted a New Drug Application (NDA) and granted Priority Review status for selumetinib as a potential new medicine for paediatric patients aged three years and older with NF1 and symptomatic, inoperable plexiform neurofibromas. This was the first acceptance of a regulatory submission for an oral monotherapy for the treatment of NF1, a rare and incurable genetic condition. A PDUFA date is set for the second quarter of 2020.

CVRM

a) *Farxiga* (heart failure)
In January 2020, the Company announced the US FDA had accepted an sNDA and granted Priority Review status for *Farxiga* to reduce the risk of CV death or the worsening of heart failure in adults with heart failure with reduced ejection fraction, with and without T2D; the PDUFA date is set for the second quarter of 2020. During the period, the Company also received regulatory submission acceptance from the European Medicines Agency (EMA). Regulatory submissions were also achieved in Japan and China during the period.

b) *Qtrilmet* (T2D)
During the period, the Company announced that the European Commission had approved *Qtrilmet* (metformin hydrochloride, saxagliptin and dapagliflozin) modified-release tablets intended to improve glycaemic control in adults with T2D.

c) *Brilinta* (stroke)
High-level results from the Phase III THALES trial showed that 90mg *Brilinta*, used twice daily and taken with aspirin for 30 days, reached a statistically significant and clinically meaningful reduction in the risk of the primary composite endpoint of stroke and death, compared to aspirin alone.

d) *Epanova* (mixed dyslipidaemia)
Following the recommendation from an independent Data Monitoring Committee, AstraZeneca decided to terminate the Phase III STRENGTH trial for *Epanova*, due to its low likelihood of demonstrating a benefit to patients with MDL who are at increased risk of CV disease. STRENGTH was a large-scale, global CVOT designed to evaluate the safety and efficacy *of Epanova* compared to placebo, both in combination with SoC statin medicines.

d) Cotadutide (NASH)
During the period, the US FDA granted Fast Track designation for cotadutide as a treatment for NASH.

Table 29: Key large CVRM outcomes trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Farxiga					
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[63] + SoC Arm 2: placebo + SoC	Time to first occurrence of CV death or hHF or an urgent HF visit	FPCD Q1 2017 LPCD Q4 2018	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 Q4 2018 First data anticipated 2021+	Recruitment ongoing Fast Track designation (US)

[63] *Quaque die*, or once a day.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
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[64] or CV death or renal death	FPCD Q1 2017 First data anticipated 2021	Fast Track designation (US)
Brilinta					
Phase III THEMIS	c.19,000 patients with T2D and CAD without a history of MI[65] or stroke	Arm 1: *Brilinta* 60mg BID[66] 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
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 LPCD Q4 2019	Primary endpoint met

e) Roxadustat (anaemia)

In November 2019, AstraZeneca and FibroGen presented, during two oral sessions, detailed results from the Phase III OLYMPUS and ROCKIES trials at the American Society of Nephrology (ASN) Kidney Week 2019 in Washington, DC. The results showed that roxadustat significantly increased haemoglobin levels in non-dialysis dependent (NDD) patients with anaemia from CKD compared to placebo, and dialysis-dependent (DD) patients with anaemia from CKD compared to epoetin alfa, respectively.

The companies presented pooled efficacy and CV safety analyses from the pivotal Phase III programme during an oral late-breaking abstract session. The primary efficacy endpoint was achieved in the pooled analyses for NDD and DD patients, and in all individual Phase III trials. The pooled analyses showed that roxadustat did not increase the risk of MACE[67], MACE+[68] and all-cause mortality in NDD patients compared to placebo and DD patients compared to epoetin alfa. In a clinically important predefined subgroup of incident dialysis[69] patients, roxadustat reduced the risk of MACE and MACE+ and showed a trend towards lower risk of all-cause mortality relative to epoetin alfa.

In December 2019, FibroGen announced the regulatory submission of an NDA to the US FDA for roxadustat as a potential new medicine for the treatment of anaemia from CKD, in both NDD and DD CKD patients. Data from the pooled analyses, together with other statistical analyses, formed part of the submission. The regulatory

[64] End-stage renal disease.
[65] Myocardial infarction.
[66] *Bis in die*, or twice a day.
[67] MACE is defined as all-cause mortality, stroke and myocardial infarction.
[68] MACE+ is defined as MACE, unstable angina requiring hospitalisation and congestive heart failure requiring hospitalisation.
[69] Patients who have been on dialysis for four months or fewer.

submission was subsequently accepted by the US FDA in February 2020 with a PDUFA date set for the fourth quarter of 2020. Roxadustat is approved in China for the treatment of patients with anaemia from CKD, regardless of whether they require dialysis, and in Japan for the treatment of DD patients with anaemia from CKD. In January 2020, FibroGen's collaborator, Astellas, submitted in Japan an sNDA for the approval of roxadustat as a potential treatment of anaemia from CKD in NDD patients.

f) *Lokelma* (hyperkalaemia)
In January 2020, *Lokelma* was approved in China for the treatment of adult patients with hyperkalaemia, (elevated levels of potassium in the blood). The approval by the NMPA was based on positive results from the extensive *Lokelma* clinical-trial programme and a pharmacodynamic trial in China which showed that patients receiving *Lokelma* experienced a significant, rapid and sustained reduction of potassium levels in the blood. In 2019, the NMPA included *Lokelma* on the Accelerated Approval list of 'Overseas New Drugs in Clinical Urgent Needs for China', recognising the significant unmet need for effective medicines treating hyperkalaemia. In Japan, a regulatory decision is expected in the first half of the year.

Respiratory (and immunology)

a) *Symbicort* (mild asthma)
In December 2019, AstraZeneca made a regulatory submission in China for *Symbicort* for the treatment of mild asthma which contained data from the Phase III SYGMA programme, looking at the use of *Symbicort* use as an anti-inflammatory reliever 'as needed'.

b) *Breztri* (COPD)
In December 2019, AstraZeneca announced that *Breztri* (budesonide/glycopyrronium/formoterol fumarate) had been approved in China for the maintenance treatment of COPD, becoming the first approval by the NMPA for a triple-combination therapy in a pressurised metered-dose inhaler. The approval followed designation of priority-review status and was based on results from the Phase III KRONOS trial, in which *Breztri* demonstrated a statistically significant improvement in trough forced expiratory volume in one second (FEV1), the regulatory endpoint for China, compared with dual-combination therapies *Bevespi* (glycopyrronium/formoterol fumarate) and PT009 (budesonide/formoterol fumarate).

