AstraZeneca PLC
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Full-year 2020 results
Accelerating the scientific and commercial evolution; 2021 guidance shows continuing progress

AstraZeneca delivered strong results in the year, in line with guidance that was reconfirmed during the year. With over half of Total Revenue coming from the fast-growing new medicines[1], the Company leveraged its revenue growth to make further progress in profitability, while the strategy of sustainable growth through innovation brought numerous further benefits for patients. AstraZeneca's patient-centric strategy, focus on innovation and capital-allocation priorities remain unchanged, with sustainable long-term growth in revenue, profit and cash generation set to continue.

Pascal Soriot, Chief Executive Officer, commented:
"The performance last year marked a significant step forward for AstraZeneca. Despite the significant impact from the pandemic, we delivered double-digit revenue growth to leverage improved profitability and cash generation. The consistent achievements in the pipeline, the accelerating performance of our business and the progress of the COVID-19 vaccine demonstrated what we can achieve, while the proposed acquisition of Alexion is intended to accelerate our scientific and commercial evolution even further.

Additional investment in new medicines continued to fuel our rapidly growing oncology and biopharmaceuticals therapy areas. *Tagrisso*'s future was enhanced with its first regulatory approval in early, potentially-curable lung cancer and further national reimbursement in China in advanced disease. *Farxiga* again expanded its potential beyond diabetes, while tezepelumab promised real hope for patients suffering from severe asthma. Thanks to the focus on an industry-leading pipeline and consistent execution, I am confident that we will continue to deliver more progress for patients and sustained, compelling results."

Table 1: Financial summary

	FY 2020			Q4 2020		
	$m	% change		$m	% change	
		Actual	CER[2]		Actual	CER
Total Revenue	26,617	9	10	7,410	11	10
- *Product Sales*	*25,890*	*10*	*11*	*7,011*	*12*	*11*
- *Collaboration Revenue*	*727*	*(11)*	*(11)*	*399*	*(4)*	*(4)*
Reported[3] EPS[4]	$2.44	n/m[5]	n/m	$0.78	n/m	n/m
Core[6] EPS	$4.02	15	18	$1.07	19	24

Highlights of Total Revenue in the year included:

- An increase in Product Sales of 10% (11% at CER) to $25,890m. The quarter was the first for many years with Product Sales in excess of $7,000m. New-medicine Total Revenue improved by 33% in the year to $13,950m, including growth in Emerging Markets of 53% (59% at CER) to $2,845m. Globally, the new medicines represented 52% of Total Revenue (FY 2019: 43%)

- Oncology growth of 23% (24% at CER) to $11,455m, while New CVRM[7] increased by 7% (9% at CER) to $4,702m. Respiratory & Immunology declined by 1% (stable at CER) to $5,375m, a reflection of the impact in China of COVID-19

- An increase in Emerging Markets of 7% (10% at CER) to $8,711m, with China growth of 10% (11% at CER) to $5,375m. In the US, Total Revenue increased by 13% to $8,833m and in Europe by 10% (9% at CER) to $5,540m. Both regions delivered stronger growth rates in the final quarter compared to the full year – see the Regional Total Revenue section for details

Guidance
The Company provides guidance for FY 2021 at CER.

Total Revenue is expected to increase by a low-teens percentage,
accompanied by faster growth in Core EPS to $4.75 to $5.00.

The guidance does not incorporate any revenue or profit impact from sales of *COVID-19 Vaccine AstraZeneca* (*C19VAZ*). The Company intends to report these sales separately from the next quarter. Similarly, the guidance excludes the proposed acquisition by the Company of Alexion Pharmaceuticals, Inc. (Alexion), anticipated to close in Q3 2021. AstraZeneca recognises the heightened risks and uncertainties from the impact of COVID-19. 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 2021 at CER:

- AstraZeneca continues its focus on improving operating leverage, while addressing its most important capital-allocation priority of re-investment in the business, namely continued investment in R&D and the support of medicines and patient access in key markets

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

Currency impact
If foreign-exchange rates for January 2021 were seen over the full year, it is anticipated that there would be a low single-digit favourable 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 9% in the year (10% at CER) to $26,617m. Product Sales grew by 10% (11% at CER) to $25,890m, driven primarily by the performances of the new medicines across Oncology and BioPharmaceuticals, including *Tagrisso* and *Farxiga*. Total Revenue included $2m of *C19VAZ* Product Sales within Other medicines; from the next quarter, AstraZeneca intends to report the *C19VAZ* sales performance separately

- The Reported Gross Profit[8] Margin was stable (up by one percentage point at CER) at 80%, while the Core Gross Profit Margin was stable, also at 80%, in line with the Company's expectations

- Reported Total Operating Expense declined by 2% in the year to $17,684m and represented 66% of Total Revenue (FY 2019: 74%). Core Total Operating Expense increased by 6% to $15,633m and comprised 59% of Total Revenue (FY 2019: 60%)

- Reported R&D Expense declined by 1% in the year to $5,991m, primarily reflecting the comparative effect of the $533m impairment of *Epanova* in FY 2019. Core R&D Expense increased by 10% to $5,872m, representing 22% of Total Revenue (FY 2019: 22%). The increases partly reflected investment in the Oncology pipeline, including the development of datopotamab deruxtecan (DS-1062), and the ending in FY 2019 of the release of the upfront funding of *Lynparza* development, as part of the collaboration with MSD[9]

- Reported SG&A Expense declined by 3% in the year to $11,294m; Core SG&A Expense increased by 3% (4% at CER) to $9,362m, representing 35% of Total Revenue (FY 2019: 37%). 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

- Reported Other Income and Expense declined by 1% in the year to $1,528m. Core Other Income and Expense fell by 2% to $1,531m

- The Reported Operating Profit Margin increased by seven percentage points in the year (eight at CER) to 19%. The Core Operating Profit Margin increased by one percentage point (two at CER) to 28% and AstraZeneca anticipates further sustainable expansion in the Core Operating Profit Margin over time

- Reported EPS of $2.44 in the year represented an increase of 137% (142% at CER). Core EPS grew by 15% (18% at CER) to $4.02

- The Board has reaffirmed its commitment to the progressive dividend policy. A stable second interim dividend of $1.90 per share has been declared, keeping the unchanged full-year dividend per share at $2.80

- Net Cash Inflow from Operating Activities of $4,799m in the year, a year-on-year increase of $1,830m, primarily reflected an underlying improvement in business performance and declines in Working Capital and Short-Term Provisions. EBITDA progression continued, with growth of 24% (27% at CER) in the year to $8,311m, while Net Debt of $12,110m represented an increase of $206m

Commercial summary

Oncology
Total Revenue increased by 23% in the year (24% at CER) to $11,455m.

Table 2: Select Oncology medicine performances

	FY 2020			Q4 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Tagrisso: Product Sales	4,328	36	36	1,157	31	28
Imfinzi: Product Sales	2,042	39	39	555	31	29
Lynparza: Product Sales	1,776	48	49	496	42	40
Lynparza: Collaboration Revenue	460	(25)	(25)	325	(7)	(7)
Calquence: Product Sales	522	n/m	n/m	182	n/m	n/m
Enhertu: Collaboration Revenue	96	n/m	n/m	33	n/m	n/m

New CVRM
Total Revenue increased by 7% in the year (9% at CER) to $4,702m.

Table 3: Select New CVRM medicine performances

	FY 2020			Q4 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Farxiga: Total Revenue	1,964	27	30	587	40	40
Brilinta: Product Sales	1,593	1	2	363	(15)	(15)
Bydureon: Product Sales	448	(18)	(18)	122	(12)	(12)
Lokelma: Product Sales	76	n/m	n/m	28	n/m	n/m
Roxadustat: Collaboration Revenue	30	n/m	n/m	11	n/m	n/m

Respiratory & Immunology

Total Revenue declined by 1% in the year (stable at CER) to $5,375m. The adverse impact of the decline in *Pulmicort* sales reduced Respiratory & Immunology Total Revenue growth by 12 percentage points.

Table 4: Select Respiratory & Immunology medicine performances

	FY 2020			Q4 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Symbicort: Product Sales	2,721	9	10	680	(5)	(5)
Pulmicort: Product Sales	996	(32)	(32)	368	(11)	(14)
Fasenra: Product Sales	949	35	34	283	38	35
Breztri: Product Sales	28	n/m	n/m	6	n/m	n/m

Emerging Markets

Total Revenue increased by 7% in the year (10% at CER) to $8,711m, including:

- A China increase of 10% (11% at CER) to $5,375m. The strong performance was limited by the adverse impacts of COVID-19 on sales of *Pulmicort* and the pricing effect of the China volume-based procurement (VBP) programme on *Brilinta, Losec* and *Arimidex*. The Company continued to prioritise patient access to its medicines and geographical expansion in the Chinese market; this included additional successful inclusion of a number of medicines on the National Reimbursement Drug List (NRDL). Admission to the list has an immediate adverse impact on pricing; typically, however, this is more than offset by a subsequent favourable effect on volumes

- An ex-China increase of 1% (9% at CER) to $3,336m, with particularly strong performances in Russia and Latin America

COVID-19

The ongoing pandemic has had a significant impact on every aspect of life in 2020, and the Company recognises the outstanding contribution of colleagues at AstraZeneca and their unrelenting focus on improving the lives of patients. The largest direct impacts of COVID-19 on the Company's portfolio of medicines included reduced sales of *Pulmicort* in China on fewer nebulisation-centre visits and reduced elective surgery, and less use globally of infused and injectable medicines, such as *Imfinzi* and *Fasenra*. There was also a decline in the number of hospital admissions around the world for the treatment of heart attacks and lower levels of elective percutaneous coronary intervention[10], adversely impacting sales of *Brilinta*. Some medicines, however, may have benefited from shifts in patient care and behaviours, including oral medicines such as *Calquence*, which saw an element of benefit from the substitution from infused-chemotherapy regimens.

AstraZeneca has collaborated to mobilise research efforts to target the SARS-CoV-2 virus, in order to provide protection to societies and people against COVID-19 and to treat patients with severe disease. *C19VAZ*, developed in collaboration with the University of Oxford, received authorisation in December 2020 for emergency supply from the UK Medicines and Healthcare Products Regulatory Agency (MHRA). Additional regulatory decisions have also been granted by regulatory authorities in a number of individual countries, including India, Argentina, Mexico and Morocco, and by the European Medicines Agency (EMA). In February 2021, the World Health Organization's (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) also recommended *C19VAZ* for use in individuals 18 years and over, with a preferred dosing interval of eight to 12 weeks.

In addition to *C19VAZ*, the Company has initiated five Phase III clinical trials of AZD7442, a long-acting antibody (LAAB) combination therapy for the prevention and treatment of COVID-19, to evaluate safety and efficacy in preventing infection and treating patients in outpatient and inpatient settings. 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 work with governments and other organisations, including agreements on the supply of *C19VAZ*, can be found in the comprehensive sustainability section of this announcement.

Sustainability summary
During the period, the Company received recognition of its broad sustainability efforts, featuring in the top five for the sector in the Dow Jones Sustainability Index (DJSI) and inclusion in the Corporate Knights Global 100 Index, which identifies globally sustainable companies.

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

a) Access to healthcare
In December 2020, AstraZeneca, through an advanced-purchase agreement with Gavi, the Vaccines Alliance, committed to enabling access to 170m doses of *C19VAZ* in up to 190 countries worldwide, through the COVAX Facility (COVAX). COVAX is a coalition co-led by CEPI, the Coalition for Epidemic Preparedness Innovations, Gavi, and the WHO. It is the only global initiative bringing governments and manufacturers together to ensure that safe and effective COVID-19 vaccines are available worldwide to both higher-income and lower-income countries.

b) Environmental protection
During the period, AstraZeneca was recognised for its leadership in sustainability by global environmental non-profit CDP, a charity that runs a global disclosure system for investors, companies, cities, states and regions to manage their environmental impacts. The Company received a place on the 'A List' for both climate action and water security. AstraZeneca was one of only three organisations worldwide to achieve this double A List recognition for five consecutive years. The Company also featured among the top 7% on CDP's 2020 Supplier Engagement Leaderboard, recognising progress in working with suppliers to address their emissions.

c) Ethics and transparency
In January 2021, the Company was recognised for its efforts in promoting inclusion and diversity by the Bloomberg Gender Equality Index (BGEI), which tracks the performance of public companies committed to disclosing their efforts to support gender equality through policy development, representation and transparency. The Company was also listed as a participant in ShareAction's Workforce Disclosure Initiative (WDI), an annual survey that aims to improve corporate transparency and accountability on workforce issues and provide companies and investors with comprehensive and comparable data to help increase the provision of good jobs worldwide.

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

Notes
The following notes refer to pages one to five.

1. *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 entirely reflected Collaboration Revenue.
2. Constant exchange rates. These are financial measures that are not accounted for according to generally accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.
3. Reported financial measures are the financial results presented in accordance with International Financial Reporting Standards (IFRS), adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the EU and as issued by the International Accounting Standards Board.
4. Earnings per share.
5. Not meaningful.
6. Core financial measures. These are non-GAAP financial measures because, unlike Reported performance, they cannot be derived directly from the information in the Group's Financial Statements. See the operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
7. New CVRM comprises *Brilinta*, Renal and Diabetes medicines.
8. 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.
9. Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.
10. Percutaneous coronary intervention is a nonsurgical procedure intended to improve blood flow to the heart.

