AstraZeneca PLC
5 November 2020 07:00 GMT

Year-to-date and Q3 2020 results
On track to meet full-year guidance; executing the strategy of sustainable growth through innovation

In the year to date, AstraZeneca delivered increases in the top line, profit and cash, underpinned by a strategy of sustainable growth through innovation. Total Revenue was in line with expectations and the operating performance continued to improve, with earnings growth in the third quarter reflecting Collaboration Revenue and Other Operating Income and Expense weighted towards the fourth quarter. As a result, full-year guidance remains unchanged.

Pascal Soriot, Chief Executive Officer, commented:
"We made encouraging headway in the quarter, despite the ongoing disruption from the COVID-19 pandemic. Highlights of the sales performance included further success in Oncology and an acceleration in the progress of *Farxiga*. Our pipeline also excelled, with *Farxiga* expanding its potential beyond diabetes and heart failure with ground-breaking new data in chronic kidney disease, while regulatory submission acceptance was achieved for anifrolumab in lupus.

In the fight against COVID-19, we advanced our vaccine collaboration with the University of Oxford and are launching Phase III trials for our long-acting antibody combination for the prophylaxis and treatment against COVID-19 for people who need an immediate defence or whose weaker immune systems mean they are less likely to benefit from a vaccine.

We continue to progress in line with our expectations and maintain our full-year guidance, which is underpinned by the strategy of sustainable growth through innovation."

Table 1: Financial summary

	YTD 2020			Q3 2020		
	$m	% change		$m	% change	
		Actual	CER[1]		Actual	CER
Total Revenue	19,207	8	10	6,578	3	3
- *Product Sales*	*18,879*	*9*	*11*	*6,520*	*6*	*7*
- *Collaboration Revenue*	*328*	*(19)*	*(18)*	*58*	*(79)*	*(78)*
Reported[2] EPS[3]	$1.66	n/m[4]	n/m	$0.49	n/m	n/m
Core[5] EPS	$2.95	13	16	$0.94	(4)	-

Highlights of Total Revenue in the year to date included:

- An increase in Product Sales of 9% (11% at CER) to $18,879m. The new medicines[6] improved by 34% (36% at CER) to $9,894m, including new-medicine growth in Emerging Markets of 61% (68% at CER) to $2,189m. Globally, the new medicines represented 52% of Total Revenue (YTD 2019: 42%). The fall in Collaboration Revenue in the third quarter primarily reflected the comparative effect of milestone receipts in Q3 2019 in respect of *Lynparza*

- Oncology growth of 23% (24% at CER) to $8,185m, while New CVRM[7] increased by 7% (10% at CER) to $3,450m. Respiratory & Immunology declined by 1% (an increase of 1% at CER) to $3,841m and fell in the third quarter by 12% to $1,165m, a result of particular challenges facing *Pulmicort* in China

- An increase in Emerging Markets of 6% (11% at CER) to $6,466m, with China growth of 9% (11% at CER) to $4,013m. The latter included an adverse impact of 14 percentage points (15 at CER) from reduced sales of *Pulmicort*. In the third quarter, China grew by 6% to $1,354m

- An increase in the US of 12% in the year to date to $6,445m and in Europe by 6% (7% at CER) to $3,709m. Europe Product Sales grew by 10% in the quarter (8% at CER) to $1,259m, with a decline in Total Revenue of 9% (11% at CER) to $1,262m reflecting the fall in level of the aforementioned *Lynparza* Collaboration Revenue receipts, which are recognised and reported in the Europe region

Guidance
The Company provides guidance for FY 2020 at CER.

Financial guidance for FY 2020 is unchanged. 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.

AstraZeneca recognises the heightened risks and uncertainties from the impact of COVID-19[8]. Variations in performance between quarters can be expected to continue.

The Company is unable to provide guidance and indications on a Reported basis because AstraZeneca 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 cautionary-statements section 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 October to December 2020 were to remain at the average of rates seen in the year to date, it is anticipated that there would be a low single-digit adverse impact on Total Revenue and Core EPS. The Company's foreign-exchange rate sensitivity analysis is contained within the operating and financial review.

Financial summary
- Total Revenue, comprising Product Sales and Collaboration Revenue, increased by 8% in the year to date (10% at CER) to $19,207m. Product Sales grew by 9% (11% at CER) to $18,879m, driven primarily by the performances of the new medicines across the three therapy areas and Emerging Markets

- The Reported and Core Gross Profit Margins[9] were stable at 80% and 81%, respectively. A Core Gross Profit Margin in the third quarter of 79% was also unchanged versus the prior year

- Reported Total Operating Expense declined by 2% in the year to date (1% at CER) to $12,646m and represented 66% of Total Revenue (YTD 2019: 73%). Core Total Operating Expense increased by 4% (5% at CER) to $10,979m and represented 57% of Total Revenue (YTD 2019: 59%)

- Reported R&D Expense increased by 8% in the year to date to $4,272m; Core R&D Expense increased by 9% to $4,165m. The increases partly reflected investment in the pipeline, including the development of datopotomab deruxtecan (DS-1062), and the ending in 2019 of the release of the upfront funding of *Lynparza* development as part of the collaboration with MSD[10]

- Reported SG&A Expense declined by 7% in the year to date (5% at CER) to $8,084m; Core SG&A Expense increased by 1% (3% at CER) to $6,524m. The difference in the movements partly reflected fair-value adjustments arising on acquisition-related liabilities, as well as an increase in legal provisions recognised in 2019, offset by additional intangible asset impairment charges recorded in the year to date

- Reported Other Income and Expense reduced by 15% in the year to date (14% at CER) to $888m. Core Other Income and Expense fell by 16% in the year to date (15% at CER) to $889m and, in the third quarter, by 19% (20% at CER) to $285m

- The Reported Operating Profit Margin increased in the year to date by six percentage points to 19%; the Core Operating Profit Margin increased by one percentage point to 28%

- Reported EPS of $1.66 in the year to date represented an increase of 111% (113% at CER). Core EPS grew by 13% (16% at CER) to $2.95

- Net Cash Inflow from Operating Activities of $3,001m in the year to date. This was a year-on-year increase of $1,407m, partly reflecting a $1,328m improvement in Reported Operating Profit to $3,675m and a favourable movement in the Increase in Working Capital and Short-Term Provisions

Commercial summary

Oncology
Total Revenue increased by 23% in the year to date (24% at CER) to $8,185m.

Table 2: Select Oncology medicine performances

	YTD 2020			Q3 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Tagrisso: Product Sales	3,171	38	39	1,155	30	30
Imfinzi: Product Sales	1,487	42	43	533	29	29
Lynparza: Product Sales	1,280	51	53	464	42	42
Lynparza: Collaboration Revenue	135	(48)	(48)	-	n/m	n/m
Calquence: Product Sales	340	n/m	n/m	145	n/m	n/m
Enhertu: Collaboration Revenue	63	n/m	n/m	27	n/m	n/m

New CVRM
Total Revenue increased by 7% in the year to date (10% at CER) to $3,450m.

Table 3: Select New CVRM medicine performances

	YTD 2020			Q3 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Farxiga: Product Sales	1,373	22	26	525	32	35
Brilinta: Product Sales	1,230	7	9	385	(7)	(7)
Bydureon: Product Sales	326	(21)	(20)	110	(14)	(14)
Lokelma: Product Sales	48	n/m	n/m	21	n/m	n/m
Roxadustat: Collaboration Revenue	19	n/m	n/m	8	n/m	n/m

Respiratory & Immunology

Total Revenue declined by 1% in the year to date (an increase of 1% at CER) to $3,841m. The impact of reduced sales of *Pulmicort* amounted to 15 percentage points of Total Revenue growth.

Table 4: Select Respiratory & Immunology medicine performances

	YTD 2020			Q3 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Symbicort: Product Sales	2,042	15	16	599	(2)	(2)
Fasenra: Product Sales	666	34	34	240	19	18
Pulmicort: Product Sales	628	(40)	(39)	151	(55)	(55)

Sales of *Pulmicort*, of which the majority were in China, were adversely impacted in the year to date by the effects of COVID-19. *Pulmicort* sales in Emerging Markets declined by 43% in the year to date (42% at CER) to $479m and by 60% in the third quarter (59% at CER) to $109m.

Emerging Markets

Emerging Markets increased by 6% in the year to date (11% at CER) to $6,466m, including:

- A China increase of 9% (11% at CER) to $4,013m; the performance was adversely impacted by the aforementioned effects of COVID-19 on sales of *Pulmicort*. Q3 2020 Total Revenue increased by 6% to $1,354m

- An ex-China increase of 3% (10% at CER) to $2,453m. Q3 2020 Total Revenue declined by 7% (an increase of 2% at CER) to $783m, partly driven by the impact of divestments in prior periods

COVID-19

The Company is managing a number of challenges from the ongoing pandemic, including:

- reduced levels of patient screenings, diagnoses, testing and elective procedures

- less face-to-face engagement with healthcare practitioners for commercial field-sales teams

- additional costs and procedures related to COVID-19, such as facilities cleaning, personal protective equipment and colleague testing. AstraZeneca is dedicated to providing safe-working environments for colleagues and suppliers

- an increase in Distribution Expense

- an impact on initiation, ongoing recruitment and follow-up in some clinical trials, primarily in the early stage. It remains prudent to assume that additional delays will arise as a consequence of the pandemic

Despite a delayed global recovery, AstraZeneca is well-placed to manage these challenges. The unprecedented environment has also provided multiple opportunities to explore more efficient ways of working, which have the potential to provide long-term benefits to patients and to the Company.

In addition, AstraZeneca has mobilised research efforts to target the SARS-CoV-2 virus, to provide protection to societies and individuals against COVID-19 and to treat patients with severe disease. Late-stage clinical trials of the recombinant adenovirus vaccine candidate, AZD1222, are ongoing in a number of countries, including the UK, Brazil, South Africa and the US. The European Medicines Agency (EMA) announced in October 2020 that its Committee for Medicinal Products for Human Use (CHMP) had started a rolling review of data for AZD1222, the first COVID-19 vaccine to be reviewed under these arrangements.

In the same month, the Company advanced into two Phase III clinical trials of AZD7442 to evaluate safety and efficacy in preventing infection, with plans for further trials for the treatment of COVID-19.

Further details of the Company's broad COVID-19 research and development programme are shown in the research and development section of this announcement. Details of AstraZeneca's potential vaccine and its work with governments and other organisations can be found in the sustainability section of this announcement.

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

a) Access to healthcare
During the period, AstraZeneca's Chief Executive Officer (CEO), Pascal Soriot, signed a vaccines pledge in collaboration with nine biopharmaceutical CEOs, committing to the continued safety and well-being of vaccinated individuals as the top priority in the development of the first COVID-19 vaccines.

b) Environmental protection
As part of its Ambition Zero Carbon strategy, the Company announced it had accelerated delivery of its renewable power-sourcing targets, achieving 100% supply of certified renewable imported power across all sites worldwide by the end of 2020, five years ahead of its original RE100 (renewable energy) commitments; along with switching to electric vehicles (EV100) and increasing energy productivity (EP100) by 2025.

c) Ethics and transparency
Highlighting the Company's continued commitment to transparency and ethical conduct, a new Data and Artificial Intelligence (AI) Ethics position statement was published during the period to establish and make visible AstraZeneca's principles around this emerging field of practice.

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

Notes
The following notes refer to pages one to five.

1. Constant exchange rates. These are financial measures that are not accounted for according to generally accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.
2. Reported financial measures are the financial results presented in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board and adopted by the EU. The UK is in the process of establishing its post-Brexit IFRS-adoption authority, which is expected to be operational later in 2020, but for the current time, will follow the EU approval process.
3. Earnings per share.
4. Not meaningful.
5. 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 Interim Financial Statements. See the operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
6. *Tagrisso*, *Imfinzi*, *Lynparza*, *Calquence*, *Enhertu*, *Koselugo*, *Farxiga*, *Brilinta*, *Lokelma*, roxadustat, *Fasenra*, *Bevespi* and *Breztri*. The new medicines are pillars in the three therapy areas of Oncology, Cardiovascular (CV), Renal & Metabolism (CVRM), and Respiratory & Immunology and are important platforms for future growth. The Total Revenue of *Enhertu* and roxadustat in the year to date entirely reflected Ongoing Collaboration Revenue.
7. New CVRM comprises *Brilinta*, Renal and Diabetes medicines.
8. Coronavirus disease; an infectious disease caused by a newly discovered coronavirus.
9. Gross Profit is defined as Total Revenue minus Cost of Sales. The calculation of Reported and Core Gross Profit Margin excludes the impact of Collaboration Revenue and any associated costs, thereby reflecting the underlying performance of Product Sales.
10. Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.

Table 5: Pipeline highlights

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

Regulatory approvals	- *Imfinzi* - ES-SCLC[11] (EU, JP) - *Enhertu* - gastric cancer (3rd line, HER2+[12]) (JP) - *Forxiga* - T2D[13] CVOT[14] (CN)
Regulatory submission acceptances and/or submissions	- *Tagrisso* - adjuvant NSCLC[15] (EGFRm[16]) (US, CN; Priority Reviews) - *Imfinzi* - new, once every four weeks (Q4W) dosing (US; Priority Review, EU; accelerated assessment) - *Imfinzi* - ES-SCLC (CN) - *Enhertu* - gastric cancer (3rd line, HER2+) (US; Priority Review) - *Brilinta* - stroke (THALES) (CN) - *Symbicort* - mild asthma (EU) - anifrolumab - lupus (SLE[17]) (US, EU)
Major Phase III data readouts or other significant developments	- *Tagrisso* - adjuvant NSCLC (EGFRm): Breakthrough Therapy Designation[18] (US) - *Lynparza* - ovarian cancer (1st line, HRD+) (PAOLA-1): positive opinion (EU) - *Lynparza* - prostate cancer (2nd line, BRCAm[19]): positive opinion (EU) - *Forxiga* - HF[20] CVOT: positive opinion (EU) - *Farxiga* - CKD[21]: Breakthrough Therapy Designation (US) - *Fasenra* - nasal polyps[22]: Phase III primary endpoints met - *Trixeo* - COPD[23]: positive opinion (EU)

[11] Extensive-stage small cell lung cancer.
[12] Human epidermal growth factor receptor 2 positive.
[13] Type-2 diabetes.
[14] CV outcomes trial.
[15] Non-small cell lung cancer.
[16] Epidermal growth factor receptor mutation.
[17] Systemic lupus erythematosus, a chronic autoimmune disease that causes inflammation throughout the body.
[18] Intended to expedite the development and review of medicines for serious or life-threatening conditions.
[19] Breast cancer susceptibility gene 1/2 mutation.
[20] Heart failure.
[21] Chronic kidney disease.
[22] Benign soft growths inside the nose.
[23] Chronic obstructive pulmonary disease.

Table 6: Pipeline - anticipated major news flow

Timing	News flow
Q4 2020	- *Tagrisso* - adjuvant NSCLC (EGFRm): regulatory submission (EU) - *Imfinzi* - new Q4W dosing: regulatory decision (US) - *Lynparza* - ovarian cancer (1st line) (PAOLA-1): regulatory decision (EU, JP) - *Lynparza* - breast cancer (BRCAm): regulatory decision (CN) - *Lynparza* - prostate cancer (2nd line, BRCAm): regulatory decision (EU) - *Enhertu* - breast cancer (3rd line, HER2+): regulatory decision (EU) - *Calquence* - CLL[24]: regulatory decision (EU) - *Forxiga* - HF CVOT: regulatory decision (EU, JP) - *Farxiga* - CKD: regulatory submission - *Brilinta* - stroke (THALES): regulatory decision (US) - roxadustat - anaemia in CKD: regulatory decision (US) - *Symbicort* - mild asthma: regulatory decision (CN) - *Trixeo* - COPD: regulatory decision (EU) - tezepelumab - severe asthma: data readout - anifrolumab - lupus (SLE): regulatory submission (JP) - AZD1222 - SARS-CoV-2: data readout, regulatory submission
H1 2021	- *Tagrisso* - adjuvant NSCLC (EGFRm): regulatory decision (US, CN) - *Imfinzi* - new Q4W dosing: regulatory decision (EU) - *Imfinzi* - unresectable, Stage III NSCLC (PACIFIC-2): data readout, regulatory submission - *Imfinzi* - NSCLC (1st line) (PEARL): data readout - *Imfinzi* +/- treme[25] - head & neck cancer (1st line): data readout, regulatory submission - *Lynparza* - pancreatic cancer (1st line, BRCAm): regulatory decision (JP) - *Lynparza* - prostate cancer (2nd line): regulatory decision (JP) - *Lynparza* - adjuvant breast cancer: data readout - *Enhertu* - gastric cancer (3rd line, HER2+): regulatory decision (US) - *Calquence* - CLL: regulatory decision (JP) - *Calquence* - CLL (2nd line) (ELEVATE R/R): data readout, regulatory submission - *Koselugo* - NF1[26] regulatory decision (EU) - *Forxiga* - HF CVOT: regulatory decision (CN) - *Brilique*/*Brilinta* - CAD[27]/T2D CVOT: regulatory decision (EU, JP, CN) - *Brilique* - stroke (THALES): regulatory decision (EU) - *Symbicort* - mild asthma: regulatory decision (EU) - *Fasenra* - nasal polyps: regulatory submission - tezepelumab - severe asthma: regulatory submission - AZD7442 - SARS-CoV-2: data readout, regulatory submission

[24] Chronic lymphocytic leukaemia.
[25] Tremelimumab.
[26] Neurofibromatosis type 1.
[27] Coronary artery disease.

Timing	News flow
H2 2021	- *Imfinzi* - ES-SCLC: regulatory decision (CN) - *Imfinzi* - NSCLC (1st line) (PEARL): regulatory submission - *Imfinzi* - adjuvant bladder cancer: data readout - *Imfinzi* - liver cancer (locoregional): data readout, regulatory submission - *Imfinzi* - biliary tract cancer: data readout - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): data readout (OS[28]), regulatory submission - *Imfinzi* +/- treme - liver cancer (1st line): data readout, regulatory submission - *Lynparza* - ovarian cancer (3rd line, BRCAm): regulatory submission - *Lynparza* - adjuvant breast cancer: regulatory submission - *Lynparza* - prostate cancer (1st line, castration-resistant): data readout, regulatory submission - *Enhertu* - breast cancer (3rd line, HER2+) (Phase III): data readout - *Enhertu* - breast cancer (2nd line, HER2+): data readout, regulatory submission - *Enhertu* - breast cancer (HER2 low[29]): data readout - *Farxiga* - HF (HFpEF[30]): data readout, regulatory submission - *Brilinta* - stroke (THALES): regulatory decision (CN) - PT027 - asthma: data readout - anifrolumab - lupus (SLE): regulatory decision (US, EU)

[28] Overall survival.
[29] HER2 immunohistochemistry (IHC) 1+ or 2+ with fluorescence in situ hybridisation (ISH) test-result negative.
[30] HF with preserved ejection fraction.

Conference call
A conference call and webcast for investors and analysts will begin at 11:45am UK time today. Details can be accessed via astrazeneca.com.

Reporting calendar
The Company intends to publish its full-year and fourth-quarter results on Thursday, 11 February 2021.

AstraZeneca
AstraZeneca (LSE/STO/Nasdaq: 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 & Immunology. 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.