Breztri was approved and launched in Japan in the third quarter of 2019.

c) *Fasenra* (eosinophilic diseases)
In the Phase IIIb ANDHI trial, *Fasenra,* when added to SoC, demonstrated a statistically significant reduction in the annual rate of asthma exacerbations when compared to placebo in patients with baseline blood eosinophil counts greater than or equal to 150 cells per microlitre. Safety and tolerability data were consistent with the known profile of the medicine and full results are expected to be presented at a forthcoming medical meeting.

Table 30: Key *Fasenra* trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
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

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[70] 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 OSTRO	Patients (aged 18-75 years) with severe bilateral nasal polyposis; symptomatic, despite SoC	Placebo or *Fasenra* 30mg Q8W SC	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 oral corticosteroids (CN)	Placebo or *Fasenra* 30mg Q8W SC	Annual asthma-exacerbation rate	FPCD Q4 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	Placebo or *Fasenra* 100mg Q8W SC	Annualised rate of moderate or severe COPD exacerbations	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing
Phase III MANDARA	Eosinophilic granulomatosis with polyangiitis	*Fasenra* 30mg or mepolizumab 3x100mg Q4W	Proportion of patients who achieve remission, defined as a score[71] =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)

[70] Oral corticosteroid.
[71] Birmingham Vasculitis Activity Score.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III NATRON	HES[72]	Placebo or *Fasenra* 30mg Q4W SC	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	Placebo or *Fasenra* 30mg Q4W SC	Proportion of patients with a histologic response Changes from baseline in dysphagia PRO[73]	Data anticipated 2021+	Initiating Orphan Drug Designation (US)

e) Anifrolumab (lupus)

In November 2019, at the American College of Rheumatology Annual Meeting in Atlanta, US, detailed results were presented from the positive Phase III TULIP 2 trial for anifrolumab, a potential new medicine for the treatment of moderate to severe SLE. The data demonstrated superiority across multiple efficacy endpoints versus placebo, with both arms receiving SoC as background treatment. TULIP 2 data were subsequently published in *The New England Journal of Medicine*; data from the TULIP 1 trial were also presented and published simultaneously in *The Lancet Rheumatology*.

The TULIP 1 trial did not meet its primary endpoint, based on the SLE Responder Index 4 composite measure[74]. The analyses of secondary endpoints showed, however, efficacy consistent with TULIP 2 on BICLA[75] response, reductions in OCS use, and improvements in skin disease activity. Regulatory submissions for anifrolumab are expected in the second half of 2020.

Table 31: Key anifrolumab trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III TULIP 1	Moderate to severely-active SLE patients on background SoC	Placebo or anifrolumab 150mg or 300mg i.v. Q4W	Response in SLE responder index at week 52	FPCD Q4 2015 LPCD Q4 2017	Primary endpoint not met Fast Track designation (US)
Phase III TULIP 2	Moderate to severely-active SLE patients on background SoC	Placebo or anifrolumab 300mg i.v. Q4W	Response in BICLA at week 52	FPCD Q4 2015 LPCD Q4 2017	Primary endpoint met Fast Track designation (US)
Phase III	Moderate to severely active SLE patients on	Placebo or anifrolumab 300mg i.v.	Long-term safety over 152 weeks	FPCD Q2 2016	Recruitment completed

[72] Hypereosinophilic syndrome.
[73] Patient-reported outcomes.
[74] The Systemic Lupus Erythematosus Responder Index, a primary outcome measure assessing changes in SLE disease activity without associated worsening symptoms in other diseases.
[75] The BILAG-Based Composite Lupus Assessment, a composite index measuring disease activity.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
TULIP LTE[76]	background SoC who have completed a Phase III anifrolumab trial	Q4W		LPCD Q4 2018 Data anticipated 2021+	Fast Track designation (US)

f) Brazikumab (Crohn's disease and ulcerative colitis)

In January 2020, it was announced that AstraZeneca will recover the global rights to brazikumab (formerly MEDI2070), a monoclonal antibody targeting IL-23, from Allergan. Brazikumab is currently in a Phase IIb/III programme in Crohn's disease and a Phase IIb trial in ulcerative colitis. AstraZeneca and Allergan will terminate their existing license agreement and all rights to brazikumab will revert to AstraZeneca. The transaction is expected to complete in the first quarter of 2020, subject to regulatory approvals associated with AbbVie Inc.'s proposed acquisition of Allergan and its timely completion. Under the termination agreement, Allergan will fund up to an agreed amount, estimated to be the total costs expected to be incurred by AstraZeneca until completion of development for brazikumab in Crohn's disease and ulcerative colitis, including the development of a companion diagnostic.

Pursuant to the 2012 collaboration between Amgen Inc (Amgen) and AstraZeneca to jointly develop and commercialise a clinical-stage inflammation portfolio, Amgen is entitled to receive a high single-digit to low double-digit royalty on sales of brazikumab if approved and launched. This includes the original inventor royalty. Other than this, AstraZeneca will own all rights and benefits arising from the medicine with no other payments due to Amgen.

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.

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[76] Long-term extension.

Condensed consolidated statement of comprehensive income - FY 2019

For the **year** ended 31 December	**2019 $m**	**2018 $m**
Product Sales	23,565	21,049
Collaboration Revenue	819	1,041
Total Revenue	24,384	22,090
Cost of sales	(4,921)	(4,936)
Gross Profit	19,463	17,154
Distribution costs	(339)	(331)
Research and development expense	(6,059)	(5,932)
Selling, general and administrative costs	(11,682)	(10,031)
Other operating income and expense	1,541	2,527
Operating Profit	2,924	3,387
Finance income	172	138
Finance expense	(1,432)	(1,419)
Share of after-tax losses in associates and joint ventures	(116)	(113)
Profit Before Tax	1,548	1,993
Taxation	(321)	57
Profit for the period	1,227	2,050
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(364)	(46)
Net losses on equity investments measured at fair value through other comprehensive income	(28)	(171)
Fair-value movements related to own credit risk on bonds designated as fair-value through profit or loss	(5)	8
Tax on items that will not be reclassified to profit or loss	21	56
	(376)	(153)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	40	(450)
Foreign exchange arising on designating borrowings in net investment hedges	(252)	(520)
Fair-value movements on cash flow hedges	(101)	(37)
Fair-value movements on cash flow hedges transferred to profit or loss	52	111
Fair-value movements on derivatives designated in net investment hedges	35	(8)
Costs of hedging	(47)	(54)
Amortisation of loss on cash flow hedge	-	1
Tax on items that may be reclassified subsequently to profit or loss	38	51
	(235)	(906)
Other comprehensive loss for the period, net of tax	(611)	(1,059)
Total comprehensive income for the period	616	991
Profit attributable to:		
Owners of the Parent	1,335	2,155
Non-controlling interests	(108)	(105)
	1,227	2,050
Total comprehensive income attributable to:		
Owners of the Parent	723	1,097
Non-controlling interests	(107)	(106)
	616	991
Basic earnings per $0.25 Ordinary Share	$1.03	$1.70
Diluted earnings per $0.25 Ordinary Share	$1.03	$1.70
Weighted average number of Ordinary Shares in issue (millions)	1,301	1,267
Diluted weighted average number of Ordinary Shares in issue (millions)	1,301	1,267