Table 5: Pipeline highlights

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

Regulatory approvals	- *Tagrisso* - adjuvant[11] NSCLC[12] (EGFRm[13]) (US) - *Imfinzi* - new Q4W[14] dosing (US, EU) - *Lynparza* - ovarian cancer (1st line[15], HRD+[16]) (PAOLA-1) (EU, JP) - *Lynparza* - prostate cancer (2nd line, BRCAm[17]) (EU, JP) - *Lynparza* - pancreatic cancer (1st line, BRCAm) (JP) - *Enhertu* - gastric cancer (2nd line+, HER2+[18]) (US) - *Enhertu* - breast cancer (3rd line, HER2+) (EU) - *Calquence* - CLL[19] (EU, JP) - *Forxiga* - HF[20] CVOT[21] (EU, JP, CN) - *Brilinta* - stroke (THALES) (US) - *Symbicort* - mild asthma (CN) - *Trixeo* - COPD[22] (EU) - *C19VAZ* - COVID-19 (UK; authorisation for emergency supply, EU; conditional marketing authorisation)
Regulatory submission acceptances and/or submissions	- *Tagrisso* - adjuvant NSCLC (EGFRm) (EU) - *Lynparza* - prostate cancer (2nd line, BRCAm) (CN) - *Farxiga* - CKD[23] (US, JP; priority reviews, EU, CN) - anifrolumab - lupus (SLE[24]) (JP)
Major Phase III data readouts or other significant developments	- *Imfinzi* - biliary tract cancer: Orphan Drug Designation (US) - *Imfinzi* + treme[25] - head & neck cancer (1st line): Phase III primary endpoint not met - tremelimumab - liver cancer: orphan designation (EU) - *Calquence* - CLL (R/R[26]) (ELEVATE R/R): Phase III primary endpoint met - tezepelumab - severe asthma: Phase III primary endpoint met

[11] Adjuvant therapy is used after surgery.
[12] Non-small cell lung cancer.
[13] Epidermal growth factor receptor mutation.
[14] Every four weeks.
[15] The first treatment given for a metastatic disease.
[16] Homologous recombination deficiency positive.
[17] Breast cancer susceptibility gene 1/2 mutation.
[18] Human epidermal growth factor receptor 2 positive.
[19] Chronic lymphocytic leukaemia, the most common type of leukaemia in adults.
[20] Heart failure.
[21] CV outcomes trial.
[22] Chronic obstructive pulmonary disease.
[23] Chronic kidney disease.
[24] Systemic lupus erythematosus, a chronic autoimmune disease that causes inflammation in connective tissues throughout the body.
[25] Tremelimumab.
[26] Relapsed/refractory.

Table 6: Pipeline - anticipated major news flow

Timing	News flow
H1 2021	- *Tagrisso* - adjuvant NSCLC (EGFRm): regulatory decision (CN) - *Imfinzi* - unresectable[27], Stage III NSCLC (PACIFIC-2): data readout, regulatory submission - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): data readout (OS[28]) - *Lynparza* - breast cancer (BRCAm): regulatory decision (CN) - *Lynparza* - adjuvant breast cancer: data readout - *Calquence* - CLL (R/R) (ELEVATE R/R): regulatory submission - *Koselugo* - NF1[29]: regulatory decision (EU) - *Farxiga* - CKD: regulatory decision (US) - *Brilique*/*Brilinta* - CAD[30]/T2D[31] CVOT: regulatory decision (EU, JP, CN) - *Brilique* - stroke (THALES): regulatory decision (EU) - roxadustat - anaemia in CKD: regulatory decision (US) - *Symbicort* - mild asthma: regulatory decision (EU) - *Fasenra* - nasal polyps[32]: regulatory submission - tezepelumab - severe asthma: regulatory submission - *C19VAZ* - SARS-CoV-2: data readout, regulatory submission (US) - AZD7442 - SARS-CoV-2: data readout, regulatory submission
H2 2021	- *Tagrisso* - adjuvant NSCLC (EGFRm): regulatory decision (EU) - *Imfinzi* - NSCLC (1st line) (PEARL): data readout, regulatory submission - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): regulatory submission - *Imfinzi* +/- treme - liver cancer (1st line): data readout, regulatory submission - *Lynparza* - adjuvant breast cancer: regulatory submission - *Lynparza* - prostate cancer (2nd line, BRCAm): regulatory decision (CN) - *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[33]): data readout - *Forxiga* - CKD: regulatory decision (EU, JP, CN) - *Farxiga* - HF (HFpEF[34]): data readout - *Brilinta* - stroke (THALES): regulatory decision (CN) - PT027 - asthma: data readout - anifrolumab - lupus (SLE): regulatory decision (US, EU, JP)

[27] The tumour cannot be removed completely through surgery.
[28] Overall survival.
[29] Neurofibromatosis type 1, a genetic condition causing tumours to grow along nerves in the skin, brain and other parts of the body.
[30] Coronary artery disease.
[31] Type-2 diabetes.
[32] Benign soft growths inside the nose.
[33] HER2 immunohistochemistry (IHC) 1 or 2 with fluorescence in situ hybridisation (ISH) test-result .
[34] HF with preserved ejection fraction.

Timing	News flow
2022	- *Imfinzi* - ES-SCLC[35]: regulatory decision (CN) - *Imfinzi* - LS-SCLC[36]: data readout, regulatory submission - *Imfinzi* - liver cancer (locoregional): data readout, regulatory submission - *Imfinzi* - biliary tract cancer: data readout, regulatory submission - *Lynparza* - ovarian cancer (3rd line, BRCAm): regulatory submission - *Enhertu* - breast cancer (3rd line, HER2+) (Phase III): regulatory submission - *Enhertu* - breast cancer (HER2 low): regulatory submission - *Calquence* - CLL: regulatory submission (CN) - *Koselugo* - NF1: regulatory submission (JP, CN) - *Farxiga* - HF (HFpEF): regulatory submission - roxadustat - MDS[37]: data readout, regulatory submission - PT027 - asthma: regulatory submission - nirsevimab - RSV[38]: data readout

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 first-quarter results on Friday, 30 April 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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[35] Extensive-stage small cell lung cancer.
[36] Limited-stage small cell lung cancer.
[37] Myelodysplastic syndrome/.
[38] Respiratory syncytial virus.

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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 twelve-month period to 31 December 2020 (the year or FY 2020) and the three-month period to 31 December 2020 (the quarter, the fourth quarter or Q4 2020), compared to the twelve-month period to 31 December 2019 (FY 2019) and the three-month period to 31 December 2019 (Q4 2019) respectively, unless stated otherwise.

Forward-looking statements in this announcement do not reflect the impact of the performance of *C19VAZ* or the proposed acquisition by the Company of Alexion, which is expected to close in Q3 2021.

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 Condensed Consolidated Financial Statements. Management believes that these non-GAAP financial measures, when provided in combination with Reported results, will provide investors and analysts with helpful supplementary information to understand better the financial performance and position of the Group on a comparable basis from period to period. These non-GAAP financial measures are not a substitute for, or superior to, financial measures prepared in accordance with GAAP. Core financial measures are adjusted to exclude certain significant items, such as:

- Amortisation and impairment of intangible assets, including impairment reversals but excluding any charges relating to IT assets

- Charges and provisions related to restructuring programmes, which includes charges that relate to the impact of restructuring programmes on capitalised IT assets

- Other specified items, principally comprising the Diabetes alliance[39], 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 financial performance section 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 in 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 Condensed 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.

[39] 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 (FY 2019: 48%), specialty-care medicines increased by 21% in the year (22% at CER) to $14,103m.

	FY 2020				Q4 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Oncology	11,455	43	23	24	3,270	24	23
BioPharmaceuticals	10,077	38	3	4	2,786	3	2
- *New CVRM*	*4,702*	*18*	*7*	*9*	*1,252*	*7*	*7*
- *Respiratory & Immunology*	*5,375*	*20*	*(1)*	*-*	*1,534*	*(1)*	*(2)*
Other medicines	5,085	19	(4)	(2)	1,354	3	2
Total	**26,617**	**100**	**9**	**10**	**7,410**	**11**	**10**

Table 8: Top-ten medicines by Total Revenue

Medicine	Therapy Area	FY 2020				Q4 2020		
		$m	% of total	% change		$m	% change	
				Actual	CER		Actual	CER
Tagrisso	Oncology	4,328	16	36	36	1,157	31	28
Symbicort	Respiratory & Immunology	2,721	10	9	10	680	(5)	(5)
Lynparza	Oncology	2,236	8	24	24	821	17	16
Imfinzi	Oncology	2,042	8	39	39	555	31	29
Farxiga	CVRM	1,964	7	27	30	587	40	40
Brilinta	CVRM	1,593	6	1	2	363	(15)	(16)
Nexium	Other medicines	1,524	6	1	2	384	7	5
Crestor	CVRM	1,182	4	(10)	(9)	298	(9)	(10)
Pulmicort	Respiratory & Immunology	996	4	(32)	(32)	368	(11)	(14)
Fasenra	Respiratory & Immunology	949	4	35	34	283	38	35
Total		**19,535**	**73**	**14**	**15**	**5,496**	**13**	**11**

Table 9: Collaboration Revenue

	FY 2020				Q4 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Lynparza: regulatory milestone revenue	160	22	n/m	n/m	25	n/m	n/m
Lynparza: sales milestone revenue	300	41	(33)	(33)	300	20	20
Enhertu: share of gross profits	94	13	n/m	n/m	31	n/m	n/m
Roxadustat: share of gross profits	30	4	n/m	n/m	11	n/m	n/m
Other Ongoing Collaboration Revenue	143	20	(32)	(32)	32	(53)	(54)
Total	**727**	**100**	**(11)**	**(11)**	**399**	**(4)**	**(4)**

Other Collaboration Revenue included *Zoladex*, *Farxiga*, *Eklira*, *Nexium* OTC[40] and other royalties. No Initial Collaboration Revenue was recorded in the year.

[40] 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 - FY 2020

Product Sales: therapy area	Medicine	FY 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
Oncology	*Tagrisso*	4,328	17	36	36
	Imfinzi	2,042	8	39	39
	Lynparza	1,776	7	48	49
	Calquence	522	2	n/m	n/m
	Koselugo	38	-	n/m	n/m
	Zoladex[41]	888	3	9	13
	Faslodex[41]	580	2	(35)	(34)
	Iressa[41]	268	1	(37)	(36)
	Arimidex[41]	185	1	(18)	(16)
	Casodex[41]	172	1	(14)	(14)
	Others	51	-	(47)	(46)
	Total Oncology	**10,850**	**42**	**25**	**26**
BioPharmaceuticals: CVRM	*Farxiga*	1,959	8	27	30
	Brilinta	1,593	6	1	2
	Onglyza	470	2	(11)	(10)
	Bydureon	448	2	(18)	(18)
	Byetta	68	-	(37)	(36)
	Other diabetes	47	-	(10)	(10)
	Lokelma	76	-	n/m	n/m
	Crestor[41]	1,180	5	(8)	(7)
	Seloken/Toprol-XL[41]	821	3	8	12
	Atacand[41]	243	1	10	15
	Others	191	1	(30)	(30)
	BioPharmaceuticals: total CVRM	**7,096**	**27**	**3**	**5**

[41] Legacy medicine.

Product Sales: therapy area	Medicine	FY 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
BioPharmaceuticals: Respiratory & Immunology	*Symbicort*	2,721	11	9	10
	Pulmicort	996	4	(32)	(32)
	Fasenra	949	4	35	34
	Daliresp/*Daxas*	217	1	1	1
	Bevespi	48	-	16	15
	Breztri	28	-	n/m	n/m
	Others	398	2	(15)	(15)
	BioPharmaceuticals: total Respiratory & Immunology	**5,357**	**21**	**(1)**	**-**
Other medicines	*Nexium*[41]	1,492	6	1	2
	Synagis[41]	372	1	4	4
	FluMist[41]	295	1	n/m	n/m
	Losec/*Prilosec*[41]	183	1	(30)	(30)
	Seroquel XR/IR[41]	117	-	(39)	(37)
	Others	128	-	(33)	(34)
	Total other medicines	**2,587**	**10**	**(1)**	**-**
	Total Product Sales	**25,890**	**100**	**10**	**11**
	Total Collaboration Revenue	**727**		**(11)**	**(11)**
	Total Revenue	**26,617**		**9**	**10**

Table 11: Therapy area and medicine performance - Q4 2020

Product Sales: therapy area	Medicine	Q4 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
Oncology	*Tagrisso*	1,157	17	31	28
	Imfinzi	555	8	31	29
	Lynparza	496	7	42	40
	Calquence	182	3	n/m	n/m
	Koselugo	17	-	n/m	n/m
	Zoladex	216	3	11	13
	Faslodex	130	2	(21)	(22)
	Iressa	67	1	(16)	(19)
	Arimidex	36	1	(29)	(30)
	Casodex	39	1	(10)	(13)
	Others	13	-	(53)	(52)
	Total Oncology	**2,908**	**41**	**28**	**26**
BioPharmaceuticals: CVRM	*Farxiga*	586	8	40	40
	Brilinta	363	5	(15)	(15)
	Onglyza	105	1	(20)	(21)
	Bydureon	122	2	(12)	(12)
	Byetta	19	-	(31)	(30)
	Other diabetes	12	-	(23)	(22)
	Lokelma	28	-	n/m	n/m
	Crestor	298	4	1	(1)
	Seloken/Toprol-XL	200	3	6	7
	Atacand	63	1	5	9
	Others	46	1	(38)	(40)
	BioPharmaceuticals: total CVRM	**1,842**	**26**	**3**	**3**

Product Sales: therapy area	Medicine	Q4 2020			
		$m	% of total Product Sales	% change	
				Actual	CER
BioPharmaceuticals: Respiratory & Immunology	*Symbicort*	680	10	(5)	(5)
	Pulmicort	368	5	(11)	(14)
	Fasenra	283	4	38	35
	Daliresp/*Daxas*	54	1	(6)	(7)
	Bevespi	12	-	8	4
	Breztri	6	-	n/m	n/m
	Others	125	2	(8)	(12)
	BioPharmaceuticals: total Respiratory & Immunology	**1,528**	**22**	**(1)**	**(2)**
Other medicines	*Nexium*	377	5	7	6
	Synagis	78	1	24	24
	FluMist	179	3	92	85
	Losec/*Prilosec*	39	1	(15)	(18)
	Seroquel XR/IR	19	-	(53)	(49)
	Others	41	1	(30)	(31)
	Total other medicines	**733**	**10**	**12**	**10**
	Total Product Sales	**7,011**	**100**	**12**	**11**
	Total Collaboration Revenue	**399**		**(4)**	**(4)**
	Total Revenue	**7,410**		**11**	**10**

Total Revenue summary

Oncology

Total Revenue of $11,455m in the year; an increase of 23% (24% at CER). The performance of *Enhertu* was reflected entirely in Collaboration Revenue.