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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 nine-month period to 30 September 2020 (the year to date or YTD 2020) and the three-month period to 30 September 2020 (the quarter, the third quarter or Q3 2020), compared to the nine-month period to 30 September 2019 (YTD 2019) and the three-month period to 30 September 2019 (Q3 2019) 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's Interim 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 the Diabetes alliance[31], 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 80 of the Annual Report and Form 20-F Information 2019. Reference should be made to the Reconciliation of Reported to Core financial measures table included in the operating and financial review in this announcement.

EBITDA is defined as Reported Profit Before Tax after adding back Net Finance Expense, results from Joint Ventures and Associates and charges for Depreciation, Amortisation and Impairment. Reference should be made to the Reconciliation of Reported Profit Before Tax to EBITDA included in the financial performance section of this announcement.

Net Debt is defined as Interest-bearing loans and borrowings and Lease liabilities, net of Cash and cash equivalents, Other investments, and net Derivative financial instruments. Reference should be made to Note 3 'Net Debt' included in the Notes to the Interim Financial Statements in 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.

[31] A prior diabetes alliance between AstraZeneca and Bristol-Myers Squibb Company (BMS). The Company acquired the entirety of BMS's interests in the alliance in 2014.

Table 7: Total Revenue by therapy area

Specialty-care medicines comprise all Oncology medicines, *Brilinta*, *Lokelma*, roxadustat and *Fasenra*. At 53% of Total Revenue (YTD 2019: 47%), specialty-care medicines increased by 22% in the year to date (23% at CER) to $10,148m.

	YTD 2020				Q3 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Oncology	8,185	43	23	24	2,861	13	13
BioPharmaceuticals	7,291	38	3	5	2,350	(4)	(3)
- *New CVRM*	*3,450*	*18*	*7*	*10*	*1,185*	*6*	*8*
- *Respiratory & Immunology*	*3,841*	*20*	*(1)*	*1*	*1,165*	*(12)*	*(12)*
Other medicines	3,731	19	(6)	(4)	1,367	(5)	(3)
Total	**19,207**	**100**	**8**	**10**	**6,578**	**3**	**3**

Table 8: Top-ten medicines by Total Revenue

Medicine	Therapy Area	YTD 2020				Q3 2020		
		$m	% of total	% change		$m	% change	
				Actual	CER		Actual	CER
Tagrisso	Oncology	3,171	17	38	39	1,155	30	30
Symbicort	Respiratory & Immunology	2,042	11	15	16	599	(2)	(2)
Imfinzi	Oncology	1,487	8	42	43	533	29	29
Lynparza	Oncology	1,415	7	28	29	464	(12)	(12)
Farxiga	CVRM	1,377	7	22	26	527	32	35
Brilinta	CVRM	1,230	6	7	9	385	(7)	(7)
Nexium	Other medicines	1,140	6	(1)	1	409	7	8
Crestor	CVRM	884	5	(11)	(9)	301	(13)	(12)
Zoladex	Oncology	717	4	14	18	233	1	3
Fasenra	Respiratory & Immunology	666	3	34	34	240	19	18
Total		**14,129**	**74**	**20**	**22**	**4,846**	**10**	**10**

Table 9: Collaboration Revenue

Other Ongoing Collaboration Revenue included *Zoladex*, *Farxiga*, *Eklira*, *Nexium* OTC[32] and other royalties. No Initial Collaboration Revenue was recorded in the year to date.

	YTD 2020				Q3 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Lynparza: regulatory milestone revenue	135	41	(48)	(48)	-	n/m	n/m
Enhertu: profit share	63	19	n/m	n/m	27	n/m	n/m
Roxadustat: profit share	19	6	n/m	n/m	8	n/m	n/m
Other Collaboration Revenue	111	34	(23)	(23)	23	(69)	(69)
Total	**328**	**100**	**(19)**	**(18)**	**58**	**(79)**	**(78)**

[32] Over the counter.

Total Revenue

The performance of the Company's medicines is shown below, with a geographical split of Product Sales shown in Note 7.

Table 10: Therapy area and medicine performance - YTD 2020

Product Sales: therapy area	Medicine	YTD 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
Oncology	*Tagrisso*	3,171	17	38	39
	Imfinzi	1,487	8	42	43
	Lynparza	1,280	7	51	53
	Calquence	340	2	n/m	n/m
	Koselugo	20	-	n/m	n/m
	Zoladex[33]	672	4	9	13
	Faslodex[33]	450	2	(38)	(37)
	Iressa[33]	201	1	(41)	(40)
	Arimidex[33]	149	1	(14)	(11)
	Casodex[33]	133	1	(16)	(14)
	Others	39	-	(44)	(43)
	Total Oncology	**7,942**	**42**	**24**	**26**
BioPharmaceuticals: CVRM	*Farxiga*	1,373	7	22	26
	Brilinta	1,230	7	7	9
	Onglyza	365	2	(8)	(6)
	Bydureon	326	2	(21)	(20)
	Byetta	50	-	(40)	(38)
	Other diabetes	35	-	(4)	(4)
	Lokelma	48	-	n/m	n/m
	Crestor[33]	882	5	(10)	(8)
	Seloken/Toprol-XL[33]	620	3	9	14
	Atacand[33]	180	1	11	18
	Others	145	1	(27)	(26)

[33] Legacy medicine.

Product Sales: therapy area	Medicine	YTD 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
	BioPharmaceuticals: total CVRM	**5,254**	**28**	**3**	**5**
BioPharmaceuticals: Respiratory & Immunology	*Symbicort*	2,042	11	15	16
	Fasenra	666	4	34	34
	Pulmicort	628	3	(40)	(39)
	Daliresp/*Daxas*	163	1	4	4
	Bevespi	36	-	19	19
	Breztri	21	-	n/m	n/m
	Others	273	1	(17)	(16)
	BioPharmaceuticals: total Respiratory & Immunology	**3,829**	**20**	**(1)**	**1**
Other medicines	*Nexium*[33]	1,115	6	(1)	1
	Synagis[33]	294	2	-	-
	Losec/*Prilosec*[33]	144	1	(34)	(32)
	FluMist[33]	116	1	n/m	n/m
	Seroquel XR/IR[33]	98	1	(35)	(34)
	Others	87	-	(35)	(35)
	Total other medicines	**1,854**	**10**	**(5)**	**(4)**
	Total Product Sales	**18,879**	**100**	**9**	**11**
	Total Collaboration Revenue	**328**		**(19)**	**(18)**
	Total Revenue	**19,207**		**8**	**10**

Table 11: Therapy area and medicine performance - Q3 2020

Product Sales: therapy area	Medicine	Q3 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
Oncology	*Tagrisso*	1,155	18	30	30
	Imfinzi	533	8	29	29
	Lynparza	464	7	42	42
	Calquence	145	2	n/m	n/m
	Koselugo	13	-	n/m	n/m
	Zoladex	230	4	2	3
	Faslodex	138	2	(33)	(32)
	Iressa	54	1	(41)	(40)
	Arimidex	42	1	(34)	(32)
	Casodex	44	1	(16)	(16)
	Others	13	-	(37)	(34)
	Total Oncology	**2,831**	**43**	**21**	**22**
BioPharmaceuticals: CVRM	*Farxiga*	525	8	32	35
	Brilinta	385	6	(7)	(7)
	Onglyza	109	2	(14)	(13)
	Bydureon	110	2	(14)	(14)
	Byetta	15	-	(46)	(44)
	Other diabetes	11	-	(19)	(20)
	Lokelma	21	-	n/m	n/m
	Crestor	300	5	(11)	(10)
	Seloken/Toprol-XL	225	3	27	32
	Atacand	54	1	(2)	4
	Others	39	1	(41)	(41)
	BioPharmaceuticals: total CVRM	**1,794**	**28**	**3**	**4**

Product Sales: therapy area	Medicine	Q3 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
BioPharmaceuticals: Respiratory & Immunology	*Symbicort*	599	9	(2)	(2)
	Fasenra	240	4	19	18
	Pulmicort	151	2	(55)	(55)
	Daliresp/*Daxas*	57	1	8	9
	Bevespi	14	-	38	36
	Breztri	10	-	n/m	n/m
	Others	90	1	(12)	(13)
	BioPharmaceuticals: total Respiratory & Immunology	**1,161**	**18**	**(12)**	**(12)**
Other medicines	*Nexium*	401	6	7	9
	Synagis	118	2	(19)	(19)
	Losec/*Prilosec*	45	1	(38)	(38)
	FluMist	116	2	n/m	n/m
	Seroquel XR/IR	35	1	(57)	(56)
	Others	19	-	(56)	(57)
	Total other medicines	**734**	**11**	**1**	**1**
	Total Product Sales	**6,520**	**100**	**6**	**7**
	Total Collaboration Revenue	**58**		**(79)**	**(78)**
	Total Revenue	**6,578**		**3**	**3**

Total Revenue summary

Oncology

Total Revenue of $8,185m in the year to date; an increase of 23% (24% at CER). The performance of *Enhertu* was reflected entirely in Collaboration Revenue.

Oncology represented 43% of overall Total Revenue (YTD 2019: 38%).

Tagrisso
Tagrisso has received regulatory approval in 87 countries, including the US, China, in the EU and Japan for the 1st-line treatment of patients with EGFRm NSCLC. To date, reimbursement has been granted in 32 countries in this setting, with further reimbursement decisions anticipated. These developments followed *Tagrisso*'s approval in 89 countries, including the US, China, in the EU and Japan for the treatment of patients with EGFR T790M[34]-mutation NSCLC, an indication in which 64 reimbursements have been obtained.

Total Revenue, entirely comprising Product Sales, amounted to $3,171m in the year to date and represented growth of 38% (39% at CER). Sales in the US increased by 26% to $1,144m.

In Emerging Markets, *Tagrisso* sales increased by 72% in the year to date (78% at CER) to $950m, with notable growth in China, following the admission in 2019 to the China National Reimbursement Drug List (NRDL) in the 2nd-line setting. Japan increased by 12% (11% at CER) to $523m despite a Q4 2019 15% price reduction. In Europe, sales of $503m in the year to date represented an increase of 49% (50% at CER), driven by use in the 1st-line setting, as more reimbursements were granted.

Imfinzi
Imfinzi has received regulatory approval in 65 countries, including the US, China, in the EU and Japan for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy (CRT). The number of reimbursements increased to 28 in the year to date. *Imfinzi* has also been approved for the treatment of ES-SCLC patients in 47 countries, with five reimbursements obtained.

Total Revenue, entirely comprising Product Sales, amounted to $1,487m in the year to date and represented growth of 42% (43% at CER), predominantly for the treatment of unresectable, Stage III NSCLC. The US increased by 17% to $885m; in Japan, growth of 28% (27% at CER) represented sales of $192m. Europe increased by 122% (125% at CER) to $254m, reflecting a growing number of reimbursements while Emerging Markets increased by 514% (543% at CER) to $113m, following recent regulatory approvals and launches including in China.

Lynparza
Lynparza has received regulatory approval in 77 countries for the treatment of ovarian cancer; it has also been approved in 71 countries for the treatment of metastatic breast cancer, and in 51 countries for the treatment of pancreatic cancer. Finally, it has also received regulatory approval in 13 countries for the 2nd-line treatment of certain prostate-cancer patients.

Product Sales in the year to date amounted to $1,280m, reflecting growth of 51% (53% at CER). The strong performance was geographically spread, with launches continuing globally. US Product Sales increased by 46% to $631m, as the launches in prostate cancer and 1st-line HRD+ ovarian cancer started to take effect. *Lynparza* continued to be the leading medicine in the poly ADP ribose polymerase-inhibitor (PARPi) class, as measured by total prescription volumes. Product Sales in Europe increased by 50% (51% at CER) to $311m, reflecting additional reimbursements and increasing BRCAm-testing rates, as well as successful recent 1st-line BRCAm ovarian cancer launches, including in the UK and Germany.

Japan Product Sales of *Lynparza* amounted to $119m, representing growth of 31% (30% at CER). Emerging Markets Product Sales of $195m, up by 94% (105% at CER), were a result of the regulatory approval of *Lynparza* as a 2nd-line maintenance treatment of patients with ovarian cancer by the China National Medical Products Administration (NMPA) in 2019. *Lynparza* was admitted to the China NRDL for the same indication, with effect from January 2020.

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

Lynparza Total Revenue amounted to $1,415m in the year to date and represented growth of 28% (29% at CER); this included Collaboration Revenue of $135m. Collaboration Revenue receipts vary quarter to quarter, with significant *Lynparza* receipts expected in the final quarter of 2020.

Enhertu
US sales, recorded by Daiichi Sankyo Company Limited (Daiichi Sankyo), amounted to $136m in the year to date, including $60m in the quarter. *Enhertu* was approved by the US Food and Drug Administration (FDA) for the treatment of 3rd-line HER2+ breast cancer at the end of 2019. Total Revenue, entirely comprising Collaboration Revenue recorded by AstraZeneca, amounted to $63m in the year to date, with $27m in the quarter.

Calquence
Total Revenue, entirely comprising Product Sales, amounted to $340m in the year to date and represented growth of 214%, with the overwhelming majority of sales in the US. *Calquence* was approved by the US FDA for the treatment of CLL in November 2019 and has received regulatory approvals in this indication in an additional 16 countries. *Calquence* has also received regulatory approvals in 20 countries for the treatment of patients with mantle cell lymphoma.

Koselugo
Total Revenue, entirely comprising Product Sales in the US, amounted to $20m in the year to date, following its launch during the second quarter of 2020 for the treatment of paediatric patients aged two years and older with NF1 who have symptomatic, inoperable plexiform neurofibromas.

Legacy: *Zoladex*
Total Revenue, predominantly comprising Product Sales, amounted to $717m in the year to date and represented growth of 14% (18% at CER).

Emerging Markets Product Sales of *Zoladex* increased by 12% (18% at CER) to $427m, reflecting increased use and access in prostate cancer. Product Sales in Europe increased by 5% (6% at CER) to $104m. In the Established RoW region, Product Sales increased by 2% to $135m.

Legacy: *Faslodex*
Total Revenue, entirely comprising Product Sales, amounted to $450m in the year to date and represented a decline of 38% (37% at CER).

Emerging Markets fell by 3% (up by 3% at CER) to $142m. US sales, however, declined by 85% to $45m, reflecting the launch in 2019 of multiple generic *Faslodex* medicines. In Europe, where generic competitor medicines are established, sales increased by 2% (3% at CER) to $171m, while in Japan, sales fell by 11% (12% at CER) to $86m, driven by a mandated price reduction in the second quarter of 2020.

Legacy: *Iressa*
Total Revenue, entirely comprising Product Sales, amounted to $201m in the year to date and represented a decline of 41% (40% at CER). Emerging Markets fell by 28% (26% at CER) to $163m, driven by the impact of *Iressa*'s inclusion in China's volume-based procurement (VBP) programme and subsequent price reduction.

BioPharmaceuticals: CVRM

Total Revenue increased by 3% in the year to date (5% at CER) to $5,278m and represented 27% of Total Revenue (YTD 2019: 29%). This included roxadustat Ongoing Collaboration Revenue of $19m, as well as sales of *Crestor* and other legacy medicines.

New CVRM Total Revenue, which excludes sales of *Crestor* and other legacy medicines, increased by 7% in the year to date (10% at CER) to $3,450m, mainly reflecting the performances of *Farxiga* and, to a lesser extent, *Brilinta*. New CVRM represented 65% of overall CVRM Total Revenue in the year to date (YTD 2019: 62%).

Farxiga
Total Revenue, predominantly comprising Product Sales, amounted to $1,377m in the year to date and represented growth of 22% (26% at CER). Q3 2020 Total Revenue increased by 32% (35% at CER) to $527m, reflecting growth across the regions.

Emerging Markets Product Sales increased by 44% in the year to date (54% at CER) to $488m. In China, *Forxiga* was admitted to the NRDL with effect from the start of 2020; as expected, this adversely impacted pricing. This effect, however, was more than offset by the volume benefit derived from the launch within the NRDL listing. The performance also reflected continued growth in the sodium-glucose cotransporter 2 (SGLT2) inhibitor class at the expense of the dipeptidyl-peptidase 4 (DPP-4) inhibitor class.

US Product Sales declined by 3% to $385m in the year to date, reflecting the impact of competitive activity on pricing and the mix of channel sales that outweighed an encouraging level of volume growth. There were, however, favourable movements in the share of new-to-brand prescriptions, a result of a regulatory approval update in Q3 2019 to reflect results from the DECLARE CVOT and the more recent HFrEF (heart failure with reduced ejection fraction) regulatory approval. US Product Sales in the quarter increased by 18% to $148m.

Product Sales in Europe increased by 33% (34% at CER) in the year to date to $363m, partly reflecting growth in the class and an acceleration of new-to-brand prescriptions, following a similar DECLARE-trial approval update. Product Sales in Europe in Q3 2020 increased by 48% (44% at CER) to $141m. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales, increased by 23% (22% at CER) to $77m.

Brilinta
Total Revenue, entirely comprising Product Sales, amounted to $1,230m in the year to date and represented growth of 7% (9% at CER). Patient uptake continued in the treatment of acute coronary syndrome and high-risk post-myocardial infarction (MI). Sales in Q3 2020, however, declined by 7% to $385m due to a continued COVID-19 impact and a wholesaler-inventory compensation in China following the VBP announcement in August 2020.

Emerging Markets sales increased by 13% (18% at CER) to $392m in the year to date. Sales in the third quarter, however, declined by 22% (20% at CER) to $102m, following announcement of the aforementioned VBP update in China in August 2020, where AstraZeneca chose not to compete on price, but still faced a mandatory price reduction of 30%, as per VBP rules. US sales, at $537m, represented an increase of 7%, partly driven by a lengthening in the average-weighted duration of treatment, resulting from the growing impact of 90-day prescriptions. Sales of *Brilique* in Europe declined by 2% in the year to date (1% at CER) to $257m, with sales adversely impacted by COVID-19, reflecting fewer elective procedures.

Onglyza
Total Revenue, entirely comprising Product Sales, amounted to $365m in the year to date and represented a decline of 8% (6% at CER). Total Revenue in Q3 2020 decreased by 14% (13% at CER) to $109m, following a declining market share.

Sales in Emerging Markets increased by 18% (23% at CER) to $154m, driven by the performance in China. US sales of *Onglyza* fell by 23% in the year to date to $134m, while Europe sales declined by 19% to $43m, highlighting the broader trend of a shift away from the DPP-4 inhibitor class. Given the significant future potential of *Farxiga*, the Company continues to prioritise commercial support over *Onglyza*.

Bydureon
Total Revenue, entirely comprising Product Sales, amounted to $326m in the year to date and represented a decline of 21% (20% at CER).

US sales of $278m reflected a decline of 18% in the year to date, resulting from competitive pressures and the impact of managed markets. *Bydureon* sales in Europe fell by 24% (23% at CER) to $38m.

Lokelma
Total Revenue, entirely comprising Product Sales, amounted to $48m in the year to date (YTD 2019: $6m), with the US representing the overwhelming majority; *Lokelma* continued to lead the new-to-brand prescription market share in the US during the period.

The medicine has received regulatory approval in several markets, including in the EU, China and Japan for the treatment of hyperkalaemia, with further launches in several markets anticipated soon.