Condensed consolidated statement of comprehensive income - Q4 2019[77]

For the **quarter** ended 31 December	**2019 $m**	**2018 $m**
Product Sales	6,250	5,768
Collaboration Revenue	414	649
Total Revenue	6,664	6,417
Cost of sales	(1,378)	(1,637)
Gross Profit	5,286	4,780
Distribution costs	(92)	(93)
Research and development expense	(2,091)	(2,012)
Selling, general and administrative costs	(3,026)	(2,600)
Other operating income and expense	500	1,002
Operating Profit	577	1,077
Finance income	39	26
Finance expense	(351)	(337)
Share of after-tax losses in associates and joint ventures	(25)	(36)
Profit Before Tax	**240**	**730**
Taxation	37	279
Profit for the period	277	1,009
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(213)	(184)
Net gains/(losses) on equity investments measured at fair value through other comprehensive income	108	(330)
Fair-value movements related to own credit risk on bonds designated as fair value through profit or loss	(4)	5
Tax on items that will not be reclassified to profit or loss	-	121
	(109)	(388)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	425	(99)
Foreign exchange arising on designating borrowings in net investment hedges	239	(71)
Fair-value movements on cash flow hedges	55	(42)
Fair-value movements on cash flow hedges transferred to profit or loss	(57)	39
Fair-value movements on derivatives designated in net investment hedges	-	(14)
Costs of hedging	(12)	(19)
Amortisation of loss on cash flow hedge	-	1
Tax on items that may be reclassified subsequently to profit or loss	(24)	12
	626	(193)
Other comprehensive income/(loss) for the period, net of tax	517	(581)
Total comprehensive income for the period	794	428
Profit attributable to:		
Owners of the Parent	313	1,034
Non-controlling interests	(36)	(25)
	277	1,009
Total comprehensive income attributable to:		
Owners of the Parent	830	453
Non-controlling interests	(36)	(25)
	794	428
Basic earnings per $0.25 Ordinary Share	$0.24	$0.82
Diluted earnings per $0.25 Ordinary Share	$0.24	$0.82
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

[77] The Q4 2019 and Q4 2018 information in respect of the three months ended 31 December 2019 and 31 December 2018 respectively included in the Condensed Financial Statements has not been audited by PricewaterhouseCoopers LLP.

Condensed consolidated statement of financial position

	At 31 Dec 2019 $m	At 31 Dec 2018 $m
Assets		
Non-current assets		
Property, plant and equipment	7,688	7,421
Right-of-use assets	647	-
Goodwill	11,668	11,707
Intangible assets	20,833	21,959
Investments in associates and joint ventures	58	89
Other investments	1,401	833
Derivative financial instruments	61	157
Other receivables	740	515
Deferred tax assets	2,718	2,379
	45,814	45,060
Current assets		
Inventories	3,193	2,890
Trade and other receivables	5,761	5,574
Other investments	849	849
Derivative financial instruments	36	258
Income tax receivable	285	207
Cash and cash equivalents	5,369	4,831
Assets held for sale	70	982
	15,563	15,591
Total assets	61,377	60,651
Liabilities		
Current liabilities		
Interest-bearing loans and borrowings	(1,822)	(1,754)
Lease liabilities	(188)	-
Trade and other payables	(13,987)	(12,841)
Derivative financial instruments	(36)	(27)
Provisions	(723)	(506)
Income tax payable	(1,361)	(1,164)
	(18,117)	(16,292)
Non-current liabilities		
Interest-bearing loans and borrowings	(15,730)	(17,359)
Lease liabilities	(487)	-
Derivative financial instruments	(18)	(4)
Deferred tax liabilities	(2,490)	(3,286)
Retirement benefit obligations	(2,807)	(2,511)
Provisions	(841)	(385)
Other payables	(6,291)	(6,770)
	(28,664)	(30,315)
Total liabilities	(46,781)	(46,607)
Net assets	14,596	14,044
Equity		
Capital and reserves attributable to equity holders of the Parent		
Share capital	328	317
Share premium account	7,941	4,427
Other reserves	2,046	2,041
Retained earnings	2,812	5,683
	13,127	12,468
Non-controlling interests	1,469	1,576
Total equity	14,596	14,044

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	-	-	-	2,155	2,155	(105)	2,050
Other comprehensive loss	-	-	-	(1,058)	(1,058)	(1)	(1,059)
Transfer to other reserves	-	-	12	(12)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,539)	(3,539)	-	(3,539)
Issue of Ordinary Shares	-	34	-	-	34	-	34
Share-based payments charge for the period	-	-	-	219	219	-	219
Settlement of share plan awards	-	-	-	(212)	(212)	-	(212)
Net movement	-	34	12	(2,538)	(2,492)	(106)	(2,598)
At 31 Dec 2018	**317**	**4,427**	**2,041**	**5,683**	**12,468**	**1,576**	**14,044**
At 1 Jan 2019	**317**	**4,427**	**2,041**	**5,683**	**12,468**	**1,576**	**14,044**
Adoption of new accounting standards[78]	-	-	-	54	54	-	54
Profit for the period	-	-	-	1,335	1,335	(108)	1,227
Other comprehensive loss	-	-	-	(612)	(612)	1	(611)
Transfer to other reserves	-	-	5	(5)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,579)	(3,579)	-	(3,579)
Issue of Ordinary Shares[79]	11	3,514	-	-	3,525	-	3,525
Share-based payments charge for the period	-	-	-	259	259	-	259
Settlement of share plan awards	-	-	-	(323)	(323)	-	(323)
Net movements	11	3,514	5	(2,871)	659	(107)	552
At 31 Dec 2019	**328**	**7,941**	**2,046**	**2,812**	**13,127**	**1,469**	**14,596**