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

Tagrisso
Tagrisso has received regulatory approval in five countries, including the US, for use as an adjuvant treatment of EGFRm NSCLC patients, with three reimbursements granted so far. This expands upon the patient benefit from use in the 1st-line treatment of patients with EGFRm NSCLC with regulatory approval in 87 countries, including the US, China, in the EU and Japan. To date, reimbursement has been granted in 40 countries in this setting, with further decisions anticipated. These developments followed *Tagrisso*'s regulatory approval in 89 countries, including the US, China, in the EU and Japan for the treatment of patients with EGFR T790M[42] NSCLC, an indication in which 66 reimbursements have been obtained.

Total Revenue, entirely comprising Product Sales, amounted to $4,328m in the year and represented growth of 36%. Sales in the US increased by 24% to $1,566m. Approval was granted by the US Food and Drug Administration (FDA) in December 2020 for the adjuvant treatment of Stage Ib to IIIa EGFRm NSCLC patients.

In Emerging Markets, *Tagrisso* sales increased by 59% in the year (63% at CER) to $1,208m, with notable growth in China; admission to the 2021 China NRDL was obtained for the 1st-line and renewed for the 2nd-line setting, commencing in March 2021. Japan increased by 16% (14% at CER) to $731m, despite a Q4 2019 price reduction of 15%. In Europe, sales of $748m in the year represented an increase of 58% (56% at CER), driven by use in the 1st-line setting, as more reimbursements were granted.

Imfinzi
Imfinzi has received regulatory approval in 67 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. *Imfinzi* has also been approved for the treatment of ES-SCLC patients in 51 countries, with five reimbursements obtained.

Total Revenue, entirely comprising Product Sales, amounted to $2,042m in the year and represented growth of 39%, predominantly for the treatment of unresectable, Stage III NSCLC patients. The US increased by 14% to $1,185m; in Japan, growth of 28% (26% at CER) represented sales of $270m. Europe increased by 106% (104% at CER) to $370m, reflecting a growing number of reimbursements, while Emerging Markets increased to $158m (FY 2019: $30m), following recent regulatory approvals and launches, including in China.

Lynparza
Lynparza has received regulatory approval in 78 countries for the treatment of ovarian cancer; it has also been approved in 76 countries for the treatment of metastatic breast cancer, and in 55 countries for the treatment of pancreatic cancer. *Lynparza* has received regulatory approval in 49 countries for the 2nd-line treatment of certain prostate-cancer patients.

Lynparza Total Revenue amounted to $2,236m in the year and represented growth of 24%; this included Collaboration Revenue of $460m.

Product Sales in the year amounted to $1,776m, reflecting growth of 48% (49% at CER). The strong performance was geographically spread, with further indication launches continuing globally. US Product Sales increased by 40% to $876m, 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 52% (51% at CER) to $435m, 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.

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

Japan Product Sales of *Lynparza* amounted to $167m, representing growth of 29% (27% at CER). Emerging Markets Product Sales were $264m, up by 98% (108% at CER). In China, *Lynparza* was admitted to the NRDL as a 1st-line treatment for BRCAm ovarian cancer patients with effect from March 2021.

Enhertu
US sales, recorded by Daiichi Sankyo Company Limited (Daiichi Sankyo), amounted to $200m in the year, including $64m in the quarter. *Enhertu* was approved at the end of 2019 by the US FDA for the treatment of 3rd-line HER2+ breast cancer. Total Revenue, entirely comprising Collaboration Revenue recorded by AstraZeneca, amounted to $96m in the year, with $33m recorded in the quarter.

Calquence
Total Revenue, entirely comprising Product Sales, amounted to $522m in the year and represented growth of 219%, with the overwhelming majority of sales in the US. *Calquence* was approved by the US FDA for the treatment of CLL in November 2019. In total, *Calquence* has received regulatory approvals for this indication in 51 countries and in 23 countries for the treatment of patients with R/R mantle cell lymphoma (MCL).

Koselugo
Total Revenue, entirely comprising Product Sales in the US, amounted to $38m in the year, following its launch during the second quarter for the treatment of the rare disease NF1 in paediatric patients aged two years and older who have symptomatic, inoperable plexiform neurofibromas.

Zoladex
Total Revenue, predominantly comprising Product Sales, amounted to $938m in the year and represented growth of 13% (17% at CER).

Emerging Markets Product Sales of *Zoladex* increased by 14% (20% at CER) to $561m, reflecting increased use and access in prostate cancer. Product Sales in Europe increased by 4% to $140m while, in the Established Rest of World (RoW) region, Product Sales increased by 1% to $182m.

Faslodex
Total Revenue, entirely comprising Product Sales, amounted to $580m in the year and represented a decline of 35% (34% at CER).

Emerging Markets fell by 9% (4% at CER) to $180m, while US sales declined by 83% to $55m, reflecting the launch in 2019 of multiple generic *Faslodex* medicines; in Europe, sales fell by 3% to $221m. In Japan, they declined by 11% (13% at CER) to $116m, driven by a mandated price reduction in the second quarter.

Iressa
Total Revenue, entirely comprising Product Sales, amounted to $268m in the year and represented a decline of 37% (36% at CER). Emerging Markets fell by 23% (22% at CER) to $221m, driven by the impact of *Iressa*'s inclusion in China's VBP programme and subsequent price reduction.

BioPharmaceuticals: CVRM

Total Revenue increased by 3% in the year (4% at CER) to $7,139m and represented 27% of Total Revenue (FY 2019: 29%). This included roxadustat Collaboration Revenue of $30m, as well as the Product 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 (9% at CER) to $4,702m, mainly reflecting the strong performance of *Farxiga*. New CVRM represented 66% of overall CVRM Total Revenue in the year (FY 2019: 63%).

Farxiga
Total Revenue, predominantly comprising Product Sales, amounted to $1,964m in the year and represented growth of 27% (30% at CER). Q4 2020 Total Revenue increased by 40% to $587m, reflecting volume growth across the regions.

Emerging Markets Product Sales increased by 46% in the year (55% at CER) to $686m. In China, *Forxiga* was admitted to the NRDL with effect from the start of 2020; as expected, this adversely impacted pricing. This was, however, more than offset by the derived volume uplift.

US Product Sales increased by 6% in the year to $569m, partly driven by regulatory approval in May 2020 for the treatment of patients with heart failure with reduced ejection fraction (HFrEF) in both patients with and without T2D, based on the compelling patient benefit seen in the results from the DAPA-HF trial. Sales in the fourth quarter increased by 31% to $184m, reflecting by the comparative effect of an adverse prior-year gross-to-net adjustment.

Product Sales in Europe increased by 36% in the year (35% at CER) to $507m, partly reflecting growth in the SGLT2[43] class, the beneficial addition of CVOT data to the label and HFrEF regulatory approval in November 2020. In Japan, sales to collaborator Ono Pharmaceutical Co., Ltd, which records in-market sales, increased by 29% (27% at CER) to $117m.

Brilinta
Total Revenue, entirely comprising Product Sales, amounted to $1,593m in the year and represented growth of 1% (2% at CER).

Global demand over the year was adversely impacted by the effects of COVID-19, reflected in fewer acute coronary syndrome hospital admissions. Sales in Q4 2020 declined by 15% to $363m, also driven by a VBP-related mandatory price reduction in China in Q3 2020.

Emerging Markets sales were stable in the year (up by 4% at CER) at $461m. Sales in the fourth quarter, however, declined by 39% (36% at CER) to $69m, following the aforementioned price reduction in China. US sales, at $732m, represented growth of 3%, with an increase in the average-weighted duration of treatment partly offset by the adverse COVID-19 impact, also reflected in fewer elective procedures. Sales of *Brilique* in Europe declined by 3% in the year to $342m, with the performance similarly impacted by COVID-19.

Onglyza
Total Revenue, entirely comprising Product Sales, amounted to $470m in the year and represented a decline of 11% (10% at CER).

Sales in Emerging Markets increased by 14% (18% at CER) to $201m, driven by the performance in China and the growing DPP-4[44] class. US sales of *Onglyza* fell by 28% in the year to $166m, while Europe sales declined by 16% (17% at CER) to $58m, highlighting the shift away from the class.

Bydureon
Total Revenue, entirely comprising Product Sales, amounted to $448m in the year and represented a decline of 18%.

US sales of $382m reflected a fall of 17% in the year, resulting from competitive pressures and the impact of managed markets. Sales in Europe declined by 20% to $53m.

Lokelma
Total Revenue, entirely comprising Product Sales, amounted to $76m in the year (FY 2019: $14m), an increase of 461% (463% at CER), despite the impact from COVID-19 on the overall market. The US represented the overwhelming majority of sales; *Lokelma* continued to lead new-to-brand prescription market share in the US. The medicine has received regulatory approval in several markets for the treatment of hyperkalaemia, including in the EU, China and Japan, with further launches anticipated in a number of markets soon. In December 2020, the medicine was excluded from the latest round of the China NRDL process.

[43] Sodium-glucose co-transporter-2.
[44] Dipeptidyl peptidase 4.

Roxadustat

Total Revenue, entirely comprising Collaboration Revenue, amounted to $30m in the year in China. Q4 2020 revenue of $11m reflected a sequential quarterly increase of 46%. The Company continued to focus in the year on achieving hospital listings and patient access across China.

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

Crestor

Total Revenue, predominantly comprising Product Sales, amounted to $1,182m in the year and represented a decline of 10% (9% at CER).

Product Sales in Emerging Markets fell by 7% (5% at CER) to $748m. The performance continued to be adversely impacted by the ongoing effects of the aforementioned VBP programme in China. US Product Sales declined by 11% to $92m. In Europe, Total Revenue fell by 31% (32% at CER) to $131m while, in Japan, where AstraZeneca collaborates with Shionogi Co., Ltd, Product Sales declined by 4% (5% at CER) to $164m.

In December 2020, it was announced that the Company had agreed to sell the commercial rights to *Crestor* in over 30 countries in Europe to Grünenthal GmbH. The divestment closed earlier in the first quarter of 2021.

BioPharmaceuticals: Respiratory & Immunology

Total Revenue declined by 1% in the year (stable at CER) to $5,375m and represented 20% of Total Revenue (FY 2019: 22%). This included Ongoing Collaboration Revenue of $18m from *Duaklir*, *Eklira* and other medicines.

Symbicort

Total Revenue, entirely comprising Product Sales, amounted to $2,721m in the year and represented an increase of 9% (10% at CER), a result of growth in the US. Q4 2020 Total Revenue declined by 5% to $680m, driven by the impact of generic competition in Europe and 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 23% in the year to $1,022m; an authorised-generic version of *Symbicort* was launched in the US by the Company's collaborator, Prasco LLC (Prasco), in January 2020. The performance in Emerging Markets in the year slowed down versus FY 2019, reflecting a reduction in hospital visits in China due to COVID-19, leading to fewer initiations. Despite this, Emerging Markets sales increased by 4% (9% at CER) to $567m.

In Europe, sales increased by 2% in the year to $694m, with positive volume growth seen in the major countries. In Japan, sales declined by 16% (18% at CER) to $189m, driven by the impact of generic competition and an unfavourable price comparison versus 2019, partly reflecting the termination of the Astellas Pharma Inc. co-promotion agreement. This impact in Japan was particularly acute in the fourth quarter, when sales declined by 53% (54% at CER) to $45m.

Pulmicort

Total Revenue, entirely comprising Product Sales, amounted to $996m in the year and represented a decline of 32%, as the continued effects of COVID-19 impacted the hospital treatment of respiratory patients. Q4 2020 Total Revenue declined by 11% (14% at CER) to $368m.

Emerging Markets, where *Pulmicort* sales fell by 33% in the year to $798m, represented 80% of the global total. Alongside the effects of COVID-19, the performance in China was impacted by a reduction in the number of paediatric patients attending outpatient nebulisation rooms. In the fourth quarter, however, the volume of adult elective procedures, a smaller use, largely recovered. *Pulmicort* can be used in this setting when oral corticosteroids (OCS) are unsuitable.

Sales in the US declined by 35% in the year to $71m, due to the fall in the use of *Pulmicort Respules*. In Japan, sales declined by 51% (52% at CER) to $30m as a result of generic competition and fell in Europe by 10% to $73m.

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 47 countries.

Total Revenue, entirely comprising Product Sales, amounted to $949m in the year and represented growth of 35% (34% at CER), a result of increased demand, despite the impact of COVID-19 on the level of new-patient starts in several countries. *Fasenra* remained the leading novel biologic in the majority of markets in the new-to-brand prescription share for patients with severe, uncontrolled asthma.

Sales in the US grew by 25% in the year to $603m, due to increased volume demand as a result of the impact of COVID-19 earlier in the year. The adverse effect of COVID-19 on the dynamic market was partially offset by the growth in market share and increased persistency. In Europe, sales of $203m represented an increase of 72% (70% at CER), reflecting ongoing successful launches and additional reimbursement. Sales in Japan increased by 16% (14% at CER) to $100m. In Emerging Markets, sales amounted to $12m (FY 2019: $5m).

Daliresp/Daxas
Total Revenue, entirely comprising Product Sales, amounted to $217m in the year and represented an increase of 1%. US sales, comprising 88% of the global total, increased by 3% to $190m.

Bevespi
Total Revenue, entirely comprising Product Sales, amounted to $48m in the year and represented an increase of 16% (15% at CER). *Bevespi* has been launched in the US, in a number of European countries and in Japan. Sales in the US increased by 7% in the year to $44m while, in Europe, sales amounted to $3m (FY 2019: $nil). *Bevespi* was recently included in the China NRDL, with effect from March 2021.

Breztri
Breztri has received regulatory approval in 34 countries, including the US, in the EU, China and Japan for the treatment of patients with COPD. With further regulatory reviews ongoing, *Breztri* has already achieved reimbursement in four countries.

Total Revenue, entirely comprising Product Sales, amounted to $28m in the year (FY 2019: $2m). Sales in the US amounted to $5m (FY 2019: $nil), largely as a result of stocking. Sales in Japan amounted to $9m (FY 2019: $2m) where prescriptions were limited by Ryotanki, a regulation which limits prescriptions to two weeks' supply in the first year of launch. In October 2020, Ryotanki was lifted for *Breztri* and the restriction no longer applied. Emerging Markets amounted to $14m (FY 2019: $nil). *Breztri* was recently included in the China NRDL, with effect from March 2021.