Roxadustat
Total Revenue, entirely comprising Ongoing Collaboration Revenue, amounted to $19m in the year to date in China. Q3 2020 revenue of $8m reflected a sequential quarterly decline of 14%, predominantly reflecting an accounting adjustment from the prior period. The Company continued to focus on achieving hospital listings across China, with more than 90,000 patients being treated for anaemia in CKD with the medicine.

In July 2020, FibroGen Inc. (FibroGen) and AstraZeneca entered into an amendment to revise the existing licence agreement for roxadustat in China. From 2021, AstraZeneca is likely to recognise the overwhelming majority of its future revenue in China as Product Sales.

Legacy: *Crestor*
Total Revenue, predominantly comprising Product Sales, amounted to $884m in the year to date and represented a decline of 11% (9% at CER).

Product Sales in Emerging Markets fell by 10% (7% at CER) to $560m. The performance was adversely impacted by the ongoing effects of the aforementioned VBP programme in China. US Product Sales declined by 19% to $71m. In Europe, Product Sales fell by 16% (15% at CER) to $94m while in Japan, where AstraZeneca collaborates with Shionogi Co., Ltd, Product Sales declined by 4% (5% at CER) to $121m.

BioPharmaceuticals: Respiratory & Immunology

Total Revenue declined by 1% in the year to date (an increase of 1% at CER) to $3,841m and represented 20% of Total Revenue (YTD 2019: 22%). This included Ongoing Collaboration Revenue of $12m from *Duaklir*, *Eklira* and other medicines. Q3 2020 Total Revenue declined by 12% to $1,165m, largely as a result of the aforementioned *Pulmicort* performance.

Symbicort
Total Revenue, entirely comprising Product Sales, amounted to $2,042m in the year to date and represented growth of 15% (16% at CER), a result of the strong performance in the US. Q3 2020 Total Revenue declined by 2% to $599m, driven by stocking effects in the US and generic competition in Japan. *Symbicort* remains the global market-volume and value leader within the inhaled corticosteroid (ICS) / long-acting beta agonist (LABA) class.

US sales grew by 29% to $755m in the year to date. An authorised-generic version of *Symbicort* was launched in the US by the Company's collaborator, Prasco, in January 2020. Q3 2020 sales fell by 3% to $197m, as a result of an unfavourable channel mix and the unwinding of increased stocks from earlier in the year. Emerging Markets sales increased by 6% in the year to date (11% at CER) to $423m, reflecting positive performances in China and Russia.

In Europe, sales increased by 3% in the year to date (4% at CER) to $521m, with positive growth seen in France, Spain and Italy. In Japan, sales increased by 10% (9% at CER) to $144m; Q3 2020 sales declined by 35% (36% at CER) to $41m. This was driven by generic competition and an unfavourable price and volume comparison versus Q3 2019, following the termination of the Astellas Pharma Inc. co-promotion agreement.

Pulmicort
Total Revenue, entirely comprising Product Sales, amounted to $628m in the year to date and represented a decline of 40% (39% at CER). Q3 2020 Total Revenue declined by 55% to $151m, as the continued effect of COVID-19 predominantly impacted the treatment of respiratory patients in the hospital setting, particularly in China.

Emerging Markets, where *Pulmicort* sales fell by 43% in the year to date (42% at CER) to $479m, represented 76% of the global total. The performance in China was impacted by COVID-19 with a reduction in the number of paediatric patients attending outpatient nebulisation rooms. The volume of adult elective procedures, where *Pulmicort* can be used in operative care when oral corticosteroids (OCS) are unsuitable, partly recovered in the quarter. Sales in the US declined by 40% to $53m, and also fell in Europe by 8% (6% at CER) to $55m.

Fasenra
Fasenra has received regulatory approval in 59 countries, including the US, in the EU and Japan for the treatment of patients with severe, uncontrolled eosinophilic asthma. With further regulatory reviews ongoing, *Fasenra* has already achieved reimbursement in 45 countries.

Total Revenue, entirely comprising Product Sales, amounted to $666m in the year to date and represented growth of 34%. Q3 2020 Total Revenue increased by 19% (18% at CER) to $240m, as a result of positive market-share progression and the increasing adoption of self-administration offsetting the impact of COVID-19 on the level of new-patient starts in several countries. *Fasenra* continued as the leading novel biologic in the new-to-brand prescription segment for patients with severe uncontrolled asthma in the majority of markets.

Sales in the US increased by 23% in the year to date to $423m. Q3 2020 US sales increased by 11% to $151m as a result of sustained market-share growth. In Europe, sales of $140m in the year to date represented an increase of 72% (74% at CER), reflecting ongoing successful launches. Sales in Japan increased by 16% (15% at CER) to $72m. In its approved indication and among new patients. In Emerging Markets, sales amounted to $10m in the year to date (YTD 2019: $4m).

Daliresp/Daxas
Total Revenue, entirely comprising Product Sales, amounted to $163m in the year to date and represented an increase of 4%. US sales, representing 87% of the global total, increased by 6% to $141m.

Bevespi
Total Revenue, entirely comprising Product Sales, amounted to $36m in the year to date and represented an increase of 19%. *Bevespi* has been launched in the US, in a number of European countries and in Japan. Sales in the US increased by 11% in the year to date to $33m.

Breztri
Total Revenue, entirely comprising Product Sales, amounted to $21m in the year to date (YTD 2019: $1m). *Breztri* has successfully launched in China and in Japan for patients with COPD. Prescriptions in Japan have been limited by Ryotanki, a regulation which limits prescriptions to two weeks' supply in the first year of launch. On 1 October 2020, Ryotanki was lifted and the restriction no longer applies. *Breztri* was recently approved and launched in the US and received a positive CHMP opinion in the EU, under the name *Trixeo*.

Broncho-Vaxom
In September 2020, AstraZeneca signed a strategic collaboration agreement with OM Pharma SA, through which the Company was granted the exclusive right to import, distribute and promote the immunological therapy *Broncho-Vaxom* (Bacterial Lysates/OM-85) in China (excluding Hong Kong, Macau and Taiwan). *Broncho-Vaxom* can prevent and treat recurrent or acute respiratory infections in patients by boosting host immunity. In China, recurrent respiratory-tract infection is a particularly common disease in children, with an incidence rate of c.20%.

Other medicines (outside the three main therapy areas)

Total Revenue, primarily comprising Product Sales, amounted to $1,903m in the year to date, representing a decline of 7% (6% at CER). The performance partly reflected the divestment of global rights to *Movantik*, excluding Europe, Canada and Israel, to RedHill Biopharma in April 2020. Other medicines Total Revenue represented 10% of overall Total Revenue (YTD 2019: 11%).

Nexium
Total Revenue, predominantly comprising Product Sales, amounted to $1,140m in the year to date, representing a decline of 1% (an increase of 1% at CER). Emerging Markets Product Sales of *Nexium* fell by 2% (increasing by 2% at CER) to $563m. In Japan, where AstraZeneca collaborates with Daiichi Sankyo, Product Sales increased by 7% (6% at CER) to $313m, while Product Sales in the US declined by 27% to $127m and in Europe, the increase was 21% to $59m.

Losec/Prilosec
Total Revenue, entirely comprising Product Sales, amounted to $144m in the year to date, representing a decline of 34% (32% at CER), partly reflecting the divestment of global commercial rights, excluding China, Japan, the US and Mexico, to Cheplapharm Arzneimittel GmbH (Cheplapharm) in October 2019. Emerging Markets fell by 18% (16% at CER) to $119m, with a decline of 23% (24% at CER) to $38m in Q3 2020 as *Losec*

was subject to a mandatory price cut as part of the impact of aforementioned VBP programme in China; sales in Europe fell by 63% to $17m in the year to date.

FluMist
Total Revenue, entirely comprising Product Sales, increased to $116m in the year to date (YTD 2019: $20m) reflecting earlier delivery and greater use of influenza vaccines. *FluMist* US sales increased to $65m in the year to date (YTD 2019: $20m). Sales in Europe amounted to $49m (YTD 2019: $nil).

Synagis
Total Revenue of $294m in the year to date, entirely comprising Product Sales, was stable. Sales in Europe, wholly reflecting sales to AbbVie Inc (AbbVie) made under the current supply agreement for markets outside the US, amounted to $247m in the year to date, representing a decline of 5%; sales in Q3 2020 fell by 33% to $97m. In the US, sales were $47m in the year to date, representing an increase of 29%; this reflected a favourable gross-to-net adjustment relating to prior periods.

The commercial rights to the sale and distribution of *Synagis* outside the US, held by AbbVie since 1997, will revert to AstraZeneca upon the expiry of the current agreement on 30 June 2021. In general, the Company will solely distribute and promote the medicine outside the US from 1 July 2021. The agreement with Swedish Orphan Biovitrum AB (publ), for the rights to *Synagis* in the US, was unaffected by this decision.

Regional Total Revenue

Table 12: Regional Total Revenue

	YTD 2020				Q3 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Emerging Markets	6,466	34	6	11	2,137	-	4
- *China*	*4,013*	*21*	*9*	*11*	*1,354*	*6*	*6*
- *Ex-China*	*2,453*	*13*	*3*	*10*	*783*	*(7)*	*2*
US	6,445	34	12	12	2,268	11	11
Europe	3,709	19	6	7	1,262	(9)	(11)
Established RoW	2,587	13	7	7	911	7	7
- *Japan*	*1,902*	*10*	*2*	*1*	*670*	*1*	*1*
- *Canada*	*459*	*2*	*33*	*36*	*161*	*34*	*37*
- *Other Est. RoW*	*226*	*1*	*7*	*12*	*80*	*17*	*14*
Total	19,207	100	8	10	6,578	3	3

Europe Total Revenue includes Product Sales that grew by 10% (8% at CER) in the quarter and by 12% (13% at CER) in the YTD 2020. A geographical split of Product Sales is shown in Note 7. For additional details, refer to Table 45 for Collaboration Revenue recognised during YTD 2020 and YTD 2019.

Table 13: Emerging Markets therapy-area performance - Total Revenue

	YTD 2020				Q3 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Oncology	2,238	35	34	40	777	26	30
BioPharmaceuticals	2,125	33	(6)	(1)	646	(17)	(13)
- *New CVRM*	*1,072*	*17*	*28*	*35*	*353*	*13*	*19*
- *Respiratory & Immunology*	*1,053*	*16*	*(26)*	*(23)*	*293*	*(37)*	*(35)*
Other medicines	2,103	33	(3)	1	714	(3)	1
Total	**6,466**	**100**	**6**	**11**	**2,137**	**-**	**4**

Table 14: Notable new-medicine performances in Emerging Markets - Total Revenue

	YTD 2020				Q3 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Tagrisso	950	15	72	78	355	59	61
Forxiga	488	8	44	54	181	37	47
Brilinta	392	6	13	18	102	(22)	(20)
Lynparza[35]	195	3	94	n/m	75	79	88

Emerging Markets Total Revenue grew by 6% (11% at CER) to $6,466m in the year to date. The new medicines represented 34% of Emerging Markets Total Revenue (YTD 2019: 22%). Total Revenue from specialty-care medicines increased by 32% (38% at CER) to $2,662m and comprised 41% of Emerging Markets sales in the year to date (YTD 2019: 33%). In the third quarter, however, Total Revenue was stable (up by 4% at CER) due to the continued effect of COVID-19 predominantly impacting the treatment of respiratory patients in the hospital setting.

China Total Revenue comprised 62% of Emerging Markets Total Revenue in the year to date and increased by 9% (11% at CER) to $4,013m. New medicines, primarily driven by *Tagrisso* and *Lynparza* in Oncology and *Forxiga* in New CVRM, delivered particularly encouraging growth and represented 33% of China Total Revenue in the year to date (YTD 2019: 19%); strong sales of *Seloken*, *Zoladex* and *Symbicort* supplemented this performance. However, the aforementioned performance of *Pulmicort* adversely impacted Total Revenue. In the third quarter of 2020, Total Revenue increased by 6% to $1,354m, with the performance reduced by sales of *Pulmicort* and the inclusion of *Brilinta*, *Losec* and *Arimidex* in the VBP programme in Q3 2020, following the Company's decision not to compete with generic competitor price in the tender process, respectively.

Ex-China Emerging Markets Total Revenue, comprising entirely of Product Sales, increased by 3% in the year to date (10% at CER) to $2,453m. The new medicines represented 35% of ex-China Emerging Markets Total Revenue (YTD 2019: 28%), increasing by 28% (39% at CER) to $863m. In the third quarter of 2020, the performance reflected the divestment of several medicines[36] in Q4 2019 and Q1 2020, in the Middle East and Africa, and the impact of lower demand in Brazil due to COVID-19.

Table 15: Ex-China Emerging Markets: Total Revenue

	YTD 2020			Q3 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Ex-China Asia Pacific	896	5	7	299	4	7
Middle East and Africa	768	-	3	237	(15)	(12)
Ex-Brazil Latin America	317	-	16	110	2	20
Russia	237	34	45	62	(4)	8
Brazil	235	(14)	10	74	(27)	1

[35] Here, excludes any Collaboration Revenue associated with the aforementioned collaboration with MSD.
[36] Including *Arimidex* and *Casodex* in Oncology in December 2019, hypertension medicines *Inderal*, *Tenormin* and *Zestril* in CVRM and *Losec* in other medicines.

Financial performance

Table 16: Reported Profit and Loss - YTD 2020

	YTD 2020 $m	YTD 2019 $m	% change Actual	% change CER
Total Revenue	19,207	17,720	8	10
- *Product Sales*	*18,879*	*17,315*	*9*	*11*
- *Collaboration Revenue*	*328*	*405*	*(19)*	*(18)*
Cost of Sales	(3,774)	(3,543)	7	9
Gross Profit	15,433	14,177	9	10
Gross Profit Margin	*80.0%*	*79.5%*	-	-
Distribution Expense	(290)	(247)	17	21
% Total Revenue	*1.5%*	*1.4%*	-	-
R&D Expense	(4,272)	(3,968)	8	8
% Total Revenue	*22.2%*	*22.4%*	-	-
SG&A Expense	(8,084)	(8,656)	(7)	(5)
% Total Revenue	*42.1%*	*48.9%*	*+7*	*+7*
Other Operating Income & Expense	888	1,041	(15)	(14)
% Total Revenue	*4.6%*	*5.9%*	*-1*	*-1*
Operating Profit	3,675	2,347	57	59
Operating Profit Margin	*19.1%*	*13.2%*	*+6*	*+6*
Net Finance Expense	(905)	(948)	(5)	(5)
Joint Ventures and Associates	(21)	(91)	(76)	(75)
Profit Before Tax	2,749	1,308	n/m	n/m
Taxation	(610)	(358)	70	71
Tax Rate	22%	27%		
Profit After Tax	2,139	950	n/m	n/m
EPS	$1.66	$0.79	n/m	n/m

Table 17: Reported Profit and Loss - Q3 2020

	Q3 2020 $m	Q3 2019 $m	% change Actual	% change CER
Total Revenue	6,578	6,406	3	3
- *Product Sales*	*6,520*	*6,132*	*6*	*7*
- *Collaboration Revenue*	*58*	*274*	*(79)*	*(78)*
Cost of Sales	(1,370)	(1,351)	1	-
Gross Profit	5,208	5,055	3	4
Gross Profit Margin	*79.0%*	*78.0%*	*+1*	*+1*
Distribution Expense	(99)	(88)	13	13
% Total Revenue	*1.5%*	*1.4%*	-	-
R&D Expense	(1,495)	(1,346)	11	11
% Total Revenue	*22.7%*	*21.0%*	*-2*	*-2*
SG&A Expense	(2,730)	(3,199)	(15)	(15)
% Total Revenue	*41.5%*	*49.9%*	*+8*	*+9*
Other Operating Income & Expense	287	335	(14)	(15)
% Total Revenue	*4.4%*	*5.2%*	*-1*	*-1*
Operating Profit	1,171	757	55	61
Operating Profit Margin	*17.8%*	*11.8%*	*+6*	*+7*
Net Finance Expense	(317)	(316)	1	(2)
Joint Ventures and Associates	(1)	(32)	(96)	(96)
Profit Before Tax	853	409	n/m	n/m
Taxation	(202)	(129)	57	63
Tax Rate	24%	32%		
Profit After Tax	651	280	n/m	n/m
EPS	$0.49	$0.23	n/m	n/m

Table 18: Reconciliation of Reported Profit Before Tax to EBITDA - YTD 2020

	YTD 2020 $m	YTD 2019 $m	% change Actual	% change CER
Reported Profit Before Tax	2,749	1,308	n/m	n/m
Net Finance Expense	905	948	(5)	(5)
Joint Ventures and Associates	21	91	(76)	(75)
Depreciation, Amortisation and Impairment	2,352	2,119	11	12
EBITDA	6,027	4,466	35	37

Table 19: Reconciliation of Reported Profit Before Tax to EBITDA - Q3 2020

	Q3 2020 $m	Q3 2019 $m	% change Actual	% change CER
Reported Profit Before Tax	853	409	n/m	n/m
Net Finance Expense	317	316	1	(2)
Joint Ventures and Associates	1	32	(96)	(96)
Depreciation, Amortisation and Impairment	801	716	12	11
EBITDA	1,972	1,473	34	37

Table 20: Reconciliation of Reported to Core financial measures - YTD 2020

YTD 2020	Reported $m	Restructuring $m	Intangible Asset Amortisation & Impairments $m	Diabetes Alliance $m	Other $m	Core[37] $m	Core % change Actual	Core % change CER
Gross Profit	15,433	44	50	-	4	15,531	8	10
Gross Profit Margin	*80.0%*					*80.5%*	-	-
Distribution Expense	(290)	-	-	-	-	(290)	17	21
R&D Expense	(4,272)	30	77	-	-	(4,165)	9	9
SG&A Expense	(8,084)	67	1,228	246	19	(6,524)	1	3
Total Operating Expense	(12,646)	97	1,305	246	19	(10,979)	4	5
Other Operating Income & Expense	888	(1)	2	-	-	889	(16)	(15)
Operating Profit	3,675	140	1,357	246	23	5,441	11	13
Operating Profit Margin	*19.1%*					*28.3%*	*+1*	*+1*
Net Finance Expense	(905)	-	-	174	154	(577)	-	(2)
Taxation	(610)	(28)	(284)	(92)	(1)	(1,015)	11	13
EPS	$1.66	$0.09	$0.82	$0.25	$0.13	$2.95	13	16

[37] Core financial measures are adjusted to exclude certain items. For more information on the Reported to Core financial adjustments, please refer to the introduction to the operating and financial review.