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

Condensed consolidated statement of cash flows

For the **year** ended 31 December	**2019 $m**	**2018 $m**
Cash flows from operating activities		
Profit before tax	1,548	1,993
Finance income and expense	1,260	1,281
Share of after-tax losses of associates and joint ventures	116	113
Depreciation, amortisation and impairment	3,762	3,753
Increase in working capital and short-term provisions	(346)	(639)
Gains on disposal of intangible assets	(1,243)	(1,885)
Fair value movements on contingent consideration arising from business combinations	(614)	(495)
Non-cash and other movements	378	(290)
Cash generated from operations	4,861	3,831
Interest paid	(774)	(676)
Tax paid	(1,118)	(537)
Net cash inflow from operating activities	2,969	2,618
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(709)	(349)
Purchase of property, plant and equipment	(979)	(1,043)
Disposal of property, plant and equipment	37	12
Purchase of intangible assets	(1,481)	(328)
Disposal of intangible assets	2,076	2,338
Movement in profit-participation liability[80]	150	-
Purchase of non-current asset investments	(13)	(102)
Disposal of non-current asset investments	18	24
Movement in short-term investments, fixed deposits and other investing instruments	194	405
Payments to associates and joint ventures	(74)	(187)
Interest received	124	193
Net cash (outflow)/inflow from investing activities	(657)	963
Net cash inflow before financing activities	2,312	3,581
Cash flows from financing activities		
Proceeds from issue of share capital	3,525	34
Issue of loans	500	2,971
Repayment of loans	(1,500)	(1,400)
Dividends paid	(3,592)	(3,484)
Hedge contracts relating to dividend payments	4	(67)
Repayment of obligations under leases	(186)	-
Movement in short-term borrowings	(516)	(98)
Net cash outflow from financing activities	(1,765)	(2,044)
Net increase in cash and cash equivalents in the period	547	1,537
Cash and cash equivalents at the beginning of the period	4,671	3,172
Exchange rate effects	5	(38)
Cash and cash equivalents at the end of the period	5,223	4,671
Cash and cash equivalents consist of:		
Cash and cash equivalents	5,369	4,831
Overdrafts	(146)	(160)
	5,223	4,671

[80] 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 Condensed Financial Information

1 Basis of preparation and accounting policies

The Condensed Consolidated Financial Statements for the year ended 31 December 2019 have been prepared in accordance with International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB) and as adopted by the EU. The UK has yet to announce its post-Brexit IFRS-adoption process and, for the current time, will follow the EU approval process.

These Condensed Consolidated Financial Statements comprise the financial results of AstraZeneca plc for the years to 31 December 2019 and 2018 together with the Statement of financial position as at 31 December 2019 and 2018. The results for the year to 31 December 2019 have been extracted from the 31 December 2019 audited Consolidated Financial Statements which have been approved by the Board of Directors. These have not yet been delivered to the Registrar of Companies but are expected to be published on 3 March 2020 within the Annual Report and Form 20-F Information 2019.

The financial information set out above does not constitute the Company's statutory accounts for the years to 31 December 2019 or 2018 but is derived from those accounts. The auditors have reported on those accounts; their reports (i) were 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 in respect of the accounts for the year to 31 December 2019 or 31 December 2018. Statutory accounts for the year to 31 December 2019 were approved by the Board of Directors for release on 14 February 2020.

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 Condensed Consolidated Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2018.

IFRS 3

AstraZeneca had proposed to adopt the October 2018 update to IFRS 3, which changed the definition of a business, from 1 January 2019, and has previously published interim financial statements on this basis. This was done on the basis that it was considered highly probable that the amendment would be endorsed by the European Commission during 2019 before its effective date of 1 January 2020 with early adoption permitted, following a recommendation from the European Financial Reporting Advisory Group (EFRAG), the association set up to provide advice to the European Commission on whether newly issued or revised IFRS Standards meet the criteria for endorsement for use in the EU.

The change in definition of a business within IFRS 3 introduces an 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. This change is expected to provide more reliable and comparable information about certain transactions as it provides more consistency in accounting in the pharmaceutical industry for substantially similar transactions that under the previous definition may have been accounted for in different ways despite limited differences in substance.

During the year, the EFRAG amended its guidance on the expected date of endorsement, and the European Commission is expected to endorse the change during 2020, with application required for accounting periods beginning on or after 1 January 2020. Accordingly, this amendment has not been applied in this preliminary announcement; this has, however, not resulted in a different accounting treatment for any transactions undertaken during the year, when compared with the amended version of IFRS 3, pending endorsement.

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.

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 $186m 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 materially 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.

IFRS 9, IAS 39 and IFRS 7

The Group has early adopted the amendments to IFRS 9 'Financial Instruments', IAS 39 'Financial Instruments: Recognition and Measurement' and IFRS 7 'Financial Instruments: Disclosures'. These relate to IBOR reform and were endorsed by the EU on 6 January 2020. The replacement of benchmark interest rates such as LIBOR and other interbank offered rates ('IBORs') is a priority for global regulators. The amendments provide relief from applying specific hedge accounting requirements to hedge relationships directly affected by IBOR reform and have the effect that IBOR reform should generally not cause hedge accounting to terminate. There is no financial impact from the early adoption of these amendments.

The Group has one IFRS 9 designated hedge relationship that is potentially impacted by IBOR reform: our euro 300m cross currency interest rate swap in a fair value hedge relationship with euro 300m of our euro 750m 0.875% 2021 non-callable bond. This swap references three-month USD LIBOR and uncertainty arising from the Group's exposure to IBOR reform will cease when the swap matures in 2021. The implications on the wider business of IBOR reform will be assessed during 2020.

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 31 December 2019 the Group has $10.4bn in financial resources (cash and cash-equivalent balances of $5.4bn, $0.9bn of liquid fixed income securities 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 2020, with only $2.0bn of borrowings due within one year). The Group's revenues are largely derived from sales of medicines 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 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 Condensed 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 year ended 31 December 2019 is stated after charging restructuring costs of $347m ($697m for the year ended 31 December 2018). These have been charged to profit as follows:

	FY 2019 $m	FY 2018 $m	Q4 2019[77] $m	Q4 2018[77] $m
Cost of sales	73[81]	432	(49)	355
Research and development expense	101	94	19	(1)
Selling, general and administrative costs	173	181	26	71
Other operating income and expense	-	(10)	-	1
Total	**347**	**697**	**(4)**	**426**

[81] Includes impairment reversals totaling $93m in relation to biologic-medicine manufacturing sites in Colorado, US.