Other medicines (outside the three main therapy areas)

Total Revenue, primarily comprising Product Sales, amounted to $2,649m in the year, representing a decline of 2%. 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 (FY 2019: 11%).

Nexium
Total Revenue, predominantly comprising Product Sales, amounted to $1,524m in the year, representing an increase of 1% (2% at CER). Emerging Markets Product Sales of *Nexium* increased by 1% (4% at CER) to $757m in the year, with particular strength in Q4 2020 when sales of $193m represented an increase of 11%, reflecting later phasing of demand in the year.

In Japan, where AstraZeneca collaborates with Daiichi Sankyo, Product Sales increased by 6% (4% at CER) to $423m, while Product Sales in the US declined by 22% to $169m. In Europe, Product Sales increased by 12% (10% at CER) to $71m.

Further to the previous VBP-programme round in Q4 2020, China concluded another round in February 2021, including *Nexium* (oral). The Company, however, chose not to compete on price and consequently accepted a mandatory price reduction of 30%.

Losec/Prilosec

Total Revenue, entirely comprising Product Sales, amounted to $183m in the year, representing a decline of 30%. This partly reflected 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 15% (14% at CER) to $152m as *Losec* was subject to a mandatory price reduction as part of the impact of aforementioned VBP programme in China; sales in Europe fell by 59% to $20m.

FluMist

Total Revenue, entirely comprising Product Sales, increased by 161% in the year (153% at CER) to $295m, reflecting the greater use of influenza vaccines as health authorities in northern-hemisphere countries expanded seasonal-vaccination programmes beyond typical levels during the ongoing COVID-19 pandemic. In the US, sales increased by 254% in the year to $70m and, in Europe, by 135% (126% at CER) to $219m.

Synagis

The commercial rights to the sale and distribution of *Synagis* outside the US, held by AbbVie Inc (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.

Total Revenue, entirely comprising Product Sales, amounted to $372m in the year, representing an increase of 4%. In Q4 2020, global sales increased by 24% to $78m, reflecting the phasing of orders from AbbVie and preparations for the aforementioned reversion of commercial rights. Sales in Europe, wholly reflecting sales to AbbVie made under the current supply agreement for markets outside the US, amounted to $325m in the year, representing an increase of 4%.

Regional Total Revenue

Table 12: Regional Total Revenue

	FY 2020				Q4 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Emerging Markets	8,711	33	7	10	2,244	7	8
- *China*	*5,375*	*20*	*10*	*11*	*1,362*	*15*	*9*
- *Ex-China*	*3,336*	*13*	*1*	*9*	*882*	*(2)*	*7*
US	8,833	33	13	13	2,388	15	15
Europe	5,540	21	10	9	1,831	17	12
Established RoW	3,533	13	6	5	947	2	(1)
- *Japan*	*2,620*	*10*	*1*	*-*	*718*	*(2)*	*(5)*
- *Canada*	*605*	*2*	*29*	*31*	*146*	*16*	*16*
- *Other Est. RoW*	*308*	*1*	*8*	*10*	*83*	*11*	*7*
Total	**26,617**	**100**	**9**	**10**	**7,410**	**11**	**10**

A geographical split of Product Sales is shown in Note 7. For additional details, refer to **Table 49: Historic Collaboration Revenue** for Collaboration Revenue recognised during FY 2020 and FY 2019.

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

	FY 2020				Q4 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Oncology	2,906	33	31	36	668	22	24
BioPharmaceuticals	3,007	35	(4)	-	882	2	2
- New CVRM	*1,407*	*16*	*24*	*31*	*335*	*12*	*17*
- Respiratory & Immunology	*1,600*	*18*	*(19)*	*(18)*	*547*	*(4)*	*(5)*
Other medicines	2,798	32	(1)	2	694	2	3
Total	**8,711**	**100**	**7**	**10**	**2,244**	**7**	**8**

Emerging Markets Total Revenue grew by 7% (10% at CER) to $8,711m in the year and, in the fourth quarter, by 7% (8% at CER) to $2,244m. The new medicines represented 33% of Emerging Markets Total Revenue in the year (FY 2019: 23%). Speciality-care medicines increased by 27% (32% at CER) to $3,414m and comprised 39% of Emerging Markets Total Revenue in the year (FY 2019: 33%).

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

	FY 2020				Q4 2020		
	$m	% of total	% change		$m	% change	
			Actual	CER		Actual	CER
Tagrisso	1,208	14	59	63	258	23	23
Forxiga	686	8	46	55	198	50	57
Brilinta	461	5	-	4	69	(40)	(37)
Lynparza[45]	264	3	98	n/m	69	n/m	n/m

China comprised 62% of Emerging Markets Total Revenue in the year and increased by 10% (11% at CER) to $5,375m. New medicines, primarily driven by *Tagrisso* and *Lynparza* in Oncology and *Forxiga* in New CVRM, delivered particularly encouraging growth and represented 31% of China Total Revenue (FY 2019: 19%); strong sales of *Zoladex*, *Seloken* and *Symbicort* supplemented this performance. The aforementioned decline of *Pulmicort* in China, however, restricted overall Total Revenue growth in the year.

In Q4 2020, China growth of 15% (9% at CER) to $1,362m reflected the impact of a mandatory 30% price reduction for *Brilinta*, *Losec* and *Arimidex*, which were unsuccessful in the latest round of VBP, following the Company's decision not to compete with generic competitor price in the tender process.

[45] Here, excludes any Collaboration Revenue associated with the aforementioned collaboration with MSD.

Table 15: Ex-China Emerging Markets: Total Revenue

	FY 2020			Q4 2020		
	$m	% change		$m	% change	
		Actual	CER		Actual	CER
Ex-China Asia Pacific	1,237	5	6	341	7	5
Middle East and Africa	1,024	(3)	1	256	(12)	(5)
Ex-Brazil Latin America	447	-	18	130	2	21
Russia	314	28	42	77	11	33
Brazil	314	(15)	10	78	(17)	11
Total	**3,336**	**1**	**9**	**882**	**(2)**	**7**

Ex-China Emerging Markets Total Revenue, primarily comprising Product Sales, increased by 1% in the year (9% at CER) to $3,336m. The new medicines represented 36% of ex-China Emerging Markets Total Revenue (FY 2019: 29%), increasing by 25% (35% at CER) to $1,194m.

Notable performances in ex-China Emerging Markets included growth in Russia of 28% (42% at CER) to $314m and a stable performance in ex-Brazil Latin America (growth of 18% at CER), representing Total Revenue of $447m.

Financial performance

Table 16: Reported Profit and Loss - FY 2020

	FY 2020 $m	FY 2019 $m	% change Actual	% change CER
Total Revenue	26,617	24,384	9	10
- *Product Sales*	*25,890*	*23,565*	*10*	*11*
- *Collaboration Revenue*	*727*	*819*	*(11)*	*(11)*
Cost of Sales	(5,299)	(4,921)	8	8
Gross Profit	21,318	19,463	10	11
Gross Profit Margin	*79.5%*	*79.1%*	-	*+1*
Distribution Expense	(399)	(339)	18	19
% Total Revenue	*1.5%*	*1.4%*	-	-
R&D Expense	(5,991)	(6,059)	(1)	(1)
% Total Revenue	*22.5%*	*24.8%*	*+2*	*+3*
SG&A Expense	(11,294)	(11,682)	(3)	(3)
% Total Revenue	*42.4%*	*47.9%*	*+5*	*+6*
Other Operating Income & Expense	1,528	1,541	(1)	(1)
% Total Revenue	*5.7%*	*6.3%*	*-1*	*-1*
Operating Profit	5,162	2,924	77	81
Operating Profit Margin	*19.4%*	*12.0%*	*+7*	*+8*
Net Finance Expense	(1,219)	(1,260)	(3)	(4)
Joint Ventures and Associates	(27)	(116)	(77)	(76)
Profit Before Tax	3,916	1,548	n/m	n/m
Taxation	(772)	(321)	n/m	n/m
Tax Rate	20%	21%		
Profit After Tax	3,144	1,227	n/m	n/m
EPS	$2.44	$1.03	n/m	n/m

Table 17: Reported Profit and Loss - Q4 2020

	Q4 2020 $m	Q4 2019 $m	% change Actual	% change CER
Total Revenue	7,410	6,664	11	10
- *Product Sales*	*7,011*	*6,250*	*12*	*11*
- *Collaboration Revenue*	*399*	*414*	*(4)*	*(4)*
Cost of Sales	(1,525)	(1,378)	11	5
Gross Profit	5,885	5,286	11	11
Gross Profit Margin	*78.2%*	*78.0%*	-	*+1*
Distribution Expense	(109)	(92)	18	16
% Total Revenue	*1.5%*	*1.4%*	-	-
R&D Expense	(1,719)	(2,091)	(18)	(19)
% Total Revenue	*23.2%*	*31.4%*	*+8*	*+8*
SG&A Expense	(3,210)	(3,026)	6	4
% Total Revenue	*43.3%*	*45.4%*	*+2*	*+2*
Other Operating Income & Expense	640	500	28	29
% Total Revenue	*8.6%*	*7.5%*	*+1*	*+1*
Operating Profit	1,487	577	n/m	n/m
Operating Profit Margin	*20.1%*	*8.7%*	*+11*	*+13*
Net Finance Expense	(314)	(312)	1	-
Joint Ventures and Associates	(6)	(25)	(79)	(79)
Profit Before Tax	1,167	240	n/m	n/m
Taxation	(162)	37	n/m	n/m
Tax Rate	14%	(15)%		
Profit After Tax	1,005	277	n/m	n/m
EPS	$0.78	$0.24	n/m	n/m

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

	FY 2020 $m	FY 2019 $m	% change Actual	% change CER
Reported Profit Before Tax	**3,916**	**1,548**	**n/m**	**n/m**
Net Finance Expense	1,219	1,260	(3)	(4)
Joint Ventures and Associates	27	116	(77)	(76)
Depreciation, Amortisation and Impairment	3,149	3,762	(16)	(16)
EBITDA	**8,311**	**6,686**	**24**	**27**

Table 19: Reconciliation of Reported Profit Before Tax to EBITDA - Q4 2020

	Q4 2020 $m	Q4 2019 $m	% change Actual	% change CER
Reported Profit Before Tax	**1,167**	**240**	**n/m**	**n/m**
Net Finance Expense	314	312	1	-
Joint Ventures and Associates	6	25	(79)	(79)
Depreciation, Amortisation and Impairment	797	1,643	(52)	(53)
EBITDA	**2,284**	**2,220**	**3**	**6**

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

FY 2020	Reported $m	Restructuring $m	Intangible Asset Amortisation & Impairments $m	Diabetes Alliance $m	Other $m	Core[46] $m	Core % change Actual	Core % change CER
Gross Profit	21,318	53	66	-	5	21,442	9	10
Gross Profit Margin	*79.5%*					*80.0%*	-	-
Distribution Expense	(399)	-	-	-	-	(399)	18	19
R&D Expense	(5,991)	35	84	-	-	(5,872)	10	10
SG&A Expense	(11,294)	162	1,657	310	(197)	(9,362)	3	4
Total Operating Expense	(17,684)	197	1,741	310	(197)	(15,633)	6	6
Other Operating Income & Expense	1,528	1	2	-	-	1,531	(2)	(2)
Operating Profit	5,162	251	1,809	310	(192)	7,340	14	17
Operating Profit Margin	*19.4%*					*27.6%*	*+1*	*+2*
Net Finance Expense	(1,219)	-	-	228	209	(782)	2	2
Taxation	(772)	(50)	(376)	(127)	13	(1,312)	18	21
EPS	$2.44	$0.15	$1.10	$0.31	$0.02	$4.02	15	18

[46] 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 - Q4 2020

Q4 2020	Reported $m	Restructuring $m	Intangible Asset Amortisation & Impairments $m	Diabetes Alliance $m	Other $m	Core[46] $m	Core % change Actual	Core % change CER
Gross Profit	5,885	9	16	-	1	5,911	12	12
Gross Profit Margin	*78.2%*					*78.6%*	*+1*	*+2*
Distribution Expense	(109)	-	-	-	-	(109)	18	16
R&D Expense	(1,719)	5	7	-	-	(1,707)	14	12
SG&A Expense	(3,210)	95	429	64	(216)	(2,838)	8	6
Total Operating Expense	(5,038)	100	436	64	(216)	(4,654)	11	8
Other Operating Income & Expense	640	2	-	-	-	642	28	29
Operating Profit	1,487	111	452	64	(215)	1,899	23	28
Operating Profit Margin	*20.1%*					*25.6%*	*+2*	*+4*
Net Finance Expense	(314)	-	-	54	55	(205)	10	15
Taxation	(162)	(22)	(92)	(35)	14	(297)	52	59
EPS	$0.78	$0.06	$0.28	$0.06	($0.11)	$1.07	19	24

Profit and Loss summary

a) Gross Profit

The increases in Reported and Core Gross Profit in the year reflected the growth in Product Sales. The Reported Gross Profit Margin was stable (up by one percentage point at CER) at 80%, while the Core Gross Profit Margin was stable at 80%, with a favourable mix of sales offset by increasing pricing pressure in China related to the impacts of the NRDL and the VBP programme. The performance was in line with the Company's expectations.

b) Total Operating Expense

Reported Total Operating Expense declined by 2% in the year to $17,684m and represented 66% of Total Revenue (FY 2019: 74%). Core Total Operating Expense increased by 6% to $15,633m and comprised 59% of Total Revenue (FY 2019: 60%).