Table 21: Reconciliation of Reported to Core financial measures - Q3 2020

Q3 2020	Reported $m	Restructuring $m	Intangible Asset Amortisation & Impairments $m	Diabetes Alliance $m	Other $m	Core[37] $m	Core % change Actual	Core % change CER
Gross Profit	5,208	9	17	-	(1)	5,233	2	3
Gross Profit Margin	*79.0%*					*79.4%*	-	-
Distribution Expense	(99)	-	-	-	-	(99)	13	13
R&D Expense	(1,495)	14	28	-	-	(1,453)	10	10
SG&A Expense	(2,730)	22	419	94	24	(2,171)	(1)	(1)
Total Operating Expense	(4,324)	36	447	94	24	(3,723)	3	3
Other Operating Income & Expense	287	(3)	1	-	-	285	(19)	(20)
Operating Profit	1,171	42	465	94	23	1,795	(4)	(1)
Operating Profit Margin	*17.8%*					*27.3%*	*-2*	*-1*
Net Finance Expense	(317)	-	-	59	50	(208)	10	8
Taxation	(202)	(8)	(101)	(32)		(343)	(10)	(7)
EPS	$0.49	$0.03	$0.28	$0.09	$0.05	$0.94	(4)	-

Profit and Loss summary

a) Gross Profit

The increases in Reported and Core Gross Profit in the year to date reflected the growth in Product Sales. The Reported and Core Gross Profit Margins were stable in the year to date at 80% and 81%, respectively. A Core Gross Profit Margin in the third quarter of 79% was also unchanged versus the prior year.

b) Total Operating Expense

Reported Total Operating Expense declined by 2% in the year to date (1% at CER) to $12,646m and represented 66% of Total Revenue (YTD 2019: 73%). Core Total Operating Expense increased by 4% (5% at CER) to $10,979m and represented 57% of Total Revenue (YTD 2019: 59%).

- The increase in Reported and Core Distribution Expense in the year to date was a result of adverse logistics impacts from the COVID-19 pandemic

- The growth in Reported and Core R&D Expense reflected investment in the pipeline, including the development of datopotomab deruxtecan and the ending in 2019 of the release of the upfront funding of *Lynparza* development, as part of the aforementioned collaboration with MSD. There were additional costs and procedures related to COVID-19, such as personal protective equipment and colleague testing. AstraZeneca has also mobilised research efforts to treat patients with severe COVID-19 symptoms

- The difference in the movements of Reported and Core SG&A Expense partly reflected fair-value adjustments arising on acquisition-related liabilities, as well as an increase in legal provisions recognised in 2019, offset by additional intangible asset impairment charges recorded in the year to date. Within Core SG&A Expense, pandemic-related savings partly compensated for investment in the launches of new medicines and expansion in China.

c) Other Operating Income and Expense[38]

Reported Other Operating Income and Expense in the year to date of $888m reflected a decline of 15% (14% at CER). Core Other Operating Income and Expense in the year to date, decreasing by 16% (15% at CER) to $889m, included $350m of income from an agreement to divest commercial rights to a number of legacy hypertension medicines. Income was also received from the monetisation of an asset previously licensed, as was a payment from Allergan (part of AbbVie) of $51m in respect of the development of brazikumab.

d) Net Finance Expense

The declines in Reported and Core Net Finance Expense partly reflected a favourable movement in loan interest, following the repayment of a $1bn bond in 2019.

e) Taxation

The Reported and Core Tax Rates for the year to date were 22% and 21%, respectively (YTD 2019: 27% and 22%, respectively). The net cash tax paid for the year to date was $1,221m, representing 44% of Reported Profit Before Tax (YTD 2019: $965m, 74%); the increase partly reflected the growth in Reported Profit Before Tax and the phasing of tax payments.

f) Non-controlling interests

Profit attributable to non-controlling interests amounted to a loss of $45m in the year to date (YTD 2019: $75m). This primarily reflected the profit-sharing agreement with Acerta Pharma with regards to *Calquence*.

g) EPS

Reported EPS of $1.66 in the year to date represented an increase of 111% (113% at CER); Core EPS increased by 13% (16% at CER) to $2.95.

[38] 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.

Table 22: Cash Flow

	YTD 2020 $m	YTD 2019 $m	Change $m
Reported Operating Profit	3,675	2,347	1,328
Depreciation, Amortisation and Impairment	2,352	2,119	233
Increase in Working Capital and Short-Term Provisions	(255)	(812)	557
Gains on Disposal of Intangible Assets	(535)	(833)	298
Non-Cash and Other Movements	(498)	313	(811)
Interest Paid	(517)	(575)	58
Taxation Paid	(1,221)	(965)	(256)
Net Cash Inflow from Operating Activities	**3,001**	**1,594**	**1,407**
Net Cash Inflow before Financing Activities	**2,578**	**879**	**1,699**
Net Cash Inflow/(Outflow) from Financing Activities	**7**	**(1,771)**	**1,778**

The increase in Net Cash Inflow from Operating Activities in the year to date primarily reflected an underlying improvement in business performance. The increase in Non-Cash and Other Movements of $811m to $498m was partly driven by a reduction in fair-value movements on business combination-related liabilities and included the effect of the re-acquisition of US rights to *Duaklir*/*Tudorza* from Circassia Pharmaceuticals plc in settlement of a loan-receivable balance included in working capital.

The increase in Net Cash Inflow before Financing Activities was a result of the aforementioned improvement in Net Cash Inflow from Operating Activities, as well as a $1,103m increase in the Disposal of Non-Current Asset Investments to $1,121m; AstraZeneca sold an undisclosed proportion of its equity portfolio in the year to date.

Recorded within the Purchase of Intangible Assets, AstraZeneca made the second of two $675m upfront payments in the second quarter of 2020 to Daiichi Sankyo, as part of the 2019 agreement on *Enhertu*. The first of three non-contingent payments were also made in the third quarter to Daiichi Sankyo in respect of the potential new Oncology medicine, datopotomab deruxtecan; the payment amounted to $350m.

Under the terms of a past agreement to acquire Pearl Therapeutics Inc., AstraZeneca made a $150m milestone payment in the quarter upon the US regulatory approval of *Breztri* for the treatment of COPD. This was the final development and regulatory milestone under that agreement. The cash payment of contingent consideration, in respect of the former BMS share of the global diabetes alliance, amounted to $394m in the year to date.

Capital Expenditure
Capital expenditure amounted to $598m in the year to date, compared to $659m in YTD 2019. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK.

Table 23: Net Debt summary

	At 30 Sep 2020 $m	At 31 Dec 2019 $m	At 30 Sep 2019 $m
Cash and cash equivalents	8,072	5,369	3,967
Other investments	374	911	909
Cash and investments	**8,446**	**6,280**	**4,876**
Overdrafts and short-term borrowings	(1,216)	(225)	(228)
Lease liabilities	(666)	(675)	(712)
Current instalments of loans	(2,186)	(1,597)	-
Non-current instalments of loans	(18,271)	(15,730)	(17,218)
Interest-bearing loans and borrowings (Gross Debt)	**(22,339)**	**(18,227)**	**(18,158)**
Net derivatives	**131**	**43**	**(16)**
Net Debt	**(13,762)**	**(11,904)**	**(13,298)**

Net Debt increased by $1,858m in the year to date, due principally to Net Cash Inflow before Financing Activities of $2,578m being offset by the payment of the second interim dividend of 2019 and first interim dividend of 2020, totalling $3,572m.

Details of the committed undrawn bank facilities are disclosed within the going-concern section of Note 1. In August 2020, AstraZeneca issued the following:

- $1.2bn of fixed-rate notes with a coupon of 0.700%, maturing in April 2026
- $1.3bn of fixed-rate notes with a coupon of 1.375%, maturing in August 2030
- $0.5bn of fixed-rate notes with a coupon of 2.125%, maturing in August 2050

In the year to date, there have been no changes to the Company's credit ratings issued by Standard and Poor's (long term: BBB+, short term A-2) and Moody's (long term: A3, short term P-2).

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. Foreign-exchange gains and losses on forward contracts for transactional hedging are taken to profit or loss. In addition, the Company's external dividend payments, paid principally in pounds sterling and Swedish krona, are fully hedged from announcement to payment date.

Table 24: 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)[39]	
Currency	**Primary Relevance**	**FY 2019[40]**	**YTD 2020[41]**	**% change**	**Product Sales**	**Core Operating Profit**
CNY	Product Sales	6.92	7.00	(1)	288	190
EUR	Product Sales	0.89	0.89	-	171	68
JPY	Product Sales	108.98	107.51	1	139	98
Other[42]					231	123
GBP	Operating Expense	0.78	0.79	-	27	(93)
SEK	Operating Expense	9.46	9.40	1	5	(51)

[39] As per the FY 2019 results announcement.
[40] Based on average daily spot rates in FY 2019.
[41] Based on average daily spot rates from 1 January 2020 to 30 September 2020.
[42] Other currencies include AUD, BRL, CAD, KRW and RUB.

Sustainability

AstraZeneca's sustainability approach has three priority areas[43], aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

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

a) Access to healthcare

During the period, AstraZeneca CEO Pascal Soriot signed a vaccines pledge in collaboration with nine biopharmaceutical companies, committing to the continued safety and well-being of vaccinated individuals as the top priority in development of the first COVID-19 vaccines. CEOs of AstraZeneca, BioNTech SE, GlaxoSmithKline plc, Johnson & Johnson, Merck Inc., known as MSD outside the United States and Canada, Moderna, Inc., Novavax, Inc., Pfizer Inc. and Sanofi-aventis Groupe SA outlined a united commitment to uphold the integrity of the scientific process as they work towards potential global regulatory filings and approvals of the first COVID-19 vaccines.

The Company continues to work with governments and other organisations, scaling up manufacturing with independent parallel supply chains around the world to produce billions of doses to a consistent and high standard of safety and efficacy. Several agreements have been signed, covering the distribution of the potential vaccine, across a number of countries and regions including the UK, US, the EU, Russia, the Middle East, Latin America, Japan, China, Australia and a wide group of low and middle-income countries. Across the world, these parallel agreements have helped to provide total manufacturing capacity approaching three billion doses of the vaccine between now and the end of 2021. AstraZeneca is committed to providing broad and equitable access to the potential vaccine on a not-for-profit basis during the pandemic.

In conjunction with the 75th (virtual) United Nations General Assembly, the Company co-hosted a panel event in partnership with Devex[44], sharing lessons learnt and reflections about partnering and achieving healthcare resilience in light of health systems challenges brought to the fore by the COVID-19 pandemic. The Company also published an accompanying thought-leadership article on how to achieve a sustainable and resilient future in the context of global health.

The Company's Healthy Heart Africa programme marked its six-year anniversary in Kenya and celebrated World Hypertension Day (17 October) with a social media campaign highlighting its work in public-private partnerships throughout Africa to support patient access to hypertension care.

The Young Health Programme (YHP) and UNICEF partnership announced Angola, Belize, Brazil, Indonesia, Jamaica and South Africa as the six 'accelerator' countries that will lead a joint initiative to promote healthier lifestyles and environments for young people. The wider collaboration between YHP and UNICEF aims to reach more than five million adolescents with non-communicable disease (NCD) prevention messages and train more than 1,000 young advocates to promote NCD prevention at local, national and international levels, as well as positively shape policies and laws around the world over the next five years.

b) Environmental protection

During the period, as part of its Ambition Zero Carbon strategy, the Company announced it had accelerated delivery of its renewable power sourcing targets, achieving 100% supply of certified renewable imported power across all sites worldwide by the end of 2020, five years ahead of its original RE100 (renewable energy)

[43] These priorities were determined through a materiality assessment conducted in 2018 with a broad range of 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 align with the United Nations Sustainable Development Goals (SDG), and, in particular, SDG three for 'Good Health'.

[44] Devex is a social enterprise and media platform for the global-development community. Devex aims to connect and inform development, health, humanitarian and sustainability professionals through news, business intelligence, and funding and career opportunities in international development.

commitments; along with switching to electric vehicles (EV100) and increasing energy productivity (EP100) in 2025.

As a Gold Sponsor of Climate Week NYC (21-27 September 2020), AstraZeneca participated in two virtual events; Katarina Ageborg, Executive Vice President, Sustainability and Chief Compliance Officer, took part in a panel for the Climate Group focused on green economic recovery from COVID-19 and was interviewed by The Climate Group about the Company's commitment to sustainability and the threat climate change presents to public health. The Company also led an expert panel discussing the role of clean heat in industrial decarbonisation and related challenges, chaired by Louise Nicholls, AstraZeneca Sustainability Advisory Board member and former Corporate Head of Human Rights, Food Sustainability and Food Packaging, at Marks and Spencer plc. Recognising the need to think beyond power in driving a clean-heat strategy, the Company joined the Renewable Thermal Collaborative (RTC) during the period in support of its clean heat objectives as part of its Ambition Zero Carbon commitments. RTC is the leading coalition for organisations committed to decarbonising the energy required for heat in buildings and industrial processes.

To drive a more innovative framework for characterising the environmental risks of active pharmaceutical ingredients the IMI PREMIER project was launched with AstraZeneca as the lead organisation. The IMI is a public-private partnership between pharmaceutical companies, the European Commission and the European Federation of Pharmaceutical Industries and Associations. Supported by the European Commission, the project benefits from €10m investment to fund the research objectives.

During the period, as part of the AZ Forest programme, the Company announced a commitment to plant 20,000 trees in Australia in 2020, as part of its 25 million tree long-term commitment in Australia. AZ Forest is a global initiative to plant 50 million trees worldwide by 2025. In partnership with local governments and One Tree Planted, a non-profit organisation focused on global reforestation, this initiative supports the World Economic Forum's '1T.org – The Champions for a Trillion Trees' platform.

c) Ethics and transparency

During the period, the Company held its first virtual Environmental, Social and Corporate Governance (ESG) investor event, led by Non-Executive Chairman of the Board, Leif Johansson and Katarina Ageborg. 'Meet AZN Management: Leading in Sustainability' virtual webcast shared insights into the Company's sustainability strategy and governance and was attended by analysts, institutional investors and ratings agencies, recognising the growing focus of the investor community on ESG strategy as a guide to sustainable business performance.

Highlighting the Company's continued commitment to transparency and ethical conduct, a new Data and AI Ethics position statement was published to establish and make visible AstraZeneca's principles around this emerging field of practice.

During the period, the Company launched the 2020 Code of Ethics awareness training across its global employee base. Integrated into a broader education and awareness campaign to mark Global Ethics Day 2020, the training takes a look at ethical decision making, featuring inspiring stories from colleagues who are going above and beyond what is required by regulation, to uphold the company values.

As part of the Company's approach to sustainability strategy and governance, the AstraZeneca Sustainability Advisory Board participated in a virtual meeting during the period to discuss current issues and future strategy. The advisory board comprises five members of the Senior Executive Team and four external sustainability experts, plus non-executive Board member Nazneen Rahman.

For more details on AstraZeneca's sustainability ambition, approach and targets, please refer to the latest Sustainability Report 2019 and Sustainability Data Summary 2019. Additional information is available at astrazeneca.com/sustainability.

Research and development

As the COVID-19 pandemic continues, the Company will evaluate the impact on the initiation of clinical trials, ongoing recruitment and follow-ups. It is prudent to assume that some delays will arise as a consequence of the pandemic.

A comprehensive breakdown of AstraZeneca's pipeline of medicines in human trials can be found in the latest 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 25: Late-stage pipeline

New molecular entities and major lifecycle events for medicines in Phase III trials or under regulatory review	20	**Oncology** - *Tagrisso* - NSCLC - *Imfinzi* - multiple cancers - *Lynparza* - multiple cancers - *Enhertu* - multiple cancers - capivasertib - breast, prostate cancer - *Calquence* - blood cancers - tremelimumab - multiple cancers - savolitinib - NSCLC[45] - monalizumab - head & neck cancer **CVRM** - *Farxiga* - multiple indications - roxadustat - anaemia in CKD **Respiratory & Immunology** - *Fasenra* - multiple indications - *Breztri/Trixeo* - COPD - PT027 - asthma - tezepelumab - severe asthma - nirsevimab - respiratory syncytial virus - anifrolumab - lupus (SLE) - brazikumab - inflammatory bowel disease **COVID-19** - AZD1222 - SARS-CoV-2 - AZD7424 - SARS-CoV-2
Total projects in clinical development	148	
Total projects in total pipeline	172	

[45] Phase II/IIb trial with potential for registration.

Oncology

During the period, AstraZeneca presented new developments at the European Society for Medical Oncology (ESMO) Virtual Congress 2020. AstraZeneca medicines and pipeline molecules featured in 114 abstracts at the congress, including 20 oral presentations and two Presidential Symposia. The data highlight the breadth of the portfolio of cancer medicines and the potential of the early-stage pipeline

Oncology: lung cancer

a) *Tagrisso*

During the period, *Tagrisso* received regulatory submission acceptance for its supplemental New Drug Application and was also granted Priority Review in the US for the adjuvant treatment of patients with early-stage (IB, II and IIIA) EGFRm NSCLC after complete tumour resection with curative intent. *Tagrisso* was also granted Breakthrough Therapy Designation in the US for the same treatment setting. In China, the regulatory submission was also completed and granted priority review.

At the aforementioned ESMO 2020 congress, *Tagrisso* results from a prespecified exploratory analysis of the positive ADAURA Phase III trial were presented during the Presidential Symposium and simultaneously published alongside the primary results in *The New England Journal of Medicine*. *Tagrisso* demonstrated a clinically meaningful improvement in central nervous system (CNS) disease; *Tagrisso* was given as adjuvant treatment for patients with early-stage (IB, II and IIIA) EGFRm NSCLC, after complete tumour resection. *Tagrisso* showed an 82% reduction in the risk of CNS recurrence or death (based on a hazard ratio [HR] of 0.18; 95% confidence interval [CI] 0.10-0.33; p<0.0001).

Table 26: Key *Tagrisso* trials

Trial	Population	Design	Timeline	Status
Phase III NeoADAURA	Neo-adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD[46] Q2 2020 First data anticipated 2021+	Recruitment ongoing
Phase III ADAURA	Adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD Q4 2015 LPCD[47] Q1 2019	Trial unblinded early due to overwhelming efficacy
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

[46] First patient commenced dosing.
[47] Last patient commenced dosing.

b) *Imfinzi*

In August 2020, *Imfinzi* received regulatory submission acceptance for its supplemental Biologics License Application (sBLA) and was also granted Priority Review in the US for a new four-week, fixed-dose regimen. During the period, *Imfinzi* was granted accelerated assessment in the EU for the same indication. If approved, *Imfinzi* could be administered intravenously every four weeks at a fixed dose of 1,500mg, consistent with the approved dosing in ES-SCLC.

During the period, *Imfinzi* was approved in the EU and Japan for the treatment of patients with ES-SCLC, in combination with etoposide plus a choice of platinum chemotherapy (either carboplatin or cisplatin). The approval was based on positive results from the CASPIAN Phase III trial. In China, the regulatory submission was also completed.

During the aforementioned ESMO 2020 congress, updated results presented from the *Imfinzi* PACIFIC Phase III trial showed that *Imfinzi* demonstrated a sustained, clinically meaningful OS and progression-free survival (PFS) benefit in patients with unresectable, Stage III NSCLC who had not progressed following concurrent CRT. The results from the updated post-hoc analyses showed an estimated four-year OS rate of 49.6% for *Imfinzi*, versus 36.3% for placebo, after CRT.

Table 27: 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 2021+	Recruitment ongoing
Phase III ADJUVANT BR.31[48]	Stage Ib-IIIa resected NSCLC	Placebo or *Imfinzi*	FPCD Q1 2015 LPCD Q1 2020 First data anticipated 2021+	Recruitment completed
Phase III MERMAID-1	Stage II-III resected NSCLC	SoC chemotherapy +/- *Imfinzi*	FPCD Q3 2020 First data anticipated 2021+	Recruitment ongoing
Phase III PACIFIC-2	Stage III unresectable locally advanced NSCLC (concurrent CRT)	Placebo or *Imfinzi*	FPCD Q2 2018 LPCD Q3 2019 First data anticipated H1 2021	Recruitment completed

[48] Conducted by the Canadian Cancer Trials Group.