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[82] $m	Cash flow $m	Non-cash & other $m	Exchange movements $m	At 31 Dec 2019 $m
Non-current instalments of loans	(17,359)	-	-	1,578	51	(15,730)
Non-current instalments of leases	-	(557)	-	70	-	(487)
Total long-term debt	**(17,359)**	**(557)**	**-**	**1,648**	**51**	**(16,217)**
Current instalments of loans	(999)	-	1,000	(1,598)	-	(1,597)
Current instalments of leases	-	(163)	206	(231)	-	(188)
Commercial paper	(211)	-	211	-	-	-
Bank collateral	(384)	-	313	-	-	(71)
Other short-term borrowings excluding overdrafts	-	-	(8)	-	-	(8)
Overdraft	(160)	-	13	-	1	(146)
Total current debt	**(1,754)**	**(163)**	**1,735**	**(1,829)**	**1**	**(2,010)**
Gross borrowings	**(19,113)**	**(720)**	**1,735**	**(181)**	**52**	**(18,227)**
Net derivative financial instruments	384	-	(214)	(127)	-	43
Net borrowings	**(18,729)**	**(720)**	**1,521**	**(308)**	**52**	**(18,184)**
Cash and cash equivalents	4,831	-	534	-	4	5,369
Other investments - current	849	-	16	(14)	(2)	849
Other investments - non-current	46	-	-	16	-	62
Cash and investments	**5,726**	**-**	**550**	**2**	**2**	**6,280**
Net debt	**(13,003)**	**(720)**	**2,071**	**(306)**	**54**	**(11,904)**

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

Other investments - non-current are included within the balance of $1,401m (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 $2,146m (31 December 2018: $1,838m) shown in non-current other payables.

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.

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

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 $56m have been recognised in the year ended 31 December 2019. These are presented in Net losses 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 $2,250m of other investments, $4,109m held in money market funds, $336m of loans designated at fair value through profit or loss, $339m of loans designated in a fair value hedge relationship and $43m of derivatives as at 31 December 2019. The total fair value of interest-bearing loans and borrowings at 31 December 2019, which have a carrying value of $18,227m in the Condensed Consolidated Statement of Financial Position, was $20,549m. 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	(454)	(255)	(709)	(349)
Revaluations	(516)	(98)	(614)	(495)
Discount unwind	287	69	356	416
At 31 December	**3,300**	**839**	**4,139**	**5,106**

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 the global diabetes alliance of $3,300m (31 December 2018: $3,983m) would increase/decrease by $330m 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 and the interim financial statements for the three months ended 30 September 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 we are able to make a reasonable estimate of the loss, AstraZeneca records the loss absorbed or makes a provision for its best estimate of the expected loss. The position could change over time and the estimates that the Company made, and upon which the Company have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Disclosures and herein.

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

Matters disclosed in respect of the fourth quarter of 2019 and to 14 February 2020

Patent litigation

***Tagrisso*: US patent proceedings**
In February of 2020, in response to Paragraph IV notices from multiple ANDA filers, AstraZeneca filed patent infringement lawsuits in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleged that a generic version of *Tagrisso*, if approved and marketed, would infringe AstraZeneca's US Patent No. 10,183,020. No trial date has been set.

***Calquence*: US patent proceedings**
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 alleging that their medicine, *Imbruvica*, infringes a US patent owned by Acerta Pharma. In November 2018, Janssen Biotech, Inc. (Janssen) intervened as a defendant.

In October 2019, AstraZeneca entered into settlement agreements with Pharmacyclics and Janssen, resolving all patent litigation between the parties relating to *Calquence* and *Imbruvica*. A provision was taken.

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 31 December 2019 of $2,146m (FY 2018: $1,838m, 2017: FY $1,823m).

***Faslodex*: US patent proceedings**
As previously disclosed, AstraZeneca had filed and then resolved a series of patent infringement lawsuits in the US District Court for the District of New Jersey (the District Court) relating to four patents listed in the US FDA Orange Book with reference to *Faslodex* after receiving a Paragraph IV notices from several companies relating to Abbreviated New Drug Applications (ANDA) seeking US FDA approval to market a generic version of *Faslodex* prior to the expiration of AstraZeneca's patents, and the District Court entered consent judgments ending all of those lawsuits. In October 2019, AstraZeneca filed a new patent infringement lawsuit in the District Court after receiving a Paragraph IV letter, relating to the same four listed patents, from another company that submitted an ANDA seeking US FDA approval to market a generic version of *Faslodex* prior to the expiration of AstraZeneca's patents.

***Onglyza*: patent proceedings outside the US**
In Canada, in November 2019, Sandoz Canada Inc. sent a Notice of Allegation to AstraZeneca challenging the validity of Canadian substance patent no. 2402894 (expiry March 2021) and formulation patent no. 2568391 (expiry May 2025) related to *Onglyza*. AstraZeneca commenced an action in response in January 2020.

***Symbicort*: US patent proceedings**
As previously disclosed, AstraZeneca brought ANDA litigations against Mylan Pharmaceuticals Inc. (Mylan) and 3M Company (3M) in the US District Court for the Northern District of West Virginia and against Teva Pharmaceuticals USA, Inc. (Teva) and Catalent Pharma Solutions, LLC (Catalent) in the US District Court for the District of Delaware. In November 2019, AstraZeneca filed an Amended Complaint in the US District Court for the Northern District of West Virginia against Mylan and 3M adding allegations that their proposed generic version of *Symbicort*, if approved and marketed, would infringe AstraZeneca's US Patent No. 10,166,247 (the '247 patent) and removing allegations of infringement of US Patent No. 7,967,011. In November 2019, Mylan and 3M responded to the Amended Complaint and alleged that their proposed generic product does not infringe the asserted patents and/or that the asserted patents are invalid and/or unenforceable. In December 2019, AstraZeneca settled its ANDA action with Teva and Catalent and that matter is now closed. The trial of the Mylan and 3M matter has been scheduled for July 2020.

***Movantik*: US patent proceedings**

As previously disclosed, in December 2018, AstraZeneca initiated ANDA litigation against Apotex, Inc. and Apotex Corp. and against MSN Laboratories in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleges that the generic companies' versions of *Movantik*, if approved and marketed, would infringe US Patent No. 9,012,469. A trial has been scheduled for March 2021.

In November 2019, AstraZeneca initiated ANDA litigation against Aurobindo Pharma U.S.A. in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleges that the generic company's versions of *Movantik*, if approved and marketed, would infringe US Patent No. 9,012,469.

Product liability litigation

***Farxiga* and *Xigduo* XR**

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

***Nexium* and *Losec*/*Prilosec*: US proceedings**

As previously disclosed, in the US, AstraZeneca is defending various lawsuits brought in federal and state courts involving multiple plaintiffs claiming that they have been diagnosed with various injuries following treatment with proton pump inhibitors, including *Nexium* and *Prilosec*. In May 2017, counsel for a group of such plaintiffs claiming that they have been diagnosed with kidney injuries filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking the transfer of any currently pending federal court cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation (MDL) proceeding. In August 2017, the JPML granted the motion and consolidated the pending federal court cases in an MDL proceeding in federal court in New Jersey for pre-trial purposes. A trial in the MDL has been scheduled for November 2021.