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

- The decline in Reported R&D Expense was partly driven by the comparative effect of the $533m impairment of *Epanova* in FY 2019. The growth in Core R&D Expense included investment in the Oncology pipeline, such as the development of datopotamab deruxtecan and the ending in FY 2019 of the release of the upfront funding of *Lynparza* development, as part of the aforementioned collaboration with MSD. There were also additional costs related to COVID-19, such as the expense of personal protective equipment and colleague testing

- AstraZeneca also mobilised research efforts to treat patients with severe COVID-19 symptoms; these efforts included the development of AZD7442, the LAAB that may have a role in the prevention and/or treatment of COVID-19. In line with IAS 20 'Accounting for Government Grants and Disclosure of Government Assistance', government grants related to the development of *C19VAZ* and AZD7442 were recognised in the Consolidated statement of comprehensive income so as to match with the related expenses that they were 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

- 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. Within Reported and 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[47]

Reported Other Operating Income and Expense in the year of $1,528m reflected a decline of 1%. Core Other Operating Income and Expense in the year, decreasing by 2% to $1,531m, included:

- $400m of income from the aforementioned agreement to divest of commercial rights to *Atacand* and *Atacand Plus* in over 70 countries to Cheplapharm

- $350m of income from an agreement to divest commercial rights to a number of legacy hypertension medicines to Atnahs Pharma

- Income from the monetisation of an asset previously licensed

- Payments from Allergan (part of AbbVie) of $107m in respect of the development of brazikumab

d) Net Finance Expense

The increase in Core Net Finance Expense partly reflected lower interest rates on cash, cash equivalents and other current investments.

[47] 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.

e) Taxation

The Reported and Core Tax Rates for the year were both 20% (FY 2019: 21% and 20%, respectively). The net cash tax paid in the year was $1,562m, representing 40% of Reported Profit Before Tax (FY 2019: $1,118m, 72%); the increase partly reflected the growth in Reported Profit Before Tax and the phasing of tax payments.

f) Non-controlling interests

Reported total comprehensive losses attributable to non-controlling interests amounted to $52m in the year (FY 2019: $108m), of which $55m related to the non-controlling interest in Acerta Pharma.

In FY 2016, AstraZeneca acquired a 55% controlling stake in Acerta Pharma, where the non-controlling interests were subject to put and call options; the put option gave rise to a liability at 31 December 2020 of $2,297m (31 December 2019: $2,146m), shown in non-current other payables. The ability of the parties to exercise their respective put and call options, as well as the timing and amount of exercise, was dependent on certain conditions, the last of which was based on the regulatory approval of *Calquence* in the EU.

In November 2020, *Calquence* received marketing approval in the EU, which removed all remaining conditionality in respect of the options. The minority shareholders were then considered to have no further substantive variability in risk and reward related to their shares, as it was considered highly likely that one of the options will be exercised, and the price of the options were then fixed. Therefore, from November 2020, no further amounts of the consolidated AstraZeneca result were attributed to the minority shareholders of Acerta Pharma and no further impact on non-controlling interests in relation to Acerta Pharma is anticipated. In addition, the non-controlling interests reserve relating to the minority shareholders of Acerta Pharma, totalling $1,401m, has been reclassified into Retained earnings (see Condensed Consolidated Statement of Changes in Equity).

g) Dividend per share

The Board reaffirms its commitment to the progressive dividend policy. A stable second interim dividend of $1.90 per share (137.4 pence, 15.76 SEK) has been declared, meaning a stable full-year dividend per share of $2.80 (207.0 pence, 23.63 SEK). Dividend payments are normally paid as follows:

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

The record date for the second interim dividend for 2020, payable on 29 March 2021, will be 26 February 2021. The ex-dividend date will be 25 February 2021. The record date for the first interim dividend for 2021, payable on 13 September 2021, will be 13 August 2021. The ex-dividend date will be 12 August 2021.

h) EPS

Reported EPS of $2.44 in the year represented an increase of 137% (142% at CER); Core EPS increased by 15% (18% at CER) to $4.02.

Table 22: Cash Flow

	FY 2020 $m	FY 2019 $m	Change $m
Reported Operating Profit	5,162	2,924	2,238
Depreciation, Amortisation and Impairment	3,149	3,762	(613)
Decrease/(increase) in Working Capital and Short-Term Provisions	361	(346)	707
Gains on Disposal of Intangible Assets	(1,030)	(1,243)	213
Non-Cash and Other Movements	(548)	(236)	(312)
Interest Paid	(733)	(774)	41
Taxation Paid	(1,562)	(1,118)	(444)
Net Cash Inflow from Operating Activities	**4,799**	**2,969**	**1,830**
Net Cash Inflow before Financing Activities	**4,514**	**2,312**	**2,202**
Net Cash Outflow from Financing Activities	**(2,203)**	**(1,765)**	**(438)**

The increase in Net Cash Inflow from Operating Activities in the year reflected an improvement in Reported Operating Profit while *C19VAZ* contributions increased Net Cash Inflow from Operating Activities by $1,062m in the year; the movement was primarily related to changes in *C19VAZ* working-capital balances within trade and other payables, trade and other receivables and inventories. The reduction in Interest Paid was partly a result of a decline on interest paid on bonds, while the increase in Taxation Paid was a reflection of the growth in Reported Profit Before Tax and the phasing of tax payments.

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 $1,363m increase in the Disposal of Non-Current Asset Investments to $1,381m. AstraZeneca sold part of its equity portfolio in the year, a large proportion of which related to the disposal of its full holding in Moderna Therapeutics, Inc. All related gains were accounted through Other Comprehensive Income.

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

Under the terms of a past agreement to acquire Pearl Therapeutics Inc., the Company made a $150m milestone payment in the year 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 $546m in the year.

Capital Expenditure
Capital Expenditure amounted to $961m in the year, compared to $979m in FY 2019. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK, to which a number of colleagues are expected to begin relocation this year.

The Company anticipates an increase in Capital Expenditure, partly driven by an expansion in its capacity for growth across a number of limited-sized projects.

Table 23: Net Debt summary

	At 31 Dec 2020 $m	At 31 Dec 2019 $m
Cash and cash equivalents	7,832	5,369
Other investments	160	911
Cash and investments	**7,992**	**6,280**
Overdrafts and short-term borrowings	(658)	(225)
Lease liabilities	(681)	(675)
Current instalments of loans	(1,536)	(1,597)
Non-current instalments of loans	(17,505)	(15,730)
Interest-bearing loans and borrowings (Gross Debt)	**(20,380)**	**(18,227)**
Net derivatives	278	43
Net Debt	**(12,110)**	**(11,904)**

Net Debt of $12,110m represented an increase of $206m in the year. EBITDA increased by 24% in the year (27% at CER) to $8,311m.

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

In the year, 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).

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)[48]	
Currency	**Primary Relevance**	**FY 2020[49]**	**YTD 2021[50]**	**% change**	**Product Sales**	**Core Operating Profit**
CNY	Product Sales	6.90	6.47	6	312	186
EUR	Product Sales	0.88	0.82	6	189	58
JPY	Product Sales	106.74	103.70	3	140	91
Other[51]					239	108
GBP	Operating Expense	0.78	0.73	6	31	(84)
SEK	Operating Expense	9.20	8.29	10	5	(59)

[48] Based on best prevailing assumptions around currency profiles.
[49] Based on average daily spot rates in FY 2020.
[50] Based on average daily spot rates from 1 January 2021 to 31 January 2021.
[51] Other currencies include AUD, BRL, CAD, KRW and RUB.

Sustainability

AstraZeneca's sustainability approach has three priority areas[52], 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:

During the period, the Company received recognition of its broad sustainability efforts, featuring in the top five for the sector in the DJSI and included in Corporate Knights Global 100 Index, which identifies globally sustainable companies.

a) Access to healthcare

In December 2020, AstraZeneca, through an advanced purchase agreement with Gavi, the Vaccines Alliance, committed to enabling access to 170m doses of *C19VAZ* in up to 190 countries worldwide through COVAX, a coalition co-led by CEPI, the Coalition for Epidemic Preparedness Innovations, Gavi, and the WHO. It is the only global initiative working with governments and manufacturers to ensure that safe and effective COVID-19 vaccines are available worldwide to both higher-income and lower-income countries. Furthermore, through additional doses announced by licensing partner Serum Institute of India Pvt. Ltd., hundreds of millions of doses of *C19VAZ* are anticipated to be available via COVAX. At a press conference held to announce the news, Pascal Soriot spoke on the importance of broad, equitable access alongside global leaders, including WHO Director Dr Tedros Adhanom Ghebreyesus, Canadian Minister for International Development, the Rt. Hon. Karina Gould, and UNICEF Executive Director Henrietta Fore, as well as COVAX and industry leadership.

AstraZeneca is committed to working with its global manufacturing network to build global vaccine capacity to around three billion doses, pending regulatory approvals. *C19VAZ* can be stored, transported and handled at normal refrigerated conditions (two to eight degrees Celsius, 36-46 degrees Fahrenheit) for at least six months and administered within existing healthcare settings.

In November 2020, the Company launched The Partnership for Health System Sustainability and Resilience with the World Economic Forum (WEF) and the London School of Economics (LSE) to identify practical solutions that will support more resilient and sustainable health systems. Part of the WEF's Great Reset initiative, the partnership will bring together a coalition of leading healthcare-system experts in eight countries initially to test, perfect and apply a Framework for Healthcare System Resilience and Sustainability, developed by the LSE. The pilot countries are Germany, France, the UK, Italy, Spain, Vietnam, Russia and Poland. Speaking about the programme at the WEF Davos Agenda event in January 2020, Pascal Soriot emphasised the importance of building crisis-resistant healthcare systems to recover from the pandemic and protect against future shocks.

In January 2021, AstraZeneca was recognised in the 2021 Access to Medicines Index, rising two places to rank seventh among peers. The accompanying report highlighted the Company's continued progress, including strengths in access-related governance, compliance and healthcare-system development.

During the period, the AstraZeneca Young Health Programme launched in the UK, focused on young people's mental health. The programme will operate in four locations over the next five years and uses youth-centred design, working together with young people, to focus on tackling their urgent mental-health needs and realise their right to good health and wellbeing. Over the five years, the programme will work with over 130,000 young people aged between 10-24 and will initially launch in Manchester, UK.

[52] 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'.

b) Environmental protection

During the period, AstraZeneca was recognised for its leadership in sustainability by global environmental non-profit CDP. The Company received a place on the 'A List' for both climate action and water security. AstraZeneca was one of only three organisations worldwide to achieve this double A-List recognition for five consecutive years. The Company also featured among the top 7% on CDP's 2020 Supplier Engagement Leaderboard, recognising progress in working with suppliers to address their emissions and driving science-based climate action across AstraZeneca's value chain.

Pascal Soriot was listed as an official supporter of the His Royal Highness The Prince of Wales's 'Terra Carta', a ten-point strategy for business to move towards a sustainable future by 2030. Launched at the One Planet Summit in Paris, AstraZeneca will be one of the founding partners looking to put nature, people and planet at the heart of global-value creation.

In partnership with government and local non-governmental organisations, AstraZeneca launched the AZ Forest programme in Indonesia, a commitment to support a healthy environment and improve socio-economic development and livelihoods for Indonesians by planting 20 million trees in the country over the next five years. This commitment is part of the global AZ Forest programme, announced at the WEF in January 2020, pledging the plantation of 50 million trees by 2025, in collaboration with One Tree Planted, a non-profit organisation focused on global reforestation. The initiative supports the WEF's '1T.org – The Champions for a Trillion Trees' platform.

c) Ethics and transparency

In January 2021, the Company was recognised for its efforts in promoting inclusion and diversity by the BGEI, which tracks the performance of public companies committed to disclosing their efforts to support gender equality through policy development, representation and transparency. The Company was also listed as a participant in ShareAction's WDI, an annual survey that aims to improve corporate transparency and accountability on workforce issues and provide companies and investors with comprehensive and comparable data to help increase the provision of good jobs worldwide.

During the period, AstraZeneca was named as a founding partner to the WEF Partnering for Racial Justice in Business Coalition, joining forces with 47 companies across 13 industries to eradicate racism in the workplace. The Company also held its first Power of Diversity week, an initiative to support all employees with the tools and knowledge needed to create a truly inclusive culture.

As part of AstraZeneca's ongoing efforts to make sustainability data transparent and accessible, a new analyst interactive reporting (AIR) centre was launched on the Company's website. AIR provides sustainability data from 2015 onwards, covering global information from key performance indicators for Access to healthcare, Environmental protection and Ethics and transparency.

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 persists, the Company will continue to evaluate impacts 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/investor-relations.html. 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	22	**Oncology** - *Tagrisso* - NSCLC - *Imfinzi* - multiple cancers - *Lynparza* - multiple cancers - *Enhertu* - multiple cancers - *Calquence* - blood cancers - tremelimumab - multiple cancers - savolitinib - NSCLC[53] - capivasertib - breast, prostate cancer - monalizumab - head & neck cancer - camizestrant (AZD9833) - breast cancer - datopotamab deruxtecan - lung cancer **CVRM** - *Farxiga* - multiple indications - roxadustat - anaemia in CKD **Respiratory & Immunology** - *Fasenra* - multiple indications - *Breztri* - asthma - tezepelumab - severe asthma - PT027 - asthma - anifrolumab - lupus (SLE) - brazikumab - inflammatory bowel disease - nirsevimab - RSV **COVID-19** - *C19VAZ* - SARS-CoV-2 - AZD7442 - SARS-CoV-2
Total projects in clinical development	145	
Total projects in total pipeline	171	

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

Oncology

The Company presented data at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition in November 2020 , the San Antonio Breast Cancer Symposium (SABCS) in December 2020 and the International Association for the Study of Lung Cancer (IASLC) 2020 World Conference on Lung Cancer (WCLC), hosted by the IASLC in January 2021. The data covered the haematology, breast and lung cancer pipelines. Key data at the ASH meeting included 27 abstracts spanning five medicines and potential new medicines, and eight different haematology conditions, including *Calquence*, MEDI2228 (BCMA ADC) and AZD4320 (dual Bcl-2/xL inhibitor).

Highlights from the SABCS symposium included updates to *Enhertu* in the DESTINY-Breast01 Phase II trial and camizestrant (AZD9833) (oral selective oestrogen receptor degrader) in the SERENA-1 Phase I trial. Key data at the IASLC 2020 WCLC included updated datopotamab deruxtecan Phase I data and new data from the *Enhertu* DESTINY-Lung01 Phase II trial, both in metastatic NSCLC.

a) *Tagrisso*

During the period, *Tagrisso* was approved in the US for the adjuvant treatment of adult patients with early-stage EGFRm NSCLC after tumour resection with curative intent, following the ADAURA Phase III trial. The approval was granted under the US FDA Real-Time Oncology Review pilot programme. Five other countries participated in a concurrent submission and review process through the FDA's Project Orbis.