Trial	Population	Design	Timeline	Status
Phase III ADRIATIC	Limited-stage SCLC	Concurrent CRT, followed by placebo or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III PEARL	Stage IV, 1st-line NSCLC	SoC chemotherapy or *Imfinzi*	FPCD Q1 2017 LPCD Q1 2019 First data anticipated H1 2021	Recruitment completed
Phase III POSEIDON	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q2 2017 LPCD Q4 2018 OS data anticipated H2 2021	PFS primary endpoint met
Phase III CASPIAN	ES-SCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q1 2017 LPCD Q2 2018	OS primary endpoint met for *Imfinzi* OS primary endpoint not met for *Imfinzi* + treme

Table 28: 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[49] or SoC BCG + *Imfinzi*	FPCD Q4 2018 LPCD Q3 2020 First data anticipated 2021+	Recruitment completed
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 H2 2021	Recruitment ongoing

[49] Bacillus Calmette-Guerin.

Trial	Population	Design	Timeline	Status
Phase III EMERALD-1	Locoregional HCC[50]	TACE[51] followed by placebo or TACE + *Imfinzi*, followed by *Imfinzi* + bevacizumab or TACE + *Imfinzi* followed by *Imfinzi*	FPCD Q1 2019 First data anticipated H2 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 LPCD Q4 2020 First data anticipated 2021+	Recruitment completed
Phase III	Resectable gastric and gastroesophageal cancer	Chemotherapy or chemotherapy + Imfinzi	Initiating	Initiating
Phase III KUNLUN	Locally advanced, unresectable oesophageal squamous cell carcinoma	Definitive CRT or CRT + *Imfinzi*	FPCD Q4 2020 First data anticipated 2021+	Recruitment ongoing
Phase III NILE	Stage IV, 1st-line cisplatin chemotherapy-eligible bladder cancer	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III KESTREL	Stage IV, 1st-line HNSCC[52]	SoC or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H1 2021	Recruitment completed

[50] Hepatocellular carcinoma.
[51] Transarterial chemoembolisation.
[52] Head and neck squamous cell carcinoma.

Trial	Population	Design	Timeline	Status
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 2021	Recruitment completed Orphan Drug Designation (ODD)[53] (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 H2 2021	Recruitment ongoing

c) *Lynparza* (multiple cancers)

At the aforementioned ESMO congress, data from the SOLO-1 Phase III trial in ovarian cancer were presented, where *Lynparza* demonstrated a long-term PFS benefit versus placebo as a 1st-line maintenance treatment in patients with newly diagnosed, advanced BRCAm ovarian cancer who had a complete or partial response following platinum-based chemotherapy. Five-year follow-up data from the SOLO-1 trial showed *Lynparza* reduced the risk of disease progression or death by 67% (based on a HR of 0.33; 95% CI 0.25-0.43) and improved PFS to a median of 56.0 months, versus 13.8 months for placebo.

At the ESMO congress, final results from the *Lynparza* prostate PROfound Phase III trial were also presented, which demonstrated a statistically significant and clinically meaningful improvement in OS, versus enzalutamide or abiraterone, in men with 2nd-line mCRPC and BRCA1/2 or ATM gene mutations, a subpopulation of HRR gene mutations. In the key secondary endpoint of OS, *Lynparza* reduced the risk of death by 31%, versus enzalutamide or abiraterone (based on a HR of 0.69; 95% CI 0.50-0.97; p=0.0175), despite 66% of men on new hormonal agent treatments having crossed over to receive treatment with *Lynparza*, following disease progression.

Table 29: 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 H1 2021	Recruitment completed
Phase III PROfound	Metastatic castration-resistant 2nd-line+ HRRm prostate cancer	SoC (abiraterone or enzalutamide) or *Lynparza*	FPCD Q2 2017 LPCD Q4 2018	Primary endpoint met Priority Review (US)

[53] The US Orphan Drug Act grants special status to a medicine or potential medicine to treat a rare disease or condition upon request of a sponsor. Designation qualifies the sponsor of the medicine for various development incentives.

Trial	Population	Design	Timeline	Status
Phase III PAOLA-1[54]	Advanced 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + *Lynparza* maintenance	FPCD Q2 2015 LPCD Q2 2018	Primary endpoint met Priority Review (US)
Phase II/III GY005	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* +/- *Lynparza* maintenance	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase III DuO-E	Advanced 1st-line endometrial cancer	Chemotherapy or chemotherapy + *Imfinzi* + *Imfinzi* maintenance or chemotherapy + *Imfinzi* followed by *Imfinzi* + *Lynparza* maintenance	FPCD Q2 2020 First data anticipated 2021+	Recruitment ongoing
Phase III PROpel	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + *Lynparza*	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase III LYNK-003	Stage IV, 1st-line colorectal cancer	Bevacizumab + 5-FU[55] maintenance or bevacizumab + *Lynparza* maintenance or *Lynparza* maintenance	First data anticipated 2021+	Initiating

During the period, Centus Biotherapeutics, a joint venture between Fujifilm Kyowa Kirin Biologics Co., Ltd. and AstraZeneca, announced that the European Commission had granted the marketing authorisation for *Equidacent* (FKB238), the company's biosimilar to *Avastin* (bevacizumab). Bevacizumab is an often-used medicine for the treatment of ovarian cancer, including in combination with *Lynparza*. AstraZeneca continues to prioritise the development of *Lynparza* and other innovative medicines.

[54] Conducted by the ARCAGY/Groupe investigators national des Etudes des Cancers Ovariens et du sein.
[55] Fluorouracil.

d) *Enhertu* (breast and other cancers)

During the period, Daiichi Sankyo announced the regulatory approval of *Enhertu* in Japan for the treatment of patients with HER2+ unresectable advanced or recurrent gastric cancer that have progressed after chemotherapy. *Enhertu* was previously granted SAKIGAKE[56] designation in Japan for this indication. Regulatory submission acceptance and for an sBLA was also received in the US for *Enhertu* for the treatment of patients with HER2+, metastatic gastric or gastroesophageal junction adenocarcinoma and a Priority Review was also granted.

Table 30: Key *Enhertu* trials

Trial	Population	Design	Timeline	Status
Phase II DESTINY-Breast01-U201	Stage IV, HER2+[57] breast cancer post trastuzumab emtansine	*Enhertu*	FPCD Q4 2017 LPCD Q4 2018	Primary objective met Breakthrough Therapy Designation (US)
Phase III DESTINY-Breast02-U301	Stage IV, HER2+ breast cancer post trastuzumab emtansine	SoC chemotherapy or *Enhertu*	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase III DESTINY-Breast03-U302	Stage IV, HER2+ breast cancer	Trastuzumab emtansine or *Enhertu*	FPCD Q4 2018 LPCD Q2 2020 First data anticipated H2 2021	Recruitment completed
Phase III DESTINY-Breast04	Stage IV, HER2-low breast cancer	SoC chemotherapy or *Enhertu*	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase III DESTINY-Breast06	Stage IV, HER2-low breast cancer post endocrine therapy	SoC chemotherapy or *Enhertu*	FPCD Q3 2020	Recruitment ongoing
Phase II DESTINY-Gastric01	Stage IV, HER2+ gastric cancer	SoC chemotherapy or *Enhertu*	FPCD Q4 2017 LPCD Q2 2019	Primary endpoint met Breakthrough Therapy Designation (US)
Phase II DESTINY-Gastric03	Stage IV, HER2+ gastric cancer	SoC chemotherapy or SoC + *Enhertu*	FPCD Q2 2020	Recruitment ongoing

[56] SAKIGAKE promotes early research and development in Japan for innovative pharmaceuticals and provides a rapid-authorisation scheme for unapproved medicines for serious and life-threatening diseases.
[57] IHC 3+ and IHC 2+/ISH. The immunohistochemistry test gives a score of 0 to 3+ that measures the amount of HER2-receptor protein on the surface of cells in a cancer tissue sample.

Trial	Population	Design	Timeline	Status
Phase II DESTINY-PanTumour02	HER2 expressing tumours	*Enhertu*	FPCD Q3 2020	Recruitment ongoing

CVRM

AstraZeneca recently presented full data from the DAPA-CKD Phase III trial at the European Society of Cardiology (ESC) Congress. The data were among 20 abstracts presented by the Company at the congress, showing the breadth of its CV, renal and metabolic pipeline.

In October 2020, AstraZeneca presented 84 abstracts, including 12 oral presentations and three late-breaking abstracts, across its renal portfolio which includes roxadustat, *Farxiga* and *Lokelma*, at the American Society of Nephrology (ASN) Kidney Week 2020 Reimagined.

a) *Forxiga* (diabetes)
In October 2020, the Company announced that the China NMPA had approved an update to the label for *Forxiga* to include the positive CV outcomes and renal data from the DECLARE-TIMI 58 Phase III trial in adults with T2D.

b) *Farxiga* (heart failure)
In October 2020, the Company announced that the CHMP had adopted a positive opinion for an indication extension of *Forxiga*'s marketing authorisation in the EU for the treatment of symptomatic chronic HFrEF with in adults with and without T2D.

During the period, the Company obtained results from the DETERMINE-preserved and DETERMINE-reduced function and symptom trials, evaluating Farxiga as a treatment for HFpEF and HFrEF, respectively. These trials had the same primary endpoints. In the DETERMINE-reduced trial, Farxiga demonstrated a statistically significant reduction in HF symptoms, as measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ)-Total Symptom Score, versus placebo. This trial did not, however, show a change from baseline in the distance walked in six minutes, and the KCCQ-Physical Limitation Score. The DETERMINE HFpEF trial did not meet any of the three aforementioned endpoints. No new safety concerns were identified. These results had no impact on Farxiga's HFrEF indication, which is approved in the US and is under regulatory review in other regions, based on ground-breaking data from the DAPA-HF trial. The large randomised DELIVER Phase III trial, evaluating Farxiga in HFpEF, is expected to read out in the second half of 2021.

c) *Farxiga* (CKD)
Phase III trial data, presented at the aforementioned ESC Congress, showed that *Farxiga*, on top of SoC, reduced the composite measure of worsening of renal function or risk of CV or renal death by 39%, compared to placebo ($p<0.0001$), in patients with CKD Stages 2-4 and elevated urinary albumin excretion. The absolute risk reduction (ARR) was 5.3% over the median time in study of 2.4 years. The trial also met all secondary endpoints, including significantly reducing death from any cause by 31% (ARR = 2.1%, $p=0.0035$) compared to placebo. The results were consistent in patients both with and without T2D.

In October 2020, the Company announced that *Farxiga* had been granted US FDA Breakthrough Therapy Designation for the treatment of patients with CKD, with and without T2D.

d) *Forxiga* (type-1 diabetes)
During the period, the European Commission renewed the licence of *Edistride* (*Forxiga* in other EU markets) for the treatment of T2D. The indication for type-1 diabetes (T1D) will, however, be withdrawn. *Edistride* 5mg was approved for the treatment of adults with insufficiently controlled T1D mellitus, as an adjunct to insulin in patients with a Body Mass Index ≥27kg/m2, when insulin alone did not provide adequate glycaemic control, despite optimal insulin therapy. *Edistride* is marketed only in Spain and Portugal, where the T2D indication will continue to be available for patients.

e) *Qtrilmet*

During the period, the Company decided not to progress with the planned launch of *Qtrilmet* (fixed-dose combination of metformin, *Forxiga* and *Onglyza*) in the EU, reflecting adverse changes in the competitive landscape. This followed the recent decision not to launch *Qternmet* in the US for the same reason.

f) *Brilinta* (stroke)

AstraZeneca made a regulatory submission during the period for *Brilinta* in stroke in China, based on results from the THALES Phase III trial.

Table 31: Key large CVRM outcomes trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Farxiga					
Phase III DAPA-HF	c.4,500 patients with HF with reduced ejection fraction, with and without T2D	Arm 1: *Farxiga* 10mg or 5mg QD[58] + SoC Arm 2: placebo + SoC	Time to first occurrence of CV death or hospitalisation due to HF or an urgent HF visit	FPCD Q1 2017 LPCD Q4 2018	Primary endpoint met
Phase III DELIVER	c.4,700 patients with HF (HFpEF) 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 H2 2021	Recruitment ongoing Fast Track designation (US)
Phase III DAPA-CKD	c.4,000 patients with CKD, with and without T2D	Arm 1: *Farxiga* 10mg or 5mg QD Arm 2: placebo	Time to first occurrence of ≥ 50% sustained decline in eGFR or reaching ESRD or CV death or renal death	FPCD Q1 2017 LPCD Q1 2020	Trial stopped early based on recommendation from an IDMC[59] Primary endpoint and secondary endpoints met Fast Track designation (US)
Brilinta					
Phase III THEMIS	c.19,000 patients with T2D and CAD without a history of MI or stroke	Arm 1: *Brilinta* 60mg BID[60] Arm 2: placebo BID on a background of aspirin if not contra-indicated[61] or not tolerated	Composite of CV death, non-fatal MI and non-fatal stroke	FPCD Q1 2014 LPCD Q2 2016	Primary endpoint met

[58] *Quaque die*, or once a day.
[59] Independent Data Monitoring Committee.
[60] *Bis in die*, or twice a day.
[61] A specific situation in which a medicine should not be used as a treatment as it may be harmful to the patient.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III THALES	c.11,000 patients with acute ischaemic stroke[62] or transient ischaemic attack	Arm 1: *Brilinta* 90mg BID Arm 2: placebo BID on a background of aspirin 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 Fast Track designation (US)

a) *Lokelma* (hyperkalaemia)

In August 2020, Premier Inc. (Premier), a leading healthcare improvement company, announced a collaboration with AstraZeneca to help reduce hospitalisations among patients with hyperkalaemia, which is characterised by higher-than-normal potassium levels. Premier has implemented evidence-based care practices with nearly 370 hospitals across the US, designed to prevent patients with hyperkalaemia from requiring treatment in the acute-care setting. The companies have developed a protocol for monitoring and treating patients, including the potential use of *Lokelma*, for the treatment of hyperkalaemia in adults. These evidence-based care practices allow hospitals to improve care delivery to potentially reduce the risk for admissions and re-admissions for patients with hyperkalaemia.

b) Roxadustat (anaemia)

During the period, AstraZeneca presented more than 40 roxadustat abstracts at the ASN Kidney Week 2020 Reimagined providing new insights on the potential of the medicine to transform the standard of care in anaemia of CKD across key patient sub-populations. Notable abstracts included:

- Two late-breaking presentations of pooled analyses of Phase III trials investigating the association between haemoglobin (Hb) levels and CV outcomes in NDD and DD CKD patients. In both analyses, incidence rates of adjudicated major adverse cardiac events (MACE[63]) and MACE+[64] were evaluated based on Hb level immediately before the event. In the both the NDD and DD CKD population, MACE and MACE+ rates were highest when Hb was less than 8g/dL, and the rates declined as Hb increased and were lowest when achieved Hb levels were greater than or equal to 10g/dL.

- An oral presentation exploring whether roxadustat can reduce the risk of hospitalisation for HF, a common comorbidity in patients with CKD

- Analyses of whether roxadustat has the potential to reduce the risk of red blood cell transfusions, a treatment for anaemia associated with additional complications, in both NDD CKD and DD CKD patients

- An analysis exploring the effect of roxadustat on achieving Hb ≥10 g/dL in patients with NDD CKD

- New data from pooled analyses of Phase III trials on DD CKD patient subgroups, including those who are receiving peritoneal dialysis and are new to dialysis

- An oral presentation highlighting that roxadustat is not associated with an increased risk of neoplasm in patients with CKD anaemia

Roxadustat is currently undergoing US FDA regulatory review, with a decision expected before the end of this year. In the year to date, FibroGen and AstraZeneca made several regulatory submissions in RoW countries, including Australia, Brazil, Canada, Chile, India, Mexico, Philippines, Singapore, South Korea, Taiwan, Thailand, and Columbia.

FibroGen and Astellas have received regulatory approval in DD, and regulatory submission acceptance for NDD in Japan. In the EU, the companies received submission acceptance from the EMA in May 2020.

[62] Ischaemic strokes are the most common type of stroke.
[63] MACE is defined as all-cause mortality, stroke and MI.
[64] MACE+ is defined as MACE, unstable angina requiring hospitalisation and congestive heart failure requiring hospitalisation.

Respiratory & Immunology

At the 2020 European Respiratory Society International Virtual Congress (ERS 2020), the Company presented 60 abstracts, including 10 oral presentations and three 'late-breakers' from across the inhaled and biologics portfolio and pipeline. Highlights included a post-hoc analysis of the ETHOS Phase III trial, showing a consistent benefit of *Breztri* in reducing the rate of moderate or severe COPD exacerbations across all seasons, compared with dual therapy.

a) *Symbicort* (mild asthma)
During the period, the Company received submission acceptance in the EU for *Symbicort Turbuhaler* as an anti-inflammatory reliever for patients with mild asthma.

b) *Breztri/Trixeo* (COPD)
During the period, *Breztri*, under the name *Trixeo*, received a positive opinion from the CHMP, recommending the medicine for marketing authorisation in the EU for maintenance treatment in adult patients with moderate to severe chronic COPD who are not adequately treated by a combination of an ICS and a LABA, or a combination of a LABA and a long-acting muscarinic antagonist.

c) *Fasenra* (eosinophil-driven diseases)
In September 2020, AstraZeneca announced positive results from the OSTRO Phase III trial for *Fasenra*, in patients with chronic rhinosinusitis with nasal polyps[65]. The trial evaluated the effect of *Fasenra* on nasal-polyp burden, assessed by change from baseline in endoscopic total nasal-polyp score (NPS), at week 40 compared to placebo. In addition, the trial evaluated the effect of *Fasenra* on patient-reported nasal blockage, assessed by change from baseline in mean nasal-blockage score (NBS), at week 40, compared to placebo. OSTRO recruited 413 patients in Europe and North America. The trial met its co-primary endpoints, demonstrating a statistically significant improvement in the endoscopic total NPS and NBS, compared to placebo, in patients with severe bilateral nasal polyps[66] who were still symptomatic, despite continued treatment with SoC. The following interventions are considered SoC for nasal polyps: intranasal corticosteroids, prior surgery and/or use of systemic corticosteroids.

In October 2020, AstraZeneca announced high-level results from the PONENTE Phase IIIb open-label trial, which showed OCS-dependent asthma patients across baseline blood eosinophil counts receiving *Fasenra* were able to eliminate the use of maintenance OCS.

On the first primary endpoint, 62% (95% CI: 58.2-66.1) of patients achieved complete elimination of daily OCS use. On the second primary endpoint, 81% (95% CI 77.2-83.7) of patients achieved complete elimination or were able to reduce their daily OCS dose to 5mg or less when further reduction was not possible due to adrenal insufficiency. Both primary endpoints were sustained for at least four weeks while maintaining asthma control.

[65] Persistent inflammation of nasal passages and benign growths inside the nose.
[66] Benign growths on both sides of the nose.