In July 2019, counsel for a similarly defined group of plaintiffs with claims pending in New Jersey state courts petitioned the New Jersey State Administrative Director of the Courts to centralise judicial management of all plaintiffs' claims alleging kidney injuries pending in that state in a coordinated multicounty litigation (MCL) proceeding. The MCL has been centralised in Atlantic County.

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. Trial is scheduled for February 2020.

Ocimum lawsuit
As previously disclosed, in December 2015, AstraZeneca was served with a complaint filed by Ocimum Biosciences, Ltd. (Ocimum) in the Superior Court for the State of Delaware that alleges, among other things, breaches of contractual obligations and misappropriation of trade secrets, relating to a now terminated 2001 licensing agreement between AstraZeneca and Gene Logic, Inc. (Gene Logic), the rights to which Ocimum purports to have acquired from Gene Logic. In December 2019, the court granted AstraZeneca's motion for summary judgment and dismissed the case.

Government investigations/proceedings

Crestor
Qui tam litigation
As previously disclosed, in the US, in January and February 2014, AstraZeneca was served with lawsuits filed in the US District Court for the District of Delaware under the *qui tam* (whistle-blower) provisions of the federal False Claims Act and related state statutes, alleging that AstraZeneca directed certain employees to promote *Crestor* off-label and provided unlawful remuneration to physicians in connection with the promotion of *Crestor*. The DOJ and all US states have declined to intervene in the lawsuits. In March 2019, AstraZeneca filed a motion to dismiss the complaint. Oral argument on the motion to dismiss is scheduled for February 2020.

Multi-product litigation
Litigation in Washington state
As previously disclosed, in September 2018, a lawsuit against AstraZeneca and several other defendants was unsealed in the US District Court for the Western District of Washington (the District Court). The complaint alleged that the defendants violated various laws, including state and federal false claims acts, by offering clinical educator and reimbursement support programmes. In September 2018, the government moved to dismiss the lawsuit against AstraZeneca and similar lawsuits filed against other companies by relator, Health Choice Alliance. In November 2019, the District Court granted the government's motion and dismissed the case.

6 Subsequent events

Following the recommendation from an independent Data Monitoring Committee, AstraZeneca decided in January 2020 to terminate the Phase III STRENGTH trial for *Epanova*, due to its low likelihood of demonstrating a benefit to patients with MDS who are at increased risk of CV disease. This was considered to be an adjusting event after the reporting period, resulting in a full impairment of the *Epanova* intangible asset of $533m recorded in Reported R&D Expense in FY 2019, and a provision for inventory and supply-related costs of $115m recorded in Reported and Core Cost of Sales, also in FY 2019.

In January 2020, the Company announced that it had agreed to divest the global commercial rights to a number of established hypertension medicines, including *Inderal*, *Tenormin* and *Zestril* to Atnahs Pharma. Atnahs Pharma will make an upfront payment of $350m to AstraZeneca. AstraZeneca may also receive future sales-contingent payments of up to $40m between 2020 and 2022. Income arising from the upfront and future payments will be reported in AstraZeneca's financial statements within Other Operating Income and Expense. The divestment is expected to complete in the first quarter of 2020.

In January 2020, the Company announced that it will recover the global rights to brazikumab (formerly MEDI2070), a monoclonal antibody targeting IL-23, from Allergan. Brazikumab is currently in a Phase IIb/III programme in Crohn's disease and a Phase IIb trial in ulcerative colitis. AstraZeneca and Allergan will terminate their existing license agreement and all rights to brazikumab will revert to AstraZeneca. The transaction is expected to complete in the first quarter of 2020, subject to regulatory approvals associated with AbbVie's proposed acquisition of Allergan and its timely completion. Under the termination agreement, Allergan will fund up to an agreed amount, estimated to be the total costs expected to be incurred by AstraZeneca until completion of development for brazikumab in Crohn's disease and ulcerative colitis, including the development of a companion diagnostic.

Pursuant to the 2012 collaboration between Amgen and AstraZeneca to jointly develop and commercialise a clinical-stage inflammation portfolio, Amgen is entitled to receive a high single-digit to low double-digit royalty on sales of brazikumab if approved and launched. This includes the original inventor royalty. Other than this, AstraZeneca will own all rights and benefits arising from the medicine with no other payments due to Amgen.

In January 2020, AstraZeneca sold a proportion of its equity portfolio, receiving consideration of $184m.

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7 Product Sales analysis - FY 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. The CER information in respect of FY 2019 included in the Consolidated Financial Information has not been audited by PricewaterhouseCoopers LLP. *Denotes a legacy medicine.