Table 26: Key *Tagrisso* Phase III trials

Trial	Population	Design	Timeline	Status
NeoADAURA	Neo-adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD[54] Q1 2021 First data anticipated 2022+	Recruitment ongoing
ADAURA	Adjuvant EGFRm NSCLC	Placebo or *Tagrisso*	FPCD Q4 2015 LPCD[55] Q1 2019	Trial unblinded early due to overwhelming efficacy Regulatory approval (US)
LAURA	Locally advanced, unresectable EGFRm NSCLC	Placebo or *Tagrisso*	FPCD Q4 2018 First data anticipated 2022+	Recruitment ongoing
FLAURA2	1st-line EGFRm NSCLC	*Tagrisso* or *Tagrisso* + platinum-based chemotherapy doublet	FPCD Q4 2019 First data anticipated 2022+	Recruitment ongoing

[54] First patient commenced dosing.
[55] Last patient commenced dosing.

b) *Imfinzi*

In November 2020, *Imfinzi* was approved by the US FDA for an additional dosing option, a 1,500mg fixed dose every four weeks in the approved indications of unresectable, Stage III NSCLC after CRT and previously treated advanced bladder cancer. This new option is consistent with the approved *Imfinzi* dosing in ES-SCLC and will be available to patients weighing more than 30kg as an alternative to the approved weight-based dosing of 10mg/kg every two weeks.

During the period, *Imfinzi* received regulatory approval in the EU for the aforementioned additional dosing option, 1,500mg fixed dose every four weeks, in the approved indication of locally advanced, unresectable Stage III NSCLC in adults whose tumours express PD-L1[56] on at least 1% of tumour cells and whose disease has not progressed following platinum-based CRT.

Table 27: Key *Imfinzi* Phase III trials in lung cancer

Trial	Population	Design	Timeline	Status
AEGEAN	Neo-adjuvant NSCLC	SoC[57] chemotherapy +/- *Imfinzi*, followed by surgery, followed by placebo or *Imfinzi*	FPCD Q1 2019 First data anticipated 2022+	Recruitment ongoing
ADJUVANT BR.31[58]	Stage Ib-IIIa resected NSCLC	Placebo or *Imfinzi*	FPCD Q1 2015 LPCD Q1 2020 First data anticipated 2022+	Recruitment completed
MERMAID-1	Stage II-III resected NSCLC	SoC chemotherapy +/- *Imfinzi*	FPCD Q3 2020 First data anticipated 2022+	Recruitment ongoing
MERMAID-2	Stage II-III NSCLC with minimal residual disease	Placebo or *Imfinzi*	FPCD Q4 2020 First data anticipated 2022+	Recruitment ongoing
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

[56] Programmed death-ligand 1.
[57] Standard of Care.
[58] Conducted by the Canadian Cancer Trials Group.

Trial	Population	Design	Timeline	Status
ADRIATIC	LS-SCLC	Concurrent CRT, followed by placebo or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2018 First data anticipated 2022	Recruitment ongoing
PEARL	Stage IV, 1st-line NSCLC	SoC chemotherapy or *Imfinzi*	FPCD Q1 2017 LPCD Q1 2019 First data anticipated 2022	Recruitment completed
POSEIDON	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + *Imfinzi* or SoC + *Imfinzi* + treme	FPCD Q2 2017 LPCD Q4 2018 OS data anticipated H1 2021	PFS[59] primary endpoint met
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 Regulatory approval

Table 28: Key *Imfinzi* Phase III trials in tumour types other than lung cancer

Trial	Population	Design	Timeline	Status
POTOMAC	Non-muscle invasive bladder cancer	SoC BCG[60] or SoC BCG + *Imfinzi*	FPCD Q4 2018 LPCD Q3 2020 First data anticipated 2022+	Recruitment completed

[59] Progression-free survival.
[60] Bacillus Calmette-Guerin.

Trial	Population	Design	Timeline	Status
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 2022+	Recruitment ongoing
EMERALD-1	Locoregional HCC[61]	TACE[62] followed by placebo or TACE + *Imfinzi*, followed by *Imfinzi* + bevacizumab or TACE + *Imfinzi* followed by *Imfinzi*	FPCD Q1 2019 First data anticipated 2022	Recruitment ongoing
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 2022+	Recruitment ongoing
CALLA	Locally advanced cervical cancer	CRT or CRT + *Imfinzi*, followed by placebo or *Imfinzi*	FPCD Q1 2019 LPCD Q4 2020 First data anticipated 2022+	Recruitment completed
MATTERHORN	Resectable gastric and gastroesophageal cancer	Neoadjuvant *Imfinzi* + FLOT chemotherapy +/- adjuvant *Imfinzi*	FPCD Q4 2020 First data anticipated 2022+	Recruitment ongoing
KUNLUN	Locally advanced, unresectable oesophageal squamous cell carcinoma	Definitive CRT or CRT + *Imfinzi*	FPCD Q4 2020 First data anticipated 2022+	Recruitment ongoing
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 2022+	Recruitment ongoing
KESTREL	Stage IV, 1st-line HNSCC[63]	SoC or *Imfinzi* or *Imfinzi* + treme	FPCD Q4 2015 LPCD Q1 2017	Primary endpoint not met

[61] Hepatocellular carcinoma.
[62] Transarterial chemoembolisation.
[63] Head and neck squamous cell carcinoma.

Trial	Population	Design	Timeline	Status
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[64] (US)
TOPAZ-1	Stage IV, 1st-line biliary-tract cancer	Gemcitabine and cisplatin SoC chemotherapy or SoC + *Imfinzi*	FPCD Q2 2019 First data anticipated 2022	Recruitment ongoing

c) *Lynparza* (multiple cancers)

During the period, *Lynparza* received regulatory approval in the EU and Japan for the additional indications of 1st-line maintenance treatment with bevacizumab for patients with HRD+ advanced ovarian cancer and patients with metastatic castration-resistant prostate cancer with mutations, a subpopulation of homologous recombination repair gene mutations (HRRm). *Lynparza* also received regulatory approval in Japan as a maintenance treatment, after platinum-based chemotherapy for patients with BRCAm unresectable pancreatic cancer, based on positive results from the POLO Phase III trial.

Table 29: Key *Lynparza* Phase III trials

Trial	Population	Design	Timeline	Status
OlympiA	Adjuvant BRCAm breast cancer	SoC placebo or *Lynparza*	FPCD Q2 2014 LPCD Q2 2019 First data anticipated H1 2021	Recruitment completed
PROfound	Metastatic castration-resistant 2nd-line+ HRRm prostate cancer	SoC (abiraterone or enzalutamide) or *Lynparza*	FPCD Q2 2017 LPCD Q4 2018	Primary endpoint met Regulatory approval
PAOLA-1[65]	Advanced 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + *Lynparza* maintenance	FPCD Q2 2015 LPCD Q2 2018	Primary endpoint met Regulatory approval

[64] 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 manufacturer. Designation qualifies the manufacturer of the medicine for various development incentives.
[65] Conducted by the ARCAGY/Groupe investigators national des Etudes des Cancers Ovariens et du sein.

Trial	Population	Design	Timeline	Status
DuO-O	Advanced 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + *Imfinzi* +/- *Lynparza* maintenance	FPCD Q1 2019 First data anticipated 2022+	Recruitment ongoing
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 2022+	Recruitment ongoing
PROpel	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + *Lynparza*	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
LYNK-003	Stage IV, 1st-line colorectal cancer	Bevacizumab + 5-FU[66] maintenance or bevacizumab + *Lynparza* maintenance or *Lynparza* maintenance	First data anticipated 2022+	Initiating

d) *Enhertu* (breast and other cancers)

In January 2021, *Enhertu* was approved by the US FDA for the treatment of adult patients for 2nd line HER2+ gastric cancer. The approval was based on the positive results from the randomised DESTINY-Gastric01 Phase II trial.

During the period, AstraZeneca announced that *Enhertu* had received regulatory approval in the EU as a monotherapy for the treatment of adult patients with unresectable or metastatic HER2+ cancer who have received two or more prior anti-HER2 based regimens. The approval was based on positive results from the single-arm DESTINY-Breast01 Phase II trial.

Updated data were presented during the period, in a Spotlight Poster Discussion at the aforementioned SABCS symposium, from the *Enhertu* DESTINY-Breast01 Phase II trial in patients with HER+ metastatic breast cancer, following two or more prior HER2-based regimens. With a median duration of follow-up of 20.5 months, patients treated with *Enhertu* (5.4mg/kg) achieved an objective response rate of 61.4% and a median duration of response of 20.8 months; the median PFS was 19.4 months. In an exploratory landmark analysis of OS, evaluated at 35% maturity, an estimated 74% of patients remained alive at 18 months.

At the aforementioned IASLC 2020 WCLC, data were presented from the DESTINY-Lung01 Phase II trial, highlighting the potential of *Enhertu* in HER2-expressing metastatic NSCLC and in metastatic HER2-mutant (HER2m) NSCLC. These are two groups of patients for whom no HER2-directed medicine is currently approved.

[66] Fluorouracil.

Table 30: Key *Enhertu* trials

Trial	Population	Design	Timeline	Status
DESTINY-Breast01-U201 Phase II	Stage IV, HER2+[67] breast cancer post trastuzumab emtansine	*Enhertu*	FPCD Q4 2017 LPCD Q4 2018	Primary objective met Breakthrough Therapy Designation[68] (US) Regulatory approval (US, EU, JP)
DESTINY-Breast02-U301 Phase III	Stage IV, HER2+ breast cancer post trastuzumab emtansine	SoC chemotherapy or *Enhertu*	FPCD Q4 2018 LPCD Q4 2020 First data anticipated H2 2021	Recruitment completed
DESTINY-Breast03-U302 Phase III	Stage IV, HER2+ breast cancer	Trastuzumab emtansine or *Enhertu*	FPCD Q4 2018 LPCD Q2 2020 First data anticipated H2 2021	Recruitment completed
DESTINY-Breast04 Phase III	Stage IV, HER2-low breast cancer	SoC chemotherapy or *Enhertu*	FPCD Q4 2018 LPCD Q4 2020 First data anticipated H2 2021	Recruitment completed
DESTINY-Breast06 Phase III	Stage IV, HER2-low breast cancer post endocrine therapy	SoC chemotherapy or *Enhertu*	FPCD Q3 2020 First data anticipated 2022+	Recruitment ongoing

[67] IHC 3+ and IHC 2+/ISH+.
[68] Intended to expedite the development and review of medicines for serious or life-threatening conditions.

Trial	Population	Design	Timeline	Status
DESTINY-Gastric01 Phase II	Stage IV, HER2+ gastric cancer	SoC chemotherapy or *Enhertu*	FPCD Q4 2017 LPCD Q2 2019	Primary endpoint met Breakthrough Therapy Designation (US) Regulatory approval (US, JP)
DESTINY-PanTumour02 Phase II	HER2-expressing tumours	*Enhertu*	FPCD Q3 2020 First data anticipated 2022+	Recruitment ongoing
DESTINY-PanTumour01 Phase II	HER2m tumours	*Enhertu*	FPCD Q1 2021 First data anticipated 2022+	Recruitment ongoing

e) *Calquence*

During the period, *Calquence* was approved in the EU for the treatment of adult patients with CLL, and in Japan for R/R CLL, the most common type of leukaemia in adults.

Positive high-level results from the ELEVATE-RR Phase III trial, published during the period, showed *Calquence* met the primary endpoint demonstrating non-inferior PFS for adults with previously treated, high-risk CLL, compared to ibrutinib. The trial also met a key secondary endpoint for safety, showing patients treated with *Calquence* had statistically significantly lower incidence of atrial fibrillation, compared to patients treated with ibrutinib. Overall, the safety and tolerability of *Calquence* were consistent with the profile seen in the broader *Calquence* clinical-development programme.

At the aforementioned ASH meeting, a pooled analysis of CV safety data for patients treated with *Calquence* for CLL, across four clinical trials, showed a low incidence of cardiac adverse events (AEs), leading to discontinuation. The analysis included patients with previously untreated and R/R CLL treated with *Calquence* alone from the ELEVATE-TN and ASCEND Phase III trials, as well as the 15-H-0016 Phase II trial and ACE-CL-001 Phase I/II trial. In the analysis, 129 patients (17%) reported a cardiac AE of any grade at a median follow up of 25.9 months, and seven patients (0.9%) discontinued treatment due to cardiac AEs.

At the same meeting, long-term follow-up results from the positive ACE-LY-004 Phase II trial were also presented. Data showed patients with R/R MCL treated with *Calquence* remained progression-free for a median of 22 months, with median OS not yet reached at three years of follow-up. The safety and tolerability profile remained consistent.

f) Datopotamab deruxtecan

At the aforementioned IASLC 2020 WCLC, updated data were presented from the TROPION-PanTumor01 Phase I trial of datopotamab deruxtecan in metastatic NSCLC, supporting its potential to redefine treatment outcomes in advanced NSCLC.

Table 31: Datopotamab deruxtecan

Trial	Population	Design	Timeline	Status
TROPION-LUNG01 Phase III	Stage IV, NSCLC	SoC chemotherapy or datopotamab deruxtecan	First data anticipated 2022+	Initiating

CVRM

a) *Farxiga* (HF, CKD)

In November 2020, *Forxiga* was approved in the EU and Japan and China for the treatment of symptomatic chronic HFrEF in adults with and without T2D. The approvals were based on results from the DAPA-HF Phase III trial where *Farxiga*, on top of SoC, reduced the composite of cardiovascular death or worsening of heart failure by 26%. *Farxiga* was approved in the US for the same indication in May 2020.

During the period, *Forxiga* received regulatory submission acceptance in the EU and China for the treatment of CKD. The submissions were based on results from the DAPA-CKD Phase III trial where *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 in patients with CKD stages 2-4 and elevated urinary albumin excretion. In January 2021, *Farxiga* was accepted for regulatory review and granted priority review in Japan and the US. The Prescription Drug User Fee Action date, the day the US FDA targets for regulatory decision, is anticipated to be during the second quarter of 2021.

b) *Brilinta* (stroke)

In November 2020, the Company received US FDA approval for *Brilinta* to reduce the risk of stroke in patients with an acute ischaemic stoke or high-risk transient ischaemic attack. The approval was based on results from the THALES Phase III trial.