Table 32: Key *Fasenra* lifecycle management trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III OSTRO	Patients aged 18-75 years with severe bilateral nasal polyps; symptomatic, despite SoC	Placebo or *Fasenra* 30mg Q8W[67] SC[68]	Nasal-polyps burden and reported nasal blockage	FPCD Q1 2018 LPCD Q2 2019	Co-primary endpoints met
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[69]	*Fasenra* 30mg or mepolizumab 3x100mg Q4W	Proportion of patients who achieve remission, defined as a score[70] =0 and an OCS dose ≤4 mg/day at weeks 36 and 48	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)
Phase III NATRON	HES[71]	Placebo or *Fasenra* 30mg Q4W SC	Time to HES worsening flare or any cytotoxic and/or immuno-suppressive therapy increase or hospitalisation	FPCD Q3 2020 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)
Phase III MESSINA	Eosinophilic oesophagitis[72]	Placebo or *Fasenra* 30mg Q4W SC	Proportion of patients with a histologic response[73] Changes from baseline in dysphagia[74] PRO[75]	FPCD Q4 2020 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)

[67] Once every eight weeks.
[68] Subcutaneous injection.
[69] A rare autoimmune condition that causes inflammation of small and medium-sized blood vessels.
[70] Birmingham Vasculitis Activity Score.
[71] Hypereosinophilic syndrome, a group of rare blood disorders.
[72] White blood cells gather in the lining of the oesophagus.
[73] An improvement in the view of tissue samples under a microscope after treatment.
[74] Difficulty with swallowing.
[75] Patient-reported outcomes.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III FJORD	BP[76]	Placebo or *Fasenra* 30mg Q4W SC	Proportion of patients with partial or complete remission of BP whilst off OCS for ≥2 months at Week 36	Data anticipated 2021+	Initiating

d) Anifrolumab (lupus: SLE)

During the period, the Company received regulatory submission acceptances for anifrolumab from the US FDA and the EMA for the treatment of adult patients with moderate to severe SLE. AstraZeneca's submissions were based on results from the two TULIP Phase III trials and the MUSE Phase II trial, in which a reduction in disease activity and OCS use, and improvement in lupus skin activity were observed with anifrolumab added to SoC compared to placebo and SoC.

Anifrolumab has a well-characterised safety profile, based on the safety and tolerability findings across all three trials. The Prescription Drug User Fee Act date, the US FDA action date to provide a regulatory decision, is anticipated to be in the third quarter of 2021. The EMA regulatory decision is expected in the second half of 2021.

COVID-19

a) AZD1222 (SARS-CoV-2 vaccine)

During the period, the University of Oxford and AstraZeneca continued the recruitment of participants into the global clinical trials of the recombinant adenovirus vaccine, AZD1222, reaching c.23,000 participants across trials in the UK, Brazil, South Africa and the US.

In October 2020, the EMA announced that the CHMP had started a rolling review of data for AZD1222. A rolling review is one of the regulatory tools that the EMA uses to flexibly progress the assessment of a promising medicine or vaccine during a public-health emergency. AZD1222 was the first potential COVID-19 vaccine to be evaluated in the EU under these arrangements.

In September 2020, a voluntary pause to vaccination in the global trials was triggered following an unexplained illness in one of the participants receiving the vaccine in the UK Phase II/III trial. The standard review process for trial-safety events involves the examination of safety data by independent monitoring committees. The recommendations from the committees were shared with international regulators. The US FDA asked for additional information, issuing a 'clinical hold' to the US Phase III trial during its review. All regulatory authorities subsequently confirmed that the trials were safe to resume, and enrolment has recommenced. It is commonplace that, in large-scale trials, some participants will become unwell, and every unexplained case has to be independently evaluated to ensure careful assessment of safety.

Data on immunogenicity and safety of in older adults was presented at IDWeek showing AZD1222 has an acceptable tolerability profile and is immunogenic in adults above 18 years of age, including older adults. Stronger immune responses were shown after a second dose given one month apart, across all adult age ranges. Local and systemic reactions were lower in older adults than younger adults (<55 years) and reactions were lessened after the second dose.

Results from late-stage trials are anticipated later this year, depending on the rate of infection within the communities where the clinical trials are being conducted. Data readouts will be submitted to regulators and published in peer-reviewed scientific journals.

[76] Bullous pemphigoid, a skin condition that causes large, itchy, fluid-filled blisters.

b) AZD7442 (long-acting antibody combination for the prevention and treatment of COVID-19

During the period, AstraZeneca announced the initiation of a Phase I trial for AZD7442, a potential LAAB combination therapy for the prevention and treatment of COVID-19 and in October 2020 announced plans to advance AZD7442 into two Phase III clinical trials in more than 6,000 participants at sites in and outside the US to evaluate safety and efficacy of a 300mg intramuscular (IM) dose in preventing infection and further trials in approximately 4,000 patients for the treatment of COVID-19 with IM or intravenous doses ranging from 300-900mg. The LAAB combination has been engineered with AstraZeneca's proprietary half-life extension technology to increase the durability of the therapy for six to 12 months following a single administration.

The US Government has committed support of around $486m for the development and supply of AZD7442 under an agreement with the Biomedical Advanced Research and Development Authority and the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense. AstraZeneca plans to supply up to 100,000 doses starting towards the end of 2020 and the US Government can acquire up to an additional one million doses in 2021 under a separate agreement.

c) Other new and existing medicines in the treatment of COVID-19

In the year to date, as well as developing preventative approaches against the SARS-CoV-2 virus, the Company also initiated clinical trials, detailed in the table below, to investigate AstraZeneca's new and existing medicines to treat the infection by suppressing the body's overactive immune response or protecting from serious complications, such as organ failure.

AstraZeneca is continuing to evaluate the use of *Calquence* (acalabrutinib), approved in a number of countries for the treatment of CLL, in the CALAVI Phase II trial, which is assessing the suppression of the cytokine storm that inflames the lungs and other organs of some COVID-19 patients. The Company is also looking at the prospect of protecting organs in the DARE-19 Phase III trial[77], assessing whether *Farxiga* can potentially reduce organ failure. *Farxiga* is being evaluated in combination with ambrisentan in the Cambridge University Hospitals NHS Trust's TACTIC-E Phase II trial. *Farxiga* is an oral SGLT2 inhibitor, principally used as a treatment for T2D, that has demonstrated benefits in HF and CKD.

The Company has joined the UK Government's ACCORD proof-of-concept clinical-trial platform, to speed the development of medicines for patients with COVID-19 and is supplying *Pulmicort* and *Symbicort* to externally sponsored research programmes, including the trials detailed below.

Table 33: Key trials in COVID-19[78]

Trial	Population	Design	Timeline	Status
AZD1222				
Phase I/II COV001[79] (UK)	Protection against COVID-19 in participants aged 18-55	MenACWY or AZD1222 n=1,077	FPCD Q2 2020 LPCD Q2 2020	Initial data readout
Phase II/III COV002[79] (UK)	Protection against COVID-19 in participants aged 18-55, 55+ and paediatric	MenACWY or AZD1222 n=12,390	FPCD Q2 2020 First data anticipated Q4 2020	Recruitment ongoing

[77] Sponsored by St. Luke's Mid-America Heart Institute, Kansas City, US.
[78] The dates in the table relating to anticipated data for the accelerated development programme for AZD1222 refer to initial data, the timing of which are uncertain and subject to change resulting from factors such as changes in the level of community transmission. The timelines provided represent the best, current estimate of when initial efficacy data may be available.
[79] Conducted by the University of Oxford.

Trial	Population	Design	Timeline	Status
Phase III D8110C00001 (US, global)	Protection against COVID-19 in participants aged 18+	Placebo or AZD1222 n=40,000	FPCD Q3 2020 First data anticipated H1 2021	Recruitment ongoing
Phase I/II COV005 ChAdOx1 nCoV-19 ZA[80] (South Africa)	Protection against COVID-19 in participants aged 18-65 HIV+[81] subgroup	Placebo or AZD1222 n=2,020	FPCD Q2 2020 First data anticipated Q4 2020	Recruitment ongoing
Phase II/III COV003[82] (Brazil)	Protection against COVID-19 in participants aged 18-55	MenACWY or AZD1222 n=10,000	FPCD Q2 2020 First data anticipated Q4 2020	Recruitment ongoing
AZD7442				
Phase I	COVID-19	Placebo or AZD7442	-	Recruitment completed
Phase III PROVENT	Protection against COVID-19 (prophylaxis)	Placebo or AZD7442 n=5,000	First data anticipated H1 2021	Initiating
Phase III STORMCHASER	Protection against COVID-19 (post-exposure prophylaxis)	Placebo or AZD7442 n=1,125	First data anticipated H1 2021	Initiating
Phase III	COVID-19 (treatment)	Current SoC or AZD7442 n=c.4,000	First data anticipated H1 2021	Initiating
Acalabrutinib				
Phase II CALAVI (US and ex-US)	COVID-19	Current SoC or SoC+ acalabrutinib	First data anticipated Q4 2020	Recruitment completed
Farxiga				
Phase III DARE-19	COVID-19	Current SoC or current SoC + *Farxiga*	First data anticipated Q4 2020	Recruitment ongoing
Phase II TACTIC-E[83]	COVID-19	Current SoC or current SoC + *Farxiga* + ambrisentan	First data anticipated Q4 2020	Recruitment ongoing
Symbicort				
Phase IIIa INHASCO[84]	COVID-19	Current SoC or SoC + *Symbicort*	First data anticipated H1 2021	Recruitment ongoing

[80] Conducted by University of Witwatersrand, South Africa.
[81] Human immunodeficiency virus-positive.
[82] Conducted by the University of Oxford.
[83] Conducted by Cambridge University Hospitals NHS Trust.
[84] Conducted by Direction de la Recherche Clinique et de l'Innovation L'Assistance Publique - Hôpitaux de Paris (DRCI AP-HP).

Trial	Population	Design	Timeline	Status
Pulmicort				
Phase IIIa TACTIC-COVID[85]	COVID-19	Current SoC or SoC + *Pulmicort*	First data anticipated Q4 2020	Recruitment ongoing
Phase IIIa STOIC[86]	COVID-19	Current SoC or SoC + *Pulmicort*	First data anticipated H1 2021	Recruitment ongoing
MEDI3506				
Phase II ACCORD[87]	COVID-19	Current SoC or current SoC + MEDI3506	First data anticipated H1 2021	Recruitment ongoing

Other developments

During the period, AstraZeneca and Samsung Biologics announced the signing of a long-term supply agreement, under which Samsung Biologics will provide large-scale commercial manufacturing capacity for substance and product for AstraZeneca's biologics medicines.

In October 2020, Lonza Group AG announced an agreement to provide capacity for the manufacturing of AZD7442 at their new facility in Portsmouth, NH, US, with operations expected to start in H1 2021.

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.

[85] Sponsored by Fundació Clinic per a la Recerca Biomèdica.
[86] Conducted by University of Oxford.
[87] Sponsored by the UK Government's Therapeutics Taskforce.

Table 34: **Condensed consolidated statement of comprehensive income - YTD 2020**

For the **nine months** ended 30 September	**2020 $m**	**2019 $m**
Total Revenue	19,207	17,720
Product Sales	*18,879*	*17,315*
Collaboration Revenue	*328*	*405*
Cost of Sales	(3,774)	(3,543)
Gross Profit	15,433	14,177
Distribution costs	(290)	(247)
Research and development expense	(4,272)	(3,968)
Selling, general and administrative costs	(8,084)	(8,656)
Other operating income and expense	888	1,041
Operating Profit	3,675	2,347
Finance income	80	133
Finance expense	(985)	(1,081)
Share of after-tax losses in associates and joint ventures	(21)	(91)
Profit Before Tax	2,749	1,308
Taxation	(610)	(358)
Profit for the period	2,139	950
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(191)	(151)
Net gains/(losses) on equity investments measured at fair value through other comprehensive income	974	(136)
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(1)	(1)
Tax on items that will not be reclassified to profit or loss	(70)	21
	712	(267)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(121)	(385)
Foreign exchange arising on designating borrowings in net investment hedges	145	(491)
Fair value movements on cash flow hedges	2	(156)
Fair value movements on cash flow hedges transferred to profit or loss	(115)	109
Fair value movements on derivatives designated in net investment hedges	39	35
Costs of hedging	10	(35)
Tax on items that may be reclassified subsequently to profit or loss	7	62
	(33)	(861)
Other comprehensive income/(loss) for the period, net of tax	679	(1,128)
Total comprehensive income/(loss) for the period	2,818	(178)
Profit attributable to:		
Owners of the Parent	2,184	1,022
Non-controlling interests	(45)	(72)
	2,139	950
Total comprehensive income attributable to:		
Owners of the Parent	2,864	(107)
Non-controlling interests	(46)	(71)
	2,818	(178)
Basic earnings per $0.25 Ordinary Share	$1.66	$0.79
Diluted earnings per $0.25 Ordinary Share	$1.66	$0.79
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,297
Diluted weighted average number of Ordinary Shares in issue (millions)	1,313	1,297

Table 35: Condensed consolidated statement of comprehensive income - Q3 2020

For the **quarter** ended 30 September	**2020 $m**	**2019 $m**
Total Revenue	6,578	6,406
Product Sales	*6,520*	*6,132*
Collaboration Revenue	*58*	*274*
Cost of Sales	(1,370)	(1,351)
Gross Profit	5,208	5,055
Distribution costs	(99)	(88)
Research and development expense	(1,495)	(1,346)
Selling, general and administrative costs	(2,730)	(3,199)
Other operating income and expense	287	335
Operating Profit	1,171	757
Finance income	7	37
Finance expense	(324)	(353)
Share of after-tax losses in associates and joint ventures	(1)	(32)
Profit Before Tax	853	409
Taxation	(202)	(129)
Profit for the period	651	280
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	14	96
Net losses on equity investments measured at fair value through other comprehensive income	(95)	(82)
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(7)	1
Tax on items that will not be reclassified to profit or loss	9	4
	(79)	19
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	373	(299)
Foreign exchange arising on designating borrowings in net investment hedges	162	(305)
Fair value movements on cash flow hedges	133	(113)
Fair value movements on cash flow hedges transferred to profit or loss	(114)	95
Fair value movements on derivatives designated in net investment hedges	(21)	44
Costs of hedging	6	(38)
Tax on items that may be reclassified subsequently to profit or loss	(22)	42
	517	(574)
Other comprehensive income/(loss) for the period, net of tax	438	(555)
Total comprehensive income/(loss) for the period	1,089	(275)
Profit attributable to:		
Owners of the Parent	648	299
Non-controlling interests	3	(19)
	651	280
Total comprehensive income attributable to:		
Owners of the Parent	1,087	(257)
Non-controlling interests	2	(18)
	1,089	(275)
Basic earnings per $0.25 Ordinary Share	$0.49	$0.23
Diluted earnings per $0.25 Ordinary Share	$0.49	$0.23
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,312
Diluted weighted average number of Ordinary Shares in issue (millions)	1,313	1,312

Table 36: Condensed consolidated statement of financial position

	At 30 Sep 2020 $m	At 31 Dec 2019 $m	At 30 Sep 2019 $m
Assets			
Non-current assets			
Property, plant and equipment	7,707	7,688	7,317
Right-of-use assets	653	647	690
Goodwill	11,711	11,668	11,595
Intangible assets	20,613	20,833	21,454
Investments in associates and joint ventures	42	58	43
Other investments	1,173	1,401	1,293
Derivative financial instruments	119	61	56
Other receivables	685	740	384
Deferred tax assets	3,243	2,718	2,554
	45,946	45,814	45,386
Current assets			
Inventories	3,683	3,193	3,129
Trade and other receivables	5,668	5,761	5,279
Other investments	374	849	813
Derivative financial instruments	37	36	9
Intangible assets	-	-	95
Income tax receivable	332	285	228
Cash and cash equivalents	8,072	5,369	3,967
Assets held for sale	-	70	-
	18,166	15,563	13,520
Total assets	64,112	61,377	58,906
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(3,402)	(1,822)	(228)
Lease liabilities	(183)	(188)	(349)
Trade and other payables	(13,406)	(13,987)	(12,538)
Derivative financial instruments	(9)	(36)	(26)
Provisions	(621)	(723)	(401)
Income tax payable	(1,321)	(1,361)	(1,234)
	(18,942)	(18,117)	(14,776)
Non-current liabilities			
Interest-bearing loans and borrowings	(18,271)	(15,730)	(17,218)
Lease liabilities	(483)	(487)	(363)
Derivative financial instruments	(16)	(18)	(55)
Deferred tax liabilities	(2,576)	(2,490)	(2,595)
Retirement benefit obligations	(2,895)	(2,807)	(2,392)
Provisions	(854)	(841)	(990)
Other payables	(6,457)	(6,291)	(6,848)
	(31,552)	(28,664)	(30,461)
Total liabilities	(50,494)	(46,781)	(45,237)
Net assets	13,618	14,596	13,669
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	328	328	328
Share premium account	7,952	7,941	7,919
Other reserves	2,039	2,046	2,052
Retained earnings	1,876	2,812	1,865
	12,195	13,127	12,164
Non-controlling interests	1,423	1,469	1,505
Total equity	13,618	14,596	13,669

Table 37: 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 2019	317	4,427	2,041	5,683	12,468	1,576	14,044
Adoption of new accounting standards	-	-	-	54	54	-	54
Profit for the period	-	-	-	1,022	1,022	(72)	950
Other comprehensive loss	-	-	-	(1,129)	(1,129)	1	(1,128)
Transfer to other reserves	-	-	11	(11)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,583)	(3,583)	-	(3,583)
Issue of Ordinary Shares	11	3,492	-	-	3,503	-	3,503
Share-based payments charge for the period	-	-	-	154	154	-	154
Settlement of share plan awards	-	-	-	(325)	(325)	-	(325)
Net movement	11	3,492	11	(3,818)	(304)	(71)	(375)
At 30 Sep 2019	**328**	**7,919**	**2,052**	**1,865**	**12,164**	**1,505**	**13,669**
At 1 Jan 2020	**328**	**7,941**	**2,046**	**2,812**	**13,127**	**1,469**	**14,596**
Profit for the period	-	-	-	2,184	2,184	(45)	2,139
Other comprehensive income	-	-	-	680	680	(1)	679
Transfer to other reserves	-	-	(7)	7	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,669)	(3,669)	-	(3,669)
Issue of Ordinary Shares	-	11	-	-	11	-	11
Share-based payments charge for the period	-	-	-	187	187	-	187
Settlement of share plan awards	-	-	-	(325)	(325)	-	(325)
Net movement	-	11	(7)	(936)	(932)	(46)	(978)
At 30 Sep 2020	**328**	**7,952**	**2,039**	**1,876**	**12,195**	**1,423**	**13,618**

Table 38: Condensed consolidated statement of cash flows

For the **nine months** ended 30 September	**2020 $m**	**2019 $m**
Cash flows from operating activities		
Profit Before Tax	2,749	1,308
Finance income and expense	905	948
Share of after-tax losses of associates and joint ventures	21	91
Depreciation, amortisation and impairment	2,352	2,119
Increase in working capital and short-term provisions	(255)	(812)
Gains on disposal of intangible assets	(535)	(833)
Fair value movements on contingent consideration arising from business combinations	(14)	(13)
Non-cash and other movements	(484)	326
Cash generated from operations	4,739	3,134
Interest paid	(517)	(575)
Tax paid	(1,221)	(965)
Net cash inflow from operating activities	3,001	1,594
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(663)	(487)
Purchase of property, plant and equipment	(598)	(659)
Disposal of property, plant and equipment	67	31
Purchase of intangible assets	(1,460)	(1,416)
Disposal of intangible assets	664	1,400
Movement in profit-participation liability	-	150
Purchase of non-current asset investments	(119)	(6)
Disposal of non-current asset investments	1,121	18
Movement in short-term investments, fixed deposits and other investing instruments	530	196
Payments to associates and joint ventures	(8)	(49)
Interest received	43	107
Net cash outflow from investing activities	(423)	(715)
Net cash inflow before financing activities	2,578	879
Cash flows from financing activities		
Proceeds from issue of share capital	11	3,503
Issue of loans	2,968	500
Repayment of loans	-	(1,500)
Dividends paid	(3,572)	(3,592)
Hedge contracts relating to dividend payments	(101)	4
Repayment of obligations under leases	(157)	(131)
Movement in short-term borrowings	858	(555)
Net cash inflow/(outflow) from financing activities	7	(1,771)
Net increase/(decrease) in cash and cash equivalents in the period	2,585	(892)
Cash and cash equivalents at the beginning of the period	5,223	4,671
Exchange rate effects	(14)	-
Cash and cash equivalents at the end of the period	7,794	3,779
Cash and cash equivalents consist of:		
Cash and cash equivalents	8,072	3,967
Overdrafts	(278)	(188)
	7,794	3,779

Notes to the Interim Financial Statements

1) Basis of preparation and accounting policies

These unaudited Interim Financial Statements for the nine months ended 30 September 2020 have been prepared in accordance with IAS 34 'Interim Financial Reporting', as issued by the International Accounting Standards Board (IASB) and as adopted by the EU. The UK is in the process of establishing its post-Brexit IFRS-adoption authority, which is expected to be operational later in 2020, but for the current time, will follow the EU approval process.