	World			Emerging Markets			US		Europe			Established RoW		
	FY 2019 $m	Actual %	CER %	FY 2019 $m	Actual %	CER %	FY 2019 $m	Actual %	FY 2019 $m	Actual %	CER %	FY 2019 $m	Actual %	CER %
Oncology														
Tagrisso	3,189	71	74	762	n/m	n/m	1,268	46	474	51	59	685	n/m	n/m
Imfinzi	1,469	n/m	n/m	30	n/m	n/m	1,041	85	179	n/m	n/m	219	n/m	n/m
Lynparza	1,198	85	89	133	n/m	n/m	626	81	287	51	59	152	n/m	n/m
Calquence	164	n/m	n/m	2	n/m	n/m	162	n/m	-	n/m	n/m	-	n/m	n/m
Faslodex	892	(13)	(11)	198	29	36	328	(39)	229	3	9	137	19	17
*Zoladex**	813	8	13	492	20	28	7	(17)	135	2	7	179	(11)	(10)
*Iressa**	423	(18)	(15)	286	-	4	17	(33)	70	(36)	(32)	50	(49)	(49)
*Arimidex**	225	6	11	152	15	21	-	n/m	28	(8)	(3)	45	(9)	(9)
*Casodex**	200	-	3	127	13	19	-	(88)	16	(20)	(15)	57	(15)	(15)
Others	94	(18)	(17)	29	(6)	(3)	-	n/m	5	(24)	(19)	60	(21)	(22)
Total Oncology	**8,667**	**44**	**47**	**2,211**	**45**	**52**	**3,449**	**43**	**1,423**	**35**	**42**	**1,584**	**53**	**52**
BioPharmaceuticals: CVRM														
Farxiga	1,543	11	14	471	40	48	537	(9)	373	18	25	162	9	10
Brilinta	1,581	20	23	462	42	49	710	21	351	1	7	58	(1)	3
Bydureon	549	(6)	(5)	11	34	39	459	(3)	66	(19)	(14)	13	(32)	(28)
Onglyza	527	(3)	-	176	3	9	230	3	70	(22)	(17)	51	(14)	(12)
Byetta	110	(13)	(11)	12	47	60	68	(9)	19	(35)	(31)	11	(24)	(20)
Other diabetes	52	33	35	1	n/m	n/m	40	18	9	88	n/m	2	23	33
Lokelma	14	n/m	n/m	-	-	-	13	n/m	1	n/m	n/m	-	-	-
*Crestor**	1,278	(11)	(8)	806	(4)	-	104	(39)	148	(27)	(23)	220	-	1
Seloken/Toprol-XL*	760	7	12	686	7	13	37	(5)	25	31	31	12	(11)	(8)
*Atacand**	221	(15)	(11)	160	2	7	12	(11)	30	(57)	(57)	19	1	7
Others	271	(9)	(6)	193	(6)	(3)	(1)	(91)	59	(16)	(12)	20	(16)	(16)
BioPharmaceuticals: total CVRM	**6,906**	**3**	**6**	**2,978**	**10**	**16**	**2,209**	**n/m**	**1,151**	**(6)**	**(1)**	**568**	**(2)**	**n/m**
BioPharmaceuticals: Respiratory														
Symbicort	2,495	(3)	-	547	11	17	829	(4)	678	(12)	(7)	441	2	3
Pulmicort	1,466	14	18	1,190	20	24	110	(5)	81	(10)	(4)	85	1	1
Fasenra	704	n/m	n/m	5	n/m	n/m	482	n/m	118	n/m	n/m	99	n/m	n/m
Daliresp/Daxas	215	14	15	4	(18)	(13)	184	19	26	(8)	(3)	1	32	35
Duaklir	77	(19)	(15)	1	44	49	3	-	71	(22)	(17)	2	(65)	(64)
Bevespi	42	26	26	-	n/m	n/m	42	25	-	n/m	n/m	-	n/m	n/m
Breztri	2	n/m	n/m	-	-	-	-	-	-	-	-	2	n/m	n/m
Others	390	(13)	(9)	240	62	70	3	(88)	133	(38)	(35)	14	(74)	(73)
BioPharmaceuticals: total Respiratory	**5,391**	**10**	**13**	**1,987**	**21**	**27**	**1,653**	**17**	**1,107**	**(10)**	**(5)**	**644**	**4**	**4**
Other medicines														
Nexium	1,483	(13)	(11)	748	8	14	218	(29)	63	(73)	(72)	454	(4)	(4)
Synagis	358	(46)	(46)	-	(100)	(100)	46	(84)	312	(17)	(17)	-	n/m	n/m
Losec/Prilosec	263	(3)	1	179	11	17	10	43	49	(30)	(26)	25	(27)	(26)
Seroquel XR/IR	191	(47)	(46)	50	(58)	(57)	34	(69)	88	(18)	(14)	19	(30)	(30)
Others	306	(23)	(20)	12	(77)	(81)	128	(4)	157	(1)	2	9	(84)	(67)
Total other medicines	**2,601**	**(24)**	**(21)**	**989**	**(3)**	**1**	**436**	**(48)**	**669**	**(29)**	**(28)**	**507**	**(14)**	**(12)**
Total Product Sales	**23,565**	**12**	**15**	**8,165**	**18**	**24**	**7,747**	**13**	**4,350**	**(2)**	**2**	**3,303**	**17**	**18**

8 Product Sales analysis - Q4 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. The Q4 2019 information in respect of the three months ended 31 December 2019 included in the Consolidated Financial Information has not been audited by PricewaterhouseCoopers LLP. *Denotes a legacy medicine.

	World			Emerging Markets			US		Europe			Established RoW		
	Q4 2019 $m	Actual %	CER %	Q4 2019 $m	Actual %	CER %	Q4 2019 $m	Actual %	Q4 2019 $m	Actual %	CER %	Q4 2019 $m	Actual %	CER %
Oncology														
Tagrisso	884	49	49	209	n/m	n/m	359	24	137	48	54	179	36	32
Imfinzi	424	62	62	12	n/m	n/m	282	31	64	n/m	n/m	66	n/m	n/m
Lynparza	351	68	69	32	81	86	194	73	79	48	54	46	75	69
Calquence	56	n/m	n/m	1	n/m	n/m	54	n/m	-	n/m	n/m	-	n/m	n/m
Faslodex	166	(39)	(38)	53	24	25	17	(88)	61	20	25	35	8	4
*Zoladex**	196	8	9	112	17	20	2	(20)	35	4	8	46	(6)	(8)
*Iressa**	80	(29)	(28)	59	(1)	-	3	(40)	9	(63)	(62)	8	(64)	(65)
*Arimidex**	51	10	11	34	28	31	-	n/m	7	(12)	(9)	11	(15)	(18)
*Casodex**	43	(6)	(5)	28	22	25	-	n/m	4	(23)	(20)	11	(38)	(40)
Others	26	15	12	7	4	4	-	n/m	-	(56)	(54)	18	34	29
Total Oncology	**2,274**	**29**	**29**	**546**	**54**	**57**	**911**	**15**	**396**	**38**	**43**	**421**	**27**	**22**
BioPharmaceuticals: CVRM														
Farxiga	419	6	7	132	40	42	141	(18)	100	18	23	47	(2)	(3)
Brilinta	428	14	15	114	21	23	210	18	89	(3)	1	15	7	11
Bydureon	139	1	1	2	n/m	n/m	119	3	16	(19)	(15)	2	(40)	(38)
Onglyza	131	(11)	(10)	45	(11)	(8)	56	(8)	17	(22)	(19)	13	(13)	(12)
Byetta	27	(16)	(15)	4	90	92	16	(15)	5	(38)	(35)	2	(32)	(30)
Other diabetes	16	35	36	-	n/m	n/m	12	13	2	42	49	1	(63)	(61)
Lokelma	8	n/m	n/m	-	-	-	7	n/m	1	n/m	n/m	-	-	-
*Crestor**	296	(16)	(15)	185	(12)	(10)	16	(63)	36	(16)	(13)	58	2	(1)
*Seloken/Toprol-XL**	190	18	20	173	17	19	7	13	7	n/m	n/m	4	2	4
*Atacand**	60	3	5	43	(1)	-	4	85	8	(1)	(1)	5	15	19
Others	72	1	4	54	6	8	(1)	-	13	(14)	(11)	5	7	5
BioPharmaceuticals: total CVRM	**1,785**	**2**	**4**	**753**	**9**	**11**	**587**	**(3)**	**293**	**(1)**	**3**	**152**	**(2)**	**(3)**
BioPharmaceuticals: Respiratory														
Symbicort	712	12	13	146	12	14	244	18	170	(8)	(5)	152	34	32
Pulmicort	413	6	7	345	12	14	21	(40)	21	(2)	2	25	3	-
Fasenra	206	65	65	1	82	88	139	56	37	n/m	n/m	29	45	41
Daliresp/Daxas	58	8	8	1	1	3	50	12	7	(19)	(16)	-	n/m	n/m
Duaklir	22	(2)	-	-	n/m	n/m	3	-	18	(12)	(11)	1	(119)	(120)
Bevespi	12	12	12	-	n/m	n/m	12	11	-	n/m	n/m	-	n/m	n/m
Breztri	1	n/m	n/m	-	-	-	-	-	-	-	-	1	n/m	n/m
Others	114	(9)	(7)	75	29	32	-	n/m	35	(37)	(36)	4	(69)	(68)
BioPharmaceuticals: total Respiratory	**1,537**	**13**	**14**	**568**	**14**	**16**	**470**	**22**	**288**	**(6)**	**(3)**	**211**	**22**	**20**
Other medicines														
Nexium	353	(10)	(10)	174	5	6	43	(25)	14	(74)	(73)	122	10	6
Synagis	63	(75)	(75)	-	(100)	(100)	10	(94)	54	(44)	(44)	-	n/m	n/m
Losec/Prilosec	46	(24)	(23)	34	12	14	3	55	4	(78)	(78)	5	(49)	(51)
Seroquel XR/IR	40	(27)	(27)	9	(27)	(27)	7	(49)	21	(20)	(17)	4	(13)	(15)
Others	151	12	14	8	(42)	(47)	29	1	111	27	30	4	(31)	(30)
Total other medicines	**653**	**(27)**	**(27)**	**224**	**n/m**	**2**	**91**	**(64)**	**204**	**(28)**	**(27)**	**134**	**3**	**n/m**
Total Product Sales	**6,250**	**8**	**9**	**2,091**	**18**	**20**	**2,059**	**1**	**1,182**	**1**	**4**	**918**	**16**	**13**