Table 32: Key large CVRM Phase III outcomes trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Farxiga					
DAPA-HF	c.4,500 patients with HFrEF, with and without T2D	SoC + placebo or SoC + *Farxiga* 10mg or 5mg QD[69]	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 Regulatory approval
DELIVER	c.4,700 patients with HF (HFpEF) with and without T2D	Placebo or *Farxiga* 10mg QD	Time to first occurrence of CV death or worsening HF	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing Fast Track[70] designation (US)

[69] *Quaque die*, or once a day.
[70] A process designed to facilitate the development, and expedite the review of medicines to treat serious conditions and fill an unmet medical need.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
DAPA-CKD	c.4,000 patients with CKD, with and without T2D	Placebo or *Farxiga* 10mg or 5mg QD	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[71] Primary endpoint and secondary endpoints met Fast Track designation (US)
DAPA-MI	c.6,400 patients with confirmed MI, either STEMI or NSTEMI, within the preceding 7 days	Placebo or *Farxiga* 10mg QD	Time to the first occurrence of any of the components of this composite: hospitalisation for HF or CV death	FPCD Q4 2020 First data anticipated 2022+	Recruitment ongoing
Brilinta					
THEMIS	c.19,000 patients with T2D and CAD without a history of MI or stroke	Aspirin plus placebo or aspirin plus *Brilinta* 60mg BID[72]	Composite of CV death, non-fatal MI and non-fatal stroke	FPCD Q1 2014 LPCD Q2 2016	Primary endpoint met Regulatory approval (US)
THALES	c.11,000 patients with acute ischaemic stroke[73] or transient ischaemic attack	Aspirin plus placebo or aspirin plus *Brilinta* 90mg BID	Prevention of the composite of subsequent stroke and death at 30 days	FPCD Q1 2018 LPCD Q4 2019	Primary endpoint met Regulatory approval (US)

c) *Lokelma* (hyperkalaemia)

In November 2020, the China National Medical Products Administration (NMPA) approved a dosing-label update for *Lokelma* to include patients with hyperkalaemia on chronic haemodialysis. The approval was based on results from the DIALIZE Phase IIIb trial, the first-ever randomised, placebo-controlled trial to evaluate a potassium binder in patients on stable haemodialysis. The trial showed sustained potassium control pre-dialysis for patients receiving *Lokelma*, compared with placebo. In December 2019, the NMPA approved *Lokelma* to treat adult patients with hyperkalaemia.

d) Roxadustat (anaemia)

In December 2020, the US FDA requested further clarifying analyses to complete its New Drug Application (NDA) review for roxadustat. AstraZeneca and FibroGen submitted the analyses before the end of the year, to assist with the completion of labelling discussions. The NDA remains under regulatory review, and the US FDA has set a new action date of 20 March 2021.

In November 2020, the Company and FibroGen presented new data on roxadustat at the aforementioned ASH meeting. The multiple trials evaluated the clinical effectiveness and safety profile of roxadustat in both the dialysis-dependent and non-dialysis dependent anaemia of CKD patient populations. Data were also presented

[71] Independent Data Monitoring Committee.
[72] *Bis in die*, or twice a day.
[73] Ischaemic strokes are the most common type of stroke.

assessing the medicine's efficacy in anaemia associated with lower-risk MDS, regardless of baseline factors; in approximately one in three patients, MDS leads to acute myeloid leukaemia.

Respiratory & Immunology

a) *Symbicort* (mild asthma)
In January 2021, AstraZeneca's *Symbicort Turbuhaler* (budesonide/formoterol 160/4.5mcg) was approved in China as an anti-inflammatory reliever to be taken as needed in response to symptoms to achieve asthma control in patients with mild asthma aged 12 years and older. This new indication for *Symbicort* aligned to the latest National Asthma Guidelines from the Chinese Thoracic Society, updated in Q4 2020, which recommended a low dose corticosteroid-formoterol combination therapy, taken as-needed, as the preferred reliever therapy in mild asthma.

b) *Breztri* (COPD)
During the period, *Breztri*, under the name *Trixeo*, received regulatory approval in the EU, following the receipt in Q3 2020 of a positive opinion from the EMA's Committee for Medicinal Products for Human Use. *Trixeo* is indicated for the 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)

Table 33: Key *Fasenra* lifecycle management Phase III trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
OSTRO	Patients aged 18-75 years with severe bilateral nasal polyps; symptomatic, despite SoC	Placebo or *Fasenra* 30mg Q8W[74] SC[75]	Nasal-polyps burden and reported nasal blockage	FPCD Q1 2018 LPCD Q2 2019	Co-primary endpoints met
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 2022+	Recruitment ongoing
MANDARA	Eosinophilic granulomatosis with polyangiitis[76]	Mepolizumab 3x100mg Q4W or *Fasenra* 30mg	Proportion of patients who achieve remission, defined as a score[77] =0 and an OCS dose ≤4 mg/day at weeks 36 and 48	FPCD Q4 2019 Data anticipated 2022+	Recruitment ongoing Orphan Drug Designation (US)

[74] Once every eight weeks.
[75] Subcutaneous injection.
[76] A rare autoimmune condition that causes inflammation of small and medium-sized blood vessels.
[77] Birmingham Vasculitis Activity Score.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
NATRON	HES[78]	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 2022	Recruitment ongoing Orphan Drug Designation (US)
MESSINA	Eosinophilic oesophagitis[79]	Placebo or *Fasenra* 30mg Q4W SC	Proportion of patients with a histologic response[80] Changes from baseline in dysphagia[81] PRO[82]	FPCD Q4 2020 Data anticipated 2022	Recruitment ongoing Orphan Drug Designation (US)
FJORD	BP[83]	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 2022+	Recruitment ongoing

d) Anifrolumab (lupus: SLE)

During the period, a new analysis of the TULIP Phase III clinical-trial programme showed that treatment with anifrolumab resulted in a greater reduction in disease flares while having a sustained reduction in doses of OCS compared to placebo, with both groups of patients receiving SoC. The data were presented in November 2020 at ACR Convergence 2020, the annual meeting of the American College of Rheumatology.

The new pooled analysis showed that 40% of patients treated with anifrolumab, plus SoC, had a sustained reduction in OCS use without experiencing a disease flare through 52 weeks (versus 17.3% in placebo plus SoC). Treatment with anifrolumab was associated with lower overall flare rates compared to placebo, and also on the skin and in the mouth (mucocutaneous), as well as in joints (musculoskeletal), the two organ domains most frequently affected at the start of the trial.

During the period, the Company completed a regulatory submission for anifrolumab to the Japanese Pharmaceuticals and Medical Devices Agency for the treatment of adult patients with moderate to severe SLE. The submission was 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. A regulatory decision is expected in the second half of 2021. Anifrolumab is also currently under regulatory review in the US, in the EU and in other countries.

e) Tezepelumab (severe asthma)

During the period, AstraZeneca, along with its collaborator Amgen Inc., announced positive results from the NAVIGATOR Phase III trial for the potential new medicine tezepelumab in patients with severe, uncontrolled asthma.

[78] Hypereosinophilic syndrome, a group of rare blood disorders.
[79] White blood cells gather in the lining of the oesophagus.
[80] An improvement in the view of tissue samples under a microscope after treatment.
[81] Difficulty with swallowing.
[82] Patient-reported outcomes.
[83] Bullous pemphigoid, a skin condition that causes large, itchy, fluid-filled blisters.

NAVIGATOR met the primary endpoint with tezepelumab added to SoC, demonstrating a statistically significant and clinically meaningful reduction in the annualised asthma exacerbation rate (AAER) over 52 weeks in the overall patient population, compared to placebo when added to SoC, namely medium- or high- ICS plus at least one additional controller medication with or without OCS.

In a subgroup of patients, with baseline eosinophil counts of less than 300 cells per microlitre, the trial also met the primary endpoint, with tezepelumab demonstrating a statistically significant and clinically meaningful reduction in AAER. Similar reductions in AAER were observed in a subgroup of patients with baseline eosinophil counts of less than 150 cells per microlitre. Tezepelumab was very well tolerated in patients with severe asthma. Preliminary analyses showed no clinically meaningful differences in safety results between the tezepelumab and placebo groups.

High-level results from the SOURCE Phase III trial also became available, which assessed the efficacy and safety of tezepelumab compared to placebo in 150 severe asthma patients who required maintenance use of OCS on top of SoC. The 48-week trial, which is not required for regulatory submission, did not meet the primary endpoint of a statistically significant reduction in the daily OCS dose, without loss of asthma control, with tezepelumab compared to placebo. Tezepelumab's effect on other efficacy parameters was similar to those observed in previous trials, including the registrational NAVIGATOR Phase III trial.

Results from the NAVIGATOR trial will be presented at this year's American Academy of Allergy Asthma and Immunology Annual Meeting. Data from the SOURCE trial will be presented at a forthcoming medical meeting.

Table 34: Key tezepelumab Phase III trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
NAVIGATOR	Severe asthma	Placebo or tezepelumab 210mg Q4W SC	Annual asthma exacerbation rate	FPCD Q1 2018 LPCD Q3 2019	Primary endpoint met Breakthrough Therapy Designation (US)

f) PT027 (asthma)

PT027 is a budesonide/albuterol metered-dose inhaler, a potential new medicine for the treatment of asthma as an anti-inflammatory reliever in development in collaboration with Avillion LLP. During the period, the TYREE Phase III trial achieved its primary endpoint. TYREE is a 60 patient, multicentre, randomised, double-blind, single-dose, two-period, crossover trial to evaluate the efficacy and safety of PT027 160/180mcg versus placebo on exercise-induced bronchoconstriction in adult and adolescent patients with asthma. In the trial, PT027 demonstrated superiority over placebo for the primary endpoint of the maximum percentage fall from post-dose, pre-exercise baseline in forced expiratory volume in one second observed up to 60 minutes, post-exercise challenge.

Results from the MANDALA and DENALI Phase III trials, intended for regulatory submission in asthma, are anticipated in the second half of 2021.

g) Nirsevimab (RSV)

In January 2021, the China Center for Drug Evaluation (CDE) under the NMPA granted Breakthrough Therapy Designation for nirsevimab, an extended half-life monoclonal antibody being in development as a passive immunisation for the prevention of lower respiratory-tract infection caused by RSV in all infants. This designation was based on the unmet need for a preventative option against RSV for all infants in China where none currently exists and should help to expedite the regulatory review of nirsevimab, following regulatory submission in the country.

COVID-19

a) *COVID-19 Vaccine AstraZeneca* (*C19VAZ*) (SARS-CoV-2)

During the period, the University of Oxford and AstraZeneca continued to enrol participants into the global clinical trials of the recombinant adenovirus vaccine, *C19VAZ*. Trials in the UK, Brazil, South Africa and the US are fully recruited and total enrolment across the trials amounts to over 55,000 participants.

The results of an interim analysis of the Phase III programme, conducted by the University of Oxford with *C19VAZ*, were peer-reviewed and published in *The Lancet* in December 2020, demonstrating that the vaccine is safe and effective at preventing symptomatic COVID-19 and that it protects against severe disease and hospitalisation.

In December 2020, the UK MHRA provided authorisation for the emergency supply of *C19VAZ* for the active immunisation of individuals aged 18 years or older. The authorisation recommended two full doses administered with an interval of between four and 12 weeks. This regimen was shown in clinical trials to be safe and effective at preventing symptomatic COVID-19, with no severe cases and no hospitalisations more than 14 days after the second dose. Additional data on dosing intervals were included in the Summary of Product Characteristics published by the UK MHRA to coincide with the authorisation.

In January 2021, *C19VAZ* received conditional marketing approval from the EMA. Additional authorisations for emergency use have also been provided by regulatory authorities in a number of individual countries, including Argentina, Mexico and Morocco, and our sub-licensee Serum Institute of India has received emergency use authorisation for supply in India.

During the period, the primary analysis, conducted by the University of Oxford, of late-stage clinical trials in the UK, Brazil and South Africa was published as a preprint in *The Lancet* confirming *C19VAZ* is safe and effective at preventing COVID-19, with no severe cases and no hospitalisations, more than 22 days after the first dose. The results demonstrated vaccine efficacy of 76% (CI 0.59-0.86) after a first dose, with protection maintained to the second dose. With an inter-dose interval of 12 weeks or more, vaccine efficacy increased to 82% (CI 0.63-0.92).

In February 2021, the WHO's SAGE recommended two doses of *C19VAZ*, in individuals aged 18 years and above, including individuals aged 65 and over. The WHO noted that the manufacturer's labelled dosing interval is four to 12 weeks and recommended an interval of eight to 12 weeks between doses. This dosing regimen was shown in clinical trials to be safe and effective in preventing symptomatic COVID-19, with no severe cases and no hospitalisations more than 14 days after the second dose. In addition, the WHO SAGE recommended *C19VAZ* in countries where new variants, including the South African variant, are prevalent.

Data on the efficacy of *C19VAZ* against new variants of the SARS-CoV-2 virus were also published in preprint during the period, showing that the vaccine remains effective against the B.1.1.7 Kent variant. The University of Oxford, however, subsequently announced that a separate exploratory analysis of the COV005 Phase I/II South Africa trial, to be published in preprint in due course, showed that the vaccine had limited efficacy against mild-moderate disease caused by the B.1.351 South African variant. It was not possible to ascertain efficacy against severe disease and hospitalisation caused by this variant, given that subjects in the trial were predominantly young, healthy adults.

In collaboration with the University of Oxford, AstraZeneca is focused on adapting *C19VAZ* to new disease strains if required and hopes to reduce the time needed to reach production at scale to between six to nine months, by utilising existing clinical data and optimising its established supply chain.

Further data continue to accrue across the clinical-trial programme, including efficacy, the effect of different dosing intervals, the impact of new variants of SARS-CoV-2 and the duration of protection offered by *C19VAZ*; we anticipate these be published in due course. AstraZeneca continues to share data with other regulatory authorities around the world.