The unaudited Interim Financial Statements for the nine months ended 30 September 2020 were approved by the Board of Directors for publication on 5 November 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 Interim 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 2019.

IFRS 3

An amendment to IFRS 3 'Business Combinations' relating to the definition of a business was endorsed by the EU in April 2020, with an effective date of 1 January 2020. 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 for which, under the previous definition, may have been accounted in different ways, despite limited differences in substance. The Group has adopted this amendment from the effective date.

IFRS 9, IAS 39 and IFRS 7

Amendments to IFRS 9 'Financial Instruments', IAS 39 'Financial Instruments: Recognition and Measurement' and IFRS 7 'Financial Instruments: Disclosures' relating to interbank offered rate (IBOR) reform were endorsed by the EU in January 2020; the Group adopted the amendments in the year ended 31 December 2019. The replacement of benchmark interest rates, such as the London Inter-bank Offered Rate (LIBOR) and other 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, namely a €300m cross-currency interest-rate swap in a fair-value hedge relationship with €300m of a €750m 0.875% 2021 non-callable bond. This swap references three-month USD LIBOR; 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 are currently being assessed.

Government grants

Government grants are recognised in the Consolidated statement of comprehensive income so as to match with the related expenses that they are intended to compensate. Where grants are received in advance of the related expenses, they are initially recognised in the Consolidated statement of financial position and released to match the related expenditure.

COVID-19

AstraZeneca has assessed the impact of the uncertainty presented by the COVID-19 pandemic on the Interim Financial Statements comprising the financial results to 30 September 2020 and the financial position as at 30 September 2020, specifically considering the impact on key judgements and significant estimates as detailed on page 173 of the Annual Report and 20-F Information 2019 along with a several other areas of increased risk.

A detailed assessment has been performed, focussing on the following areas:

- recoverable value of goodwill, intangible assets and property, plant and equipment

- impact on key assumptions used to estimate contingent-consideration liabilities
- key assumptions used in estimating the Group's defined-benefit pension obligations
- basis for estimating clinical-trial accruals
- key assumptions used in estimating rebates, chargebacks and returns for US Product Sales
- valuations of unlisted equity investments
- expected credit losses associated with changes in credit risk relating to trade and other receivables
- net realisable value of inventories
- fair value of certain financial instruments
- recoverability of deferred-tax assets
- effectiveness of hedge relationships

There were no material accounting impacts identified relating to the above areas during the nine-month period ended 30 September 2020.

The Group will continue to monitor these areas of increased judgement, estimation and risk for material changes.

Going concern

The Group has considerable financial resources available. As at 30 September 2020, the Group had $12.6bn in financial resources (cash and cash-equivalent balances of $8.1bn, $0.4bn 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 2021 and $0.2bn is available until December 2020), with only $3.6bn of borrowings due within one year). Subsequent to 30 September 2020, the $3.4bn committed facilities were extended to April 2024, and the $0.7bn facilities amended and made available until November 2022. The Group's revenues are largely derived from sales of medicines 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 affect adversely revenues in many of the mature markets. The Group, however, anticipates new revenue streams from both recently launched medicines and those 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. In the current environment, the Directors have also considered the impact of possible future COVID-19 related scenarios and believe the Group retains sufficient liquidity to continue to operate.

Based on the above paragraph, the going-concern basis has been adopted in these Interim Financial Statements.

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 2019.

Financial information

The comparative figures for the financial year ended 31 December 2019 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) Intangible assets

In accordance with IAS 36 'Impairment of Assets', reviews for triggers at an individual asset or cash-generating-unit level were conducted and impairment tests carried out where triggers were identified. This resulted in a total impairment charge of $188m being recorded against intangible assets during the nine months ended 30 September 2020.

During the first quarter of 2020, a charge of $102m was recorded in relation to *Bydureon* (revised carrying amount of $596m). The impairment was driven by an overall reduction in forecast Total Revenue over the remaining asset life, reflecting expectations of returns from promotional activities, including a level of anticipated impact resulting from the restrictions in place due to the COVID-19 pandemic. If Total Revenue projections for *Bydureon* were to decline by a further 10% over the forecast period, it would result in a reduction in the recoverable amount of c.$100m.

During the second quarter of 2020, charges recorded included $65m and $31m in relation to *Duaklir* and *Eklira*/*Tudorza*, respectively. The revised carrying amounts are $281m and $127m, respectively. In addition, there was also a $95m impairment reversal in relation to *FluMist* with revised carrying amount of $253m.

The $95m impairment reversal in relation to *FluMist* reflected a change in expected sales volumes, following pre-orders received during the period.

The impairment charges for *Duaklir* and *Eklira*/*Tudorza* were a consequence of revised market-volume and share assumptions, following adverse performances during H1 2020, compared to previous forecasts during the H1 2020. If Total Revenue projections for these medicines were to decline by a further 20% over the forecast period, it would result in additional reductions to the recoverable amounts of c.$60m for *Duaklir* and c.$30m for *Eklira*/*Tudorza*. During the third quarter, additional impairment charges were recorded of $34m and $14m in relation to the US rights for *Duaklir* and *Eklira*/*Tudorza,* respectively, (revised carrying amount of $17m and $53m, respectively).

During the third quarter, an additional impairment for a development asset of $21m was taken, due to the cessation of the development programme.

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 2019. Net Debt is a non-GAAP financial measure.

Table 39: Net Debt

	At 1 Jan 2020 $m	Cash flow $m	Non-cash & other $m	Exchange movements $m	At 30 Sep 2020 $m
Non-current instalments of loans	(15,730)	(2,968)	545	(118)	(18,271)
Non-current instalments of leases	(487)	-	2	2	(483)
Total long-term debt	**(16,217)**	**(2,968)**	**547**	**(116)**	**(18,754)**
Current instalments of loans	(1,597)	-	(557)	(32)	(2,186)
Current instalments of leases	(188)	172	(168)	1	(183)
Commercial paper	-	(793)	-	-	(793)
Bank collateral	(71)	(62)	-	-	(133)
Other short-term borrowings excluding overdrafts	(8)	(3)	-	(1)	(12)
Overdraft	(146)	(137)	-	5	(278)
Total current debt	**(2,010)**	**(823)**	**(725)**	**(27)**	**(3,585)**
Gross borrowings	**(18,227)**	**(3,791)**	**(178)**	**(143)**	**(22,339)**
Net derivative financial instruments	43	101	(13)	-	131
Net borrowings	**(18,184)**	**(3,690)**	**(191)**	**(143)**	**(22,208)**
Cash and cash equivalents	5,369	2,722	-	(19)	8,072
Other investments - current	849	(530)	61	(6)	374
Other investments - non-current	62	-	(62)	-	-
Cash and investments	**6,280**	**2,192**	**(1)**	**(25)**	**8,446**
Net Debt	**(11,904)**	**(1,498)**	**(192)**	**(168)**	**(13,762)**

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

Other investments - non-current are included within the balance of $1,173m (31 December 2019: $1,401m) in the Condensed consolidated 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 $2,255m (31 December 2019: $2,146m), shown in non-current other payables.

Net Debt increased by $1,858m in the year to date, principally due to Net cash inflow before financing activities of $2,578m being offset by the payment of the second interim dividend of 2019 and first interim dividend of 2020 of $3,572m.

Details of the committed undrawn bank facilities are disclosed within the going-concern section of Note 1.

During the nine months to 30 September 2020, there were no changes to the Company's credit ratings issued by Standard and Poor's (long term: BBB+, short term A-2) and Moody's (long term: A3, short term P-2).

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. During the period, equity investments previously categorised as Level 3 in the fair-value hierarchy (carrying value of $103m at 31 December 2019) are now categorised as Level 1 (carrying value of $132m at 30 September 2020) on availability of quoted prices in an active market. There have been no other changes of significance to the categorisation or fair-value hierarchy classification of financial instruments from those detailed in the Notes to the Group Financial Statements in the Annual Report and Form 20-F Information 2019.

The Group holds certain equity investments that are categorised as Level 3 in the fair-value hierarchy and for which fair-value gains of $63m have been recognised in the nine months ended 30 September 2020. All other fair-value gains and/or losses that are presented in Net gains/(losses) on equity investments measured at fair value through other comprehensive income in the Condensed consolidated statement of comprehensive income for the nine months ended 30 September 2020 are Level 1 fair-value measurements.

Financial instruments measured at fair value include $1,547m of other investments, $7,024m held in money-market funds, $342m of loans designated at fair value through profit or loss, $355m of loans designated in a fair-value hedge relationship and $131m of derivatives as at 30 September 2020. The total fair value of interest-bearing loans and borrowings at 30 September 2020, which have a carrying value of $22,339m in the Condensed consolidated statement of financial position, was $25,704m. 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:

Table 40: Financial instruments - contingent consideration

	2020			2019
	Diabetes alliance $m	**Other $m**	**Total $m**	**Total $m**
At 1 January	3,300	839	4,139	5,106
Settlements	(394)	(269)	(663)	(487)
Revaluations	(22)	8	(14)	(13)
Discount unwind	174	38	212	269
At 30 September	**3,058**	**616**	**3,674**	**4,875**

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 $3,058m (31 December 2019: $3,300m) would increase/decline by $306m with an increase/decline in sales of 10%, as compared with the current estimates.

Included within the BMS contingent consideration liability are estimates of royalties payable in relation to *Bydureon*. The revised Total Revenue projections for *Bydureon* also resulted in a $22m reduction in the contingent consideration balance as at 30 September 2020. A further 10% reduction in *Bydureon* Total Revenue would result in an additional $22m reduction.

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 2019 and H1 2020 results (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 has relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Disclosures and herein.

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

Matters disclosed in respect of the third quarter of 2020 and to 5 November 2020

Patent litigation

Enhertu

US patent proceeding

In October 2020, Seagen Inc. filed a complaint against Daiichi Sankyo Company, Limited in the US District Court for the Eastern District of Texas alleging that *Enhertu* infringes US Patent No 10,808,039. AstraZeneca Pharmaceuticals LP co-commercialises *Enhertu* with Daiichi Sankyo, Inc. in the United States.

Faslodex

Patent proceedings outside the US

As previously disclosed, in Italy, Actavis Group Ptc ehf. and Actavis Italy S.p.A. filed actions alleging that the Italian part of European Patent No. EP 1,250,138 (the '138 patent) and European Patent Nos. EP 2,266,573 (the '573 patent) are invalid. In July 2018, the Court of Turin determined that the '138 patent is invalid. In July 2019, the Court of Milan determined that the '573 patent is invalid. AstraZeneca appealed both decisions. In June 2020, the Court of Appeal of Turin upheld the invalidity decision as to the '138 patent. In August 2020, the Court of Milan denied AstraZeneca's requests for a preliminary injunction against Teva Italia Srl. Patent infringement and patent-invalidity proceedings are ongoing against various parties.

As previously disclosed, in France, in June 2018 the Commercial Court of Nanterre denied AstraZeneca's request for a preliminary injunction against Sandoz SAS (Sandoz) to prevent a potential launch of its generic *Faslodex* in France. Additionally, in June 2018 Sandoz served AstraZeneca with an invalidation writ against European Patent Nos. EP 2,266,573; EP 1,250,138; and EP 1,272,195. Patent infringement and patent invalidity proceedings are ongoing with Sandoz. A trial of the matter is scheduled for November 2020.

Symbicort

US patent proceedings

As previously disclosed, AstraZeneca initiated ANDA litigation against Mylan Pharmaceuticals Inc. (Mylan) and 3M Company (3M) in the US District Court for the Northern District of West Virginia. In the action, AstraZeneca alleges that the defendants' generic versions of *Symbicort*, if approved and marketed, would infringe various AstraZeneca patents. Mylan and 3M alleged that their proposed generic product does not infringe the asserted patents and/or that the asserted patents are invalid and/or unenforceable. In July 2020, AstraZeneca added Kindeva Drug Delivery L.P. (Kindeva) as a defendant in the case. In September 2020, Mylan, 3M and Kindeva

stipulated to patent infringement to the extent that the asserted patent claims are found to be valid and enforceable, but reserved the right to seek a vacatur of the stipulation if the U.S. Court of Appeals for the Federal Circuit reverses or modifies the District Court's claim construction. In October 2020, following a stipulation by AstraZeneca, 3M and Kindeva, 3M was dismissed from the action. The trial of the matter was heard in October 2020 and closing argument is scheduled for January 2021.

Product Liability Litigation

Nexium* and *Losec*/*Prilosec
As previously disclosed, in the US, AstraZeneca is defending various lawsuits brought in federal and state courts involving multiple plaintiffs claiming that they have been diagnosed with various injuries following treatment with proton pump inhibitors (PPIs), including *Nexium* and *Prilosec*. The vast majority of those lawsuits relate to allegations of kidney injuries. In particular, 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 addition to the MDL cases, there are cases filed in several state courts around the US; a trial in Delaware state court has been scheduled for February 2022.

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 alleged, among other things, breaches of contractual obligations relating to a 2013 merger agreement between AstraZeneca and Amplimmune. Following the trial of the matter in February 2020, post-trial oral argument was heard in August 2020. A decision is awaited.

Anti-Terrorism Act Civil Lawsuit
As previously disclosed, in July 2020, the US District Court for the District of Columbia granted AstraZeneca's and certain other pharmaceutical and/or medical-device companies' motion and dismissed a lawsuit filed by US nationals (or their estates, survivors, or heirs) who were killed or wounded in Iraq between 2005 and 2011, which had alleged that the defendants violated the US Anti-Terrorism Act and various state laws by selling pharmaceuticals and medical supplies to the Iraqi Ministry of Health. The plaintiffs are appealing the District Court's order dismissing the litigation.

Definiens
In July 2020, AstraZeneca received a notice of arbitration filed with the German Institution of Arbitration from the sellers of Definiens AG (Sellers) regarding the 2014 Share Purchase Agreement (SPA) between AstraZeneca and the Sellers. The Sellers claim they are owed approximately $140m in earn-outs under the SPA. AstraZeneca disputes the claims of the Sellers. The arbitration tribunal has not yet set a timetable for the arbitration.

***Seroquel XR* Antitrust Litigation**
As previously disclosed, in 2019 and 2020, AstraZeneca was named in several related complaints brought in the US District Court for the Southern District of New York (the Court), including several putative class-action lawsuits that were purportedly brought on behalf of classes of direct purchasers or end payors of *Seroquel XR*, that allege AstraZeneca and generic medicine manufacturers violated antitrust laws when settling patent litigation related to *Seroquel XR*. In August 2020, the Court granted AstraZeneca's motions to transfer all such lawsuits to the US District Court for the District of Delaware.

Government investigations/proceedings

Iraqi Ministry of Health Anti-Corruption Probe
As previously disclosed, in July 2018, AstraZeneca, along with other companies, received an inquiry from the US Department of Justice (DOJ) pursuant to the Foreign Corrupt Practices Act in connection with an anticorruption investigation relating to activities in Iraq, including interactions with the Iraqi government. In August 2020, the DOJ notified AstraZeneca that it does not intend to institute an enforcement action and is closing the inquiry.

Toprol-XL

Louisiana Attorney General Litigation

As previously disclosed, in July 2020, the Louisiana First Circuit Court of Appeals (the Appellate Court) reversed and remanded a Louisiana state trial court (the Trial Court) ruling that had granted AstraZeneca's motion for summary judgment and dismissed a state court complaint, brought by the Attorney General for the State of Louisiana, alleging that AstraZeneca engaged in unlawful monopolisation and unfair trade practices in connection with the enforcement of its *Toprol-XL* patents. In August 2020, AstraZeneca petitioned the Louisiana Supreme Court to review the decision of the Appellate Court and reinstate the Trial Court's summary judgment ruling. That petition remains pending.

Taxation

As previously disclosed in the Annual Report and Form 20-F Information 2019, AstraZeneca faces a number of audits and reviews in jurisdictions around the world and, in some cases, is in dispute with the tax authorities. The issues under discussion are often complex and can require many years to resolve. Accruals for tax contingencies require management to make key judgements with respect to the ultimate outcome of current and potential future tax audits, and actual results could vary from these estimates. The total net accrual to cover the worldwide tax exposure for transfer pricing and other international tax contingencies of $138m (31 December 2019: $140m) reflected the progress in those tax audits and reviews during the year to date and for those audits where AstraZeneca and tax authorities are in dispute, AstraZeneca estimates the potential for reasonably possible additional liabilities above and beyond the amount provided to be up to $233m, including associated interest (December 2019: $76m). There was no material change to this estimate in the quarter. The Company believes, however, that it is unlikely that these additional liabilities will arise. It is possible that some of these contingencies may reduce in the future to the extent that any tax authority challenge is concluded, or matters lapse following expiry of the relevant statutes of limitation resulting in a reduction in the tax charge in future periods.

There was no material change in the period to the other tax contingencies.

6) Subsequent Events

In October 2020, AstraZeneca agreed to sell the commercial rights to *Atacand* and *Atacand Plus* in around 70 countries globally to Cheplapharm , which will pay AstraZeneca a total of $400m in non-contingent consideration, with $250m payable on completion and the remainder in the first half of 2021. The present value of the consideration will be recognised in the Company's financial statements within Other Operating Income and Expense.

In October 2020, $3.4bn committed bank facilities were extended to April 2024 (with two additional one-year extension options at lenders' discretion). Additionally, in November 2020, further committed facilities totalling $0.7bn were amended and extended to November 2021 (with an additional extension option to November 2022 at the Group's discretion).