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. The sequential quarterly Product Sales information included in the Consolidated Financial Information has not been audited by PricewaterhouseCoopers LLP. *Denotes a legacy medicine.

	Q1 2019	Actual	CER	Q2 2019	Actual	CER	Q3 2019	Actual	CER	Q4 2019	Actual	CER
Oncology												
Tagrisso	630	6	6	784	24	25	891	14	13	884	(1)	-
Imfinzi	295	13	13	338	15	15	412	22	22	424	3	4
Lynparza	237	13	13	283	19	20	327	16	15	351	7	8
Calquence	29	21	23	35	21	19	44	27	27	56	25	25
Faslodex	254	(6)	(6)	267	5	6	205	(23)	(23)	166	(20)	(19)
*Zoladex**	194	7	6	197	2	1	226	15	16	196	(14)	(12)
*Iressa**	134	20	18	118	(12)	(11)	91	(23)	(22)	80	(13)	(12)
*Arimidex**	51	11	10	60	18	17	63	5	5	51	(20)	(18)
*Casodex**	48	4	3	57	19	18	52	(8)	(6)	43	(18)	(17)
Others	20	(13)	(14)	28	40	29	20	(27)	(22)	26	30	26
Total Oncology	**1,892**	**7**	**6**	**2,167**	**15**	**15**	**2,334**	**8**	**8**	**2,274**	**(3)**	**(2)**
BioPharmaceuticals: CVRM												
Farxiga	349	(12)	(12)	377	8	9	398	5	5	419	5	6
Brilinta	348	(7)	(8)	389	12	12	416	7	8	428	3	3
Bydureon	142	3	3	141	(1)	-	127	(10)	(10)	139	9	10
Onglyza	153	3	3	116	(24)	(24)	127	9	11	131	3	4
Byetta	30	(6)	(5)	25	(17)	(16)	28	10	13	27	(2)	(4)
Other diabetes	11	(8)	(17)	11	-	8	14	26	22	16	17	17
Lokelma	-	n/m	n/m	2	n/m	n/m	4	m/n	n/m	8	87	74
*Crestor**	335	(5)	(6)	310	(7)	(7)	337	9	9	296	(12)	(11)
*Seloken/Toprol-XL**	225	41	38	168	(25)	(25)	177	6	8	190	7	8
*Atacand**	50	(14)	(15)	56	12	14	55	(1)	(1)	60	8	9
Others	71	(3)	(5)	63	(11)	(8)	65	4	2	72	13	16
BioPharmaceuticals: total CVRM	**1,714**	**(2)**	**(3)**	**1,658**	**(3)**	**(3)**	**1,749**	**5**	**6**	**1,785**	**2**	**3**
BioPharmaceuticals: Respiratory												
Symbicort	585	(8)	(8)	585	-	1	613	5	4	712	16	17
Pulmicort	383	(2)	(2)	333	(13)	(13)	337	1	3	413	22	23
Fasenra	129	3	4	167	29	30	202	21	21	206	2	2
Daliresp/Daxas	48	(11)	(12)	56	17	18	53	(6)	(7)	58	10	10
Duaklir	20	(9)	(6)	17	(15)	(16)	18	7	5	22	19	20
Bevespi	10	-	(5)	10	-	2	10	4	8	12	8	5
Breztri	-	-	-	-	-	-	1	-	-	1	(74)	(73)
Others	108	(14)	(16)	84	(22)	(23)	84	-	4	114	36	35
BioPharmaceuticals: total Respiratory	**1,283**	**(6)**	**(6)**	**1,252**	**(2)**	**(2)**	**1,319**	**5**	**6**	**1,537**	**17**	**17**
Other medicines												
Nexium	363	(7)	(8)	393	8	8	374	(5)	(4)	353	(6)	(6)
Synagis	53	(79)	(79)	96	81	81	146	52	53	63	(57)	(57)
Losec/Prilosec	76	27	26	68	(11)	(10)	73	8	9	46	(38)	(38)
Seroquel XR/IR	37	(34)	(33)	32	(14)	(10)	82	n/m	n/m	40	(50)	(49)
Others	47	(65)	(64)	52	11	11	56	8	-	151	n/m	n/m
Total other medicines	**576**	**(35)**	**(36)**	**641**	**11**	**12**	**731**	**14**	**14**	**653**	**(11)**	**(10)**
Total Product Sales	**5,465**	**(5)**	**(6)**	**5,718**	**5**	**5**	**6,132**	**7**	**8**	**6,250**	**2**	**3**

Shareholder information

Announcement first quarter 2019 results and Annual General Meeting:	29 April 2020
Announcement of first half and second quarter results	30 July 2020
Announcement of year to date and third quarter results	5 November 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.

Addresses for correspondence

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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 medicines; 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 medicines that achieve commercial success; the risk of delay to new product launches; the risk that new medicines 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 medicines; the difficulties of obtaining and maintaining regulatory approvals for medicines; 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 medicines; 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 media 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.