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7) Table 41: Product Sales year-on-year analysis - YTD 2020[88]

	World			Emerging Markets			US		Europe			Established RoW		
	$m	% change		$m	% change		$m	% change	$m	% change		$m	% change	
		Actual	CER		Actual	CER		Actual		Actual	CER		Actual	CER
Oncology														
Tagrisso	3,171	38	39	950	72	78	1,144	26	503	49	50	574	14	13
Imfinzi	1,487	42	43	113	n/m	n/m	885	17	254	n/m	n/m	235	53	53
Lynparza	1,280	51	53	195	94	n/m	631	46	311	50	51	143	34	34
Calquence	340	n/m	n/m	3	n/m	n/m	335	n/m	-	-	-	2	n/m	n/m
Koselugo	20	n/m	n/m	-	-	-	20	n/m	-	-	-	-	-	-
*Zoladex**	672	9	13	427	12	18	6	17	104	5	6	135	2	2
*Faslodex**	450	(38)	(37)	142	(3)	3	45	(85)	171	2	3	92	(9)	(10)
*Iressa**	201	(41)	(40)	163	(28)	(26)	10	(25)	11	(81)	(81)	17	(60)	(60)
*Arimidex**	149	(14)	(11)	121	3	7	-	-	3	(88)	(88)	25	(27)	(27)
*Casodex**	133	(16)	(14)	104	4	7	1	(93)	2	(84)	(84)	26	(42)	(41)
Others	39	(44)	(43)	20	(8)	(4)	1	n/m	4	(29)	(28)	14	(66)	(66)
Total Oncology	**7,942**	**24**	**26**	**2,238**	**34**	**40**	**3,078**	**21**	**1,363**	**33**	**34**	**1,263**	**9**	**8**
BioPharmaceuticals: CVRM														
Farxiga	1,373	22	26	488	44	54	385	(3)	363	33	34	137	19	19
Brilinta	1,230	7	9	392	13	18	537	7	257	(2)	(1)	44	2	5
Onglyza	365	(8)	(6)	154	18	23	134	(23)	43	(19)	(19)	34	(10)	(9)
Bydureon	326	(21)	(20)	3	(70)	(68)	278	(18)	38	(24)	(23)	7	(30)	(26)
Byetta	50	(40)	(38)	8	1	7	24	(52)	11	(26)	(25)	7	(19)	(17)
Other diabetes	35	(4)	(4)	5	n/m	n/m	20	(30)	9	35	38	1	56	38
Lokelma	48	n/m	n/m	3	n/m	n/m	37	n/m	3	n/m	n/m	5	n/m	n/m
*Crestor**	882	(10)	(8)	560	(10)	(7)	71	(19)	94	(16)	(15)	157	(3)	(3)
*Seloken/Toprol-XL**	620	9	14	592	15	21	9	(69)	12	(37)	(37)	7	(12)	(7)
*Atacand**	180	11	18	133	14	21	7	(11)	22	-	-	18	24	27
Others	145	(27)	(26)	93	(33)	(31)	-	-	45	(2)	(1)	7	(55)	(54)
BioPharmaceuticals: total CVRM	**5,254**	**3**	**5**	**2,431**	**9**	**15**	**1,502**	**(7)**	**897**	**5**	**6**	**424**	**2**	**3**
BioPharmaceuticals: Respiratory & Immunology														
Symbicort	2,042	15	16	423	6	11	755	29	521	3	4	343	18	20
Fasenra	666	34	34	10	n/m	n/m	423	23	140	72	74	93	34	34
Pulmicort	628	(40)	(39)	479	(43)	(42)	53	(40)	55	(8)	(6)	41	(32)	(32)
Daliresp/Daxas	163	4	4	3	(12)	(9)	141	6	18	(7)	(6)	1	(8)	(6)
Bevespi	36	19	19	1	n/m	n/m	33	11	2	n/m	n/m	-	-	-
Breztri	21	n/m	n/m	14	n/m	n/m	3	n/m	-	-	-	4	n/m	n/m
Others	273	(17)	(16)	122	(27)	(25)	8	n/m	132	(12)	(11)	11	(5)	(2)
BioPharmaceuticals: total Respiratory & Immunology	**3,829**	**(1)**	**1**	**1,052**	**(26)**	**(23)**	**1,416**	**20**	**868**	**6**	**7**	**493**	**14**	**15**
Other medicines														
*Nexium**	1,115	(1)	1	563	(2)	2	127	(28)	59	21	21	366	10	10
*Synagis**	294	-	-	-	-	-	47	29	247	(5)	(5)	-	-	-
*Losec/Prilosec**	144	(34)	(32)	119	(18)	(16)	3	(50)	17	(63)	(63)	5	(74)	(75)
*FluMist**	116	n/m	n/m	-	-	-	65	n/m	49	n/m	n/m	2	n/m	n/m
*Seroquel XR/IR**	98	(35)	(34)	41	(2)	1	22	(19)	21	(68)	(68)	14	(7)	(8)
Others	87	(35)	(35)	6	45	42	38	(53)	38	(15)	(15)	5	3	3
Total other medicines	**1,854**	**(5)**	**(4)**	**729**	**(5)**	**(1)**	**302**	**(13)**	**431**	**(7)**	**(8)**	**392**	**5**	**5**
Total Product Sales	**18,879**	**9**	**11**	**6,450**	**6**	**11**	**6,298**	**11**	**3,559**	**12**	**13**	**2,572**	**8**	**8**

[88] The table 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. *Denotes a legacy medicine.

8) Table 42: Product Sales year-on-year analysis - Q3 2020[89]

	World			Emerging Markets			US		Europe			Established RoW		
	$m	% change		$m	% change		$m	% change	$m	% change		$m	% change	
		Actual	CER		Actual	CER		Actual		Actual	CER		Actual	CER
Oncology														
Tagrisso	1,155	30	30	355	59	61	419	20	178	42	37	203	6	5
Imfinzi	533	29	29	50	n/m	n/m	311	9	87	59	55	85	30	29
Lynparza	464	42	42	75	79	88	224	32	114	48	44	51	33	33
Calquence	145	n/m	n/m	2	91	115	142	n/m	-	-	-	1	n/m	n/m
Koselugo	13	n/m	n/m	-	-	-	13	n/m	-	-	-	-	-	-
*Zoladex**	230	2	3	139	(4)	(1)	1	(1)	36	4	3	54	18	17
*Faslodex**	138	(33)	(32)	41	(16)	(11)	12	(81)	54	(6)	(8)	31	(19)	(19)
*Iressa**	54	(41)	(40)	43	(31)	(30)	3	(50)	3	(83)	(83)	5	(30)	(33)
*Arimidex**	42	(34)	(32)	32	(31)	(29)	-	-	1	(83)	(84)	9	(15)	(15)
*Casodex**	44	(16)	(16)	34	-	2	1	n/m	1	(79)	(84)	8	(42)	(39)
Others	13	(39)	(36)	6	8	22	1	n/m	1	(45)	(47)	5	(60)	(61)
Total Oncology	**2,831**	**21**	**22**	**777**	**26**	**30**	**1,127**	**23**	**475**	**26**	**23**	**452**	**7**	**6**
BioPharmaceuticals: CVRM														
Farxiga	525	32	35	181	37	47	148	18	141	48	44	55	27	26
Brilinta	385	(7)	(7)	102	(22)	(20)	185	3	84	(8)	(11)	14	(5)	(5)
Onglyza	109	(14)	(13)	55	24	27	29	(47)	14	(18)	(19)	11	(1)	1
Bydureon	110	(14)	(14)	1	(55)	(51)	93	(13)	14	(14)	(16)	2	(7)	(3)
Byetta	15	(46)	(44)	3	(12)	(8)	6	(66)	3	(28)	(22)	3	(3)	(12)
Other diabetes	11	(19)	(20)	1	n/m	n/m	6	(44)	3	23	21	1	n/m	n/m
Lokelma	21	n/m	n/m	2	n/m	n/m	16	n/m	1	n/m	n/m	2	n/m	n/m
*Crestor**	300	(11)	(10)	191	(11)	(9)	26	(23)	30	(18)	(19)	53	1	-
*Seloken/Toprol-XL**	225	27	32	216	31	36	3	(17)	4	(30)	(30)	2	(30)	(25)
*Atacand**	54	(2)	4	39	(5)	4	2	13	7	6	6	6	3	1
Others	39	(41)	(41)	28	(36)	(38)	-	-	10	(37)	(36)	1	(91)	(79)
BioPharmaceuticals: total CVRM	**1,794**	**3**	**4**	**819**	**5**	**10**	**514**	**(4)**	**311**	**6**	**4**	**150**	**5**	**5**
BioPharmaceuticals: Respiratory & Immunology														
Symbicort	599	(2)	(2)	132	(4)	1	197	(3)	165	7	4	105	(11)	(11)
Fasenra	240	19	18	3	12	26	151	11	52	43	39	34	24	23
Pulmicort	151	(55)	(55)	109	(60)	(59)	17	(49)	14	(8)	(12)	11	(44)	(45)
Daliresp/Daxas	57	8	9	1	(10)	(13)	51	15	5	(30)	(33)	-	-	-
Bevespi	14	38	36	1	-	-	12	23	1	n/m	n/m	-	-	-
Breztri	10	n/m	n/m	5	n/m	n/m	3	n/m	-	-	-	2	31	37
Others	90	(12)	(13)	42	(20)	(20)	1	(52)	44	(3)	(5)	3	(16)	(15)
BioPharmaceuticals: total Respiratory & Immunology	**1,161**	**(12)**	**(12)**	**293**	**(37)**	**(35)**	**432**	**1**	**281**	**9**	**6**	**155**	**(9)**	**(9)**
Other medicines														
*Nexium**	401	7	9	193	(6)	(2)	47	(17)	22	34	25	139	45	45
*Synagis**	118	(19)	(19)	(5)	-	-	26	n/m	97	(33)	(33)	-	-	-
*Losec/Prilosec**	45	(38)	(38)	38	(23)	(24)	-	(83)	7	(50)	(52)	-	(98)	(97)
*FluMist**	116	n/m	n/m	-	n/m	n/m	65	n/m	49	n/m	n/m	2	n/m	n/m
*Seroquel XR/IR**	35	(57)	(56)	13	(22)	(19)	8	(81)	7	(66)	(65)	7	70	69
Others	19	(56)	(57)	3	n/m	n/m	5	(85)	10	(41)	(46)	1	n/m	n/m
Total other medicines	**734**	**1**	**1**	**242**	**(9)**	**(6)**	**151**	**5**	**192**	**(10)**	**(12)**	**149**	**38**	**38**
Total Product Sales	**6,520**	**6**	**7**	**2,131**	**-**	**4**	**2,224**	**10**	**1,259**	**10**	**8**	**906**	**7**	**7**

[89] The table 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. *Denotes a legacy medicine.

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9) Table 43: Product Sales quarterly sequential analysis - 2020[90]

	Q1 2020			Q2 2020			Q3 2020		
	$m	% change		$m	% change		$m	% change	
		Actual	CER		Actual	CER		Actual	CER
Oncology									
Tagrisso	982	11	11	1,034	5	7	1,155	12	9
Imfinzi	462	9	9	492	6	8	533	8	6
Lynparza	397	13	13	419	5	7	464	11	8
Calquence	88	58	58	107	21	23	145	36	35
Koselugo	-	-	-	7	n/m	n/m	13	75	75
*Zoladex**	225	15	15	217	(3)	-	230	6	3
*Faslodex**	166	-	-	146	(12)	(9)	138	(5)	(8)
*Iressa**	77	(3)	(4)	70	(9)	(7)	54	(23)	(24)
*Arimidex**	50	(1)	(2)	58	17	16	42	(28)	(27)
*Casodex**	42	(2)	(3)	47	14	12	44	(7)	(8)
Others	13	(52)	(52)	12	(11)	(1)	13	4	3
Total Oncology	**2,502**	**10**	**10**	**2,609**	**4**	**6**	**2,831**	**8**	**6**
BioPharmaceuticals: CVRM									
Farxiga	405	(3)	(3)	443	9	13	525	19	16
Brilinta	408	(5)	(5)	437	7	9	385	(12)	(13)
Onglyza	141	8	8	115	(19)	(17)	110	(6)	(6)
Bydureon	100	(28)	(28)	116	16	17	109	(5)	(7)
Byetta	20	(24)	(24)	15	(28)	(28)	15	1	4
Other diabetes	13	(22)	(22)	10	(21)	(19)	11	9	6
Lokelma	11	42	42	17	56	58	21	22	26
*Crestor**	301	2	1	281	(7)	(4)	300	7	5
*Seloken/Toprol-XL**	177	(6)	(6)	218	23	27	225	4	3
*Atacand**	66	11	12	59	(11)	(5)	54	(9)	(12)
Others	59	(21)	(22)	48	(18)	(16)	39	(19)	(22)
BioPharmaceuticals: total CVRM	**1,701**	**(5)**	**(5)**	**1,759**	**3**	**6**	**1,794**	**2**	**-**
BioPharmaceuticals: Respiratory & Immunology									
Symbicort	790	11	11	653	(17)	(15)	599	(8)	(11)
Fasenra	199	(3)	(3)	227	14	15	240	5	4
Pulmicort	380	(8)	(9)	97	(74)	(73)	151	56	49
Daliresp/Daxas	53	(8)	(8)	53	(1)	(3)	57	8	11
Bevespi	12	9	9	10	(19)	(21)	14	47	46
Breztri	4	n/m	n/m	7	58	64	10	45	48
Others	113	(16)	(17)	70	(38)	(36)	90	27	22
BioPharmaceuticals: total Respiratory & Immunology	**1,551**	**1**	**1**	**1,117**	**(28)**	**(26)**	**1,161**	**4**	**1**
Other medicines									
*Nexium**	338	(4)	(4)	377	12	14	401	6	4
*Synagis**	85	35	35	90	6	7	118	31	29
*Losec/Prilosec**	54	18	17	45	(15)	(15)	45	-	-
*FluMist**	-	n/m	n/m	-	n/m	n/m	116	n/m	n/m
*Seroquel XR/IR**	36	(12)	(12)	27	(26)	(23)	35	32	29
Others	44	(71)	(70)	24	(46)	(42)	19	(17)	(19)
Total other medicines	**557**	**(15)**	**(15)**	**563**	**1**	**4**	**734**	**30**	**27**
Total Product Sales	**6,311**	**1**	**1**	**6,048**	**(4)**	**(2)**	**6,520**	**8**	**6**

[90] The table 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. *Denotes a legacy medicine.

10) Table 44: Product Sales quarterly sequential analysis - 2019[91]

	Q1 2019			Q2 2019			Q3 2019			Q4 2019		
	$m	% change		$m	% change		$m	% change		$m	% change	
		Actual	CER		Actual	CER		Actual	CER		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
Onglyza	153	3	3	116	(24)	(24)	127	9	11	131	3	4
Bydureon	142	3	3	141	(1)	-	127	(10)	(10)	139	9	10
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	n/m	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 & Immunology												
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
Bevespi	10	-	(5)	10	-	2	10	4	8	12	8	5
Breztri	-	-	-	-	-	-	1	-	-	1	(74)	(73)
Others	128	(14)	(12)	101	(21)	(23)	102	1	(1)	135	33	38
BioPharmaceuticals: total Respiratory & Immunology	**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**

[91] 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. *Denotes a legacy medicine.

Table 45: Historic Collaboration Revenue

		YTD 2020	YTD 2019	FY 2019	FY 2018
		$m	$m	$m	$m
Initial Collaboration Revenue	Crestor (Spain)	-	-	-	61
Ongoing Collaboration Revenue	*Lynparza*: regulatory milestones	135	60	60	140
	Lynparza: sales milestones	-	200	450	250
	Lynparza/selumetinib: option payments	-	-	100	400
	Crestor (Spain)	-	-	39	-
	Enhertu: profit share	63	-	-	-
	Roxadustat: profit share	19	-	-	-
	Royalty income	47	42	62	49
	Other Collaboration Revenue	64	103	108	141
	Total	**328**	**405**	**819**	**1,041**

Table 46: Other Operating Income and Expense

The table below provides an analysis of Reported Other Operating Income and Expense.

	YTD 2020 $m	YTD 2019 $m	FY 2019 $m	FY 2018 $m
Hypertension medicines (ex-US, India and Japan)	350	-	-	-
Monetisation of an asset previously licensed	120	-	-	-
Brazikumab licence termination funding	51	-	-	-
Inderal, *Tenormin*, *Seloken* and *Omepral* (Japan)	51	-	-	-
Synagis (US)	-	515	515	-
Losec (ex-China, Japan, US and Mexico)	-	243	243	-
Seroquel and Seroquel XR (US, Canada, Europe and Russia)	-	-	213	-
Arimidex and *Casodex* (various countries)	-	-	181	-
Nexium (Europe) and *Vimovo* (ex-US)	-	-	-	728
Seroquel	-	-	-	527
Legal settlement	-	-	-	346
Atacand	-	-	-	210
Anaesthetics	-	-	-	172
Alvesco, *Omnaris* and *Zetonna*	-	-	-	139
Other	316	283	389	405
Total	**888**	**1,041**	**1,541**	**2,527**

Shareholder information

Announcement of full year and fourth quarter results	11 February 2021
Announcement of first quarter results	30 April 2021
Announcement of half year and second quarter results	29 July 2021
Announcement of year to date and third quarter results	12 November 2021

Dividends are normally be paid as follows:

First interim: announced with the half year and fourth quarter results and paid in March

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

The record date for the second interim dividend for 2020, payable on 29 March 2021, will be 26 February 2021. The ex-dividend date will be 25 February 2021.

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

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Cautionary statements regarding forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act of 1995, AstraZeneca (hereafter 'the Group') provides 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 the Group believes its 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 the Group undertakes no obligation to update these forward-looking statements. The Group identifies 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 the Group's control, include, among other things:

- the risk of failure or delay in delivery of pipeline or launch of new medicines
- the risk of failure to meet regulatory or ethical requirements for medicine development or approval
- the risk of failure to obtain, defend and enforce effective intellectual property (IP) protection and IP challenges by third parties
- the impact of competitive pressures including expiry or loss of IP rights, and generic competition
- the impact of price controls and reductions
- the impact of economic, regulatory and political pressures
- the impact of uncertainty and volatility in relation to the UK's exit from the EU
- the risk of failures or delays in the quality or execution of the Group's commercial strategies
- the risk of failure to maintain supply of compliant, quality medicines
- the risk of illegal trade in the Group's medicines
- the impact of reliance on third-party goods and services
- the risk of failure in information technology, data protection or cybercrime
- the risk of failure of critical processes
- any expected gains from productivity initiatives are uncertain
- the risk of failure to attract, develop, engage and retain a diverse, talented and capable workforce
- the risk of failure to adhere to applicable laws, rules and regulations
- the risk of the safety and efficacy of marketed medicines being questioned
- the risk of adverse outcome of litigation and/or governmental investigations
- the risk of failure to adhere to increasingly stringent anti-bribery and anti-corruption legislation
- the risk of failure to achieve strategic plans or meet targets or expectations
- the risk of failure in financial control or the occurrence of fraud
- the risk of unexpected deterioration in the Group's financial position
- and the impact that the COVID-19 global pandemic may have or continue to have on these risks, on the Group's ability to continue to mitigate these risks, and on the Group's operations, financial results or financial condition

Nothing in this document, or any related presentation/webcast, should be construed as a profit forecast.