Table 35: Key *C19VAZ* trials in COVID-19

Trial	Population	Design	Timeline	Status
COV001[84] (UK) Phase I/II	Protection against COVID-19 in participants aged 18-55	MenACWY or *C19VAZ*	FPCD Q2 2020 LPCD Q2 2020	Initial data readout Recruitment completed Regulatory approval (UK, EU)
COV002[84] (UK) Phase II/III	Protection against COVID-19 in participants aged 18-55, 55+	MenACWY or *C19VAZ*	FPCD Q2 2020 LPCD Q4 2020	Initial data readout Recruitment completed Regulatory approval (UK, EU)
COV003 (Brazil) Phase II/III	Protection against COVID-19 in participants aged 18-55	MenACWY or *C19VAZ*	FPCD Q2 2020 LPCD Q4 2020	Initial data readout Recruitment completed Regulatory approval (UK, EU)
COV005 ChAdOx1 nCoV-19 ZA[85] (South Africa) Phase I/II	Protection against COVID-19 in participants aged 18-65 HIV+[86] subgroup	Placebo or *C19VAZ*	FPCD Q2 2020 LPCD Q4 2020 First data anticipated H1 2021	Recruitment completed
D8110C00001 (US, global) Phase III	Protection against COVID-19 in participants aged 18+	Placebo or *C19VAZ*	FPCD Q3 2020 First data anticipated H1 2021	Recruitment completed

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

AZD7442, a long-acting antibody (LAAB) combination therapy for the prevention and treatment of COVID-19, has advanced into five Phase III clinical trials.

The LAAB combination has been engineered with AstraZeneca's proprietary half-life extension technology, which triples the durability of its action compared to conventional antibodies and with a further modification to reduce binding of the Fc (fragment-crystallisable) portion of the antibody to Fc receptors on other cells to reduce the theoretical risk of antibody-dependent enhanced disease.

[84] Conducted by the University of Oxford.
[85] Conducted by University of Witwatersrand, South Africa.
[86] Human immunodeficiency virus-positive.

Table 36: Key AZD7442 Phase II/III trials in COVID-19

Trial	Population	Design	Timeline	Status
PROVENT	Protection against COVID-19 (prophylaxis)	Placebo or AZD7442 300mg IM[87]	FPCD Q4 2020 First data anticipated H2 2021	Recruitment ongoing
STORM CHASER	Protection against COVID-19 (post-exposure prophylaxis)	Placebo or AZD7442 300mg IM	FPCD Q4 2020 First data anticipated H1 2021	Recruitment ongoing
TACKLE	COVID-19 (outpatient treatment)	Placebo or AZD7442 600mg IM	FPCD Q1 2021 First data anticipated H1 2021	Recruitment ongoing
ACTIV-2[88]	COVID-19 (outpatient treatment)	Placebo or AZD7442	FPCD Q1 2021	Initiating
ACTIV-3[88]	COVID-19 (inpatient treatment)	Placebo or AZD7442	FPCD Q1 2021	Recruitment ongoing

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

During 2020, as well as developing preventative approaches against the SARS-CoV-2 virus, the Company also initiated clinical trials, detailed in the table below, to evaluate 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.

In November 2020, AstraZeneca announced that the CALAVI Phase II trials for *Calquence*, in patients hospitalised with respiratory symptoms of COVID-19, did not meet the primary efficacy endpoint. The addition of *Calquence* to best supportive care did not increase the proportion of patients who remained alive and free of respiratory failure.

The Company is continuing to evaluate whether *Farxiga* can reduce organ failure in COVID-19 in the DARE-19 Phase III trial. *Farxiga* is also 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 in patients both with and without T2D.

AstraZeneca has joined the UK Government's ACCORD proof-of-concept clinical-trial platform, to speed the development of medicines for patients with COVID-19, evaluating the use of IL33 monoclonal antibody medicine MEDI3506 in suppressing the overactive immune response that can characterise COVID-19. The Company is also supplying *Pulmicort* and *Symbicort* to externally sponsored research programmes, including the trials detailed in the table below.

[87] Intramuscular.
[88] Conducted by the NIH.

Table 37: Other key trials in COVID-19[89]

Trial	Population	Design	Timeline	Status
Farxiga				
DARE-19[90] Phase III	COVID-19	Current SoC or current SoC + *Farxiga*	FPCD Q2 2020 LPCD Q1 2021 First data anticipated H1 2021	Recruitment completed
TACTIC-E[91] Phase II	COVID-19	Current SoC or current SoC + *Farxiga* + ambrisentan	FPCD Q4 2020 First data anticipated H1 2021	Recruitment ongoing
Symbicort				
INHASCO[92] Phase IIIa	COVID-19	Current SoC or SoC + *Symbicort*	FPCD Q2 2020 First data anticipated H1 2021	Recruitment ongoing
Pulmicort				
TACTIC-COVID[93] Phase IIIa	COVID-19	Current SoC or SoC + *Pulmicort*	FPCD Q2 2020 First data anticipated H1 2021	Recruitment ongoing
MEDI3506 (IL33 monoclonal antibody)				
ACCORD[94] Phase II	COVID-19	Current SoC or current SoC + MEDI3506	FPCD Q2 2020 First data anticipated H1 2021	Recruitment ongoing

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. For Alexion pipeline updates, please visit alexion.com.

[89] The dates in the table relating to anticipated data for the accelerated development programme for *C19VAZ* 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.
[90] Sponsored by St. Luke's Mid-America Heart Institute, Kansas City, US.
[91] Conducted by Cambridge University Hospitals NHS Trust.
[92] Conducted by Direction de la Recherche Clinique et de l'Innovation L'Assistance Publique - Hôpitaux de Paris (DRCI AP-HP).
[93] Sponsored by Fundació Clinic per a la Recerca Biomèdica.
[94] Sponsored by the UK Government's Therapeutics Taskforce.

Table 38: **Condensed consolidated statement of comprehensive income - FY 2020**

For the **year** ended 31 December	**2020 $m**	**2019 $m**
Total Revenue	26,617	24,384
Product Sales	*25,890*	*23,565*
Collaboration Revenue	*727*	*819*
Cost of Sales	(5,299)	(4,921)
Gross Profit	21,318	19,463
Distribution costs	(399)	(339)
Research and development expense	(5,991)	(6,059)
Selling, general and administrative costs	(11,294)	(11,682)
Other operating income and expense	1,528	1,541
Operating Profit	5,162	2,924
Finance income	87	172
Finance expense	(1,306)	(1,432)
Share of after-tax losses in associates and joint ventures	(27)	(116)
Profit Before Tax	3,916	1,548
Taxation	(772)	(321)
Profit for the period	3,144	1,227
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(168)	(364)
Net gains/(losses) on equity investments measured at fair value through other comprehensive income	938	(28)
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(1)	(5)
Tax on items that will not be reclassified to profit or loss	(81)	21
	688	(376)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	443	40
Foreign exchange arising on designated borrowings in net investment hedges	573	(252)
Fair value movements on cash flow hedges	180	(101)
Fair value movements on cash flow hedges transferred to profit or loss	(254)	52
Fair value movements on derivatives designated in net investment hedges	8	35
Gains/(costs) of hedging	9	(47)
Tax on items that may be reclassified subsequently to profit or loss	(39)	38
	920	(235)
Other comprehensive income/(loss) for the period, net of tax	1,608	(611)
Total comprehensive income for the period	4,752	616
Profit attributable to:		
Owners of the Parent	3,196	1,335
Non-controlling interests	(52)	(108)
	3,144	1,227
Total comprehensive income attributable to:		
Owners of the Parent	4,804	723
Non-controlling interests	(52)	(107)
	4,752	616
Basic earnings per $0.25 Ordinary Share	$2.44	$1.03
Diluted earnings per $0.25 Ordinary Share	$2.44	$1.03
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,301
Diluted weighted average number of Ordinary Shares in issue (millions)	1,313	1,301

Table 39: Condensed consolidated statement of comprehensive income - Q4 2020[95]

For the **quarter** ended 31 December	**2020 $m**	**2019 $m**
Total Revenue	7,410	6,664
Product Sales	*7,011*	*6,250*
Collaboration Revenue	*399*	*414*
Cost of Sales	(1,525)	(1,378)
Gross Profit	5,885	5,286
Distribution costs	(109)	(92)
Research and development expense	(1,719)	(2,091)
Selling, general and administrative costs	(3,210)	(3,026)
Other operating income and expense	640	500
Operating Profit	1,487	577
Finance income	7	39
Finance expense	(321)	(351)
Share of after-tax losses in associates and joint ventures	(6)	(25)
Profit Before Tax	1,167	240
Taxation	(162)	37
Profit for the period	1,005	277
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	23	(213)
Net losses on equity investments measured at fair value through other comprehensive income	(36)	108
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	-	(4)
Tax on items that will not be reclassified to profit or loss	(11)	-
	(24)	(109)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	564	425
Foreign exchange arising on designated borrowings in net investment hedges	428	239
Fair value movements on cash flow hedges	178	55
Fair value movements on cash flow hedges transferred to profit or loss	(139)	(57)
Fair value movements on derivatives designated in net investment hedges	(31)	-
Costs of hedging	(1)	(12)
Tax on items that may be reclassified subsequently to profit or loss	(46)	(24)
	953	626
Other comprehensive income for the period, net of tax	929	517
Total comprehensive income for the period	1,934	794
Profit attributable to:		
Owners of the Parent	1,012	313
Non-controlling interests	(7)	(36)
	1,005	277
Total comprehensive income attributable to:		
Owners of the Parent	1,940	830
Non-controlling interests	(6)	(36)
	1,934	794
Basic earnings per $0.25 Ordinary Share	$0.78	$0.24
Diluted earnings per $0.25 Ordinary Share	$0.78	$0.24
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

[95] The Q4 2020 and Q4 2019 information in respect of the three months ended 31 December 2020 and 31 December 2019 respectively included in the Condensed Financial Statements has not been audited by PricewaterhouseCoopers LLP.

Table 40: Condensed consolidated statement of financial position

	At 31 Dec 2020 $m	At 31 Dec 2019 $m
Assets		
Non-current assets		
Property, plant and equipment	8,251	7,688
Right-of-use assets	666	647
Goodwill	11,845	11,668
Intangible assets	20,947	20,833
Investments in associates and joint ventures	39	58
Other investments	1,108	1,401
Derivative financial instruments	171	61
Other receivables	720	740
Deferred tax assets	3,438	2,718
	47,185	45,814
Current assets		
Inventories	4,024	3,193
Trade and other receivables	7,022	5,761
Other investments	160	849
Derivative financial instruments	142	36
Income tax receivable	364	285
Cash and cash equivalents	7,832	5,369
Assets held for sale	-	70
	19,544	15,563
Total assets	66,729	61,377
Liabilities		
Current liabilities		
Interest-bearing loans and borrowings	(2,194)	(1,822)
Lease liabilities	(192)	(188)
Trade and other payables	(15,785)	(13,987)
Derivative financial instruments	(33)	(36)
Provisions	(976)	(723)
Income tax payable	(1,127)	(1,361)
	(20,307)	(18,117)
Non-current liabilities		
Interest-bearing loans and borrowings	(17,505)	(15,730)
Lease liabilities	(489)	(487)
Derivative financial instruments	(2)	(18)
Deferred tax liabilities	(2,918)	(2,490)
Retirement benefit obligations	(3,202)	(2,807)
Provisions	(584)	(841)
Other payables	(6,084)	(6,291)
	(30,784)	(28,664)
Total liabilities	(51,091)	(46,781)
Net assets	15,638	14,596
Equity		
Capital and reserves attributable to equity holders of the Parent		
Share capital	328	328
Share premium account	7,971	7,941
Other reserves	2,024	2,046
Retained earnings	5,299	2,812
	15,622	13,127
Non-controlling interests	16	1,469
Total equity	15,638	14,596

Table 41: 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	-	-	-	1,335	1,335	(108)	1,227
Other comprehensive loss	-	-	-	(612)	(612)	1	(611)
Transfer to other reserves	-	-	5	(5)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,579)	(3,579)	-	(3,579)
Issue of Ordinary Shares	11	3,514	-	-	3,525	-	3,525
Share-based payments charge for the period	-	-	-	259	259	-	259
Settlement of share plan awards	-	-	-	(323)	(323)	-	(323)
Net movement	11	3,514	5	(2,871)	659	(107)	552
At 31 Dec 2019	**328**	**7,941**	**2,046**	**2,812**	**13,127**	**1,469**	**14,596**
At 1 Jan 2020	**328**	**7,941**	**2,046**	**2,812**	**13,127**	**1,469**	**14,596**
Profit for the period	-	-	-	3,196	3,196	(52)	3,144
Other comprehensive income	-	-	-	1,608	1,608	-	1,608
Transfer to other reserves[96]	-	-	(22)	1,423	1,401	(1,401)	-
Transactions with owners:							
Dividends	-	-	-	(3,668)	(3,668)	-	(3,668)
Issue of Ordinary Shares	-	30	-	-	30	-	30
Share-based payments charge for the period	-	-	-	277	277	-	277
Settlement of share plan awards	-	-	-	(349)	(349)	-	(349)
Net movement	-	30	(22)	2,487	2,495	(1,453)	1,042
At 31 Dec 2020	**328**	**7,971**	**2,024**	**5,299**	**15,622**	**16**	**15,638**

[96] The non-controlling interests reserve relating to the minority shareholders of Acerta Pharma, totalling $1,401m, has been reclassified into Retained earnings.

Table 42: Condensed consolidated statement of cash flows

For the **year** ended 31 December	**2020 $m**	**2019 $m**
Cash flows from operating activities		
Profit Before Tax	3,916	1,548
Finance income and expense	1,219	1,260
Share of after-tax losses of associates and joint ventures	27	116
Depreciation, amortisation and impairment	3,149	3,762
Decrease/(increase) in working capital and short-term provisions	361	(346)
Gains on disposal of intangible assets	(1,030)	(1,243)
Fair value movements on contingent consideration arising from business combinations	(272)	(614)
Non-cash and other movements	(276)	378
Cash generated from operations	7,094	4,861
Interest paid	(733)	(774)
Tax paid	(1,562)	(1,118)
Net cash inflow from operating activities	4,799	2,969
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(822)	(709)
Purchase of property, plant and equipment	(961)	(979)
Disposal of property, plant and equipment	106	37
Purchase of intangible assets	(1,645)	(1,481)
Disposal of intangible assets	951	2,076
Movement in profit-participation liability	40	150
Purchase of non-current asset investments	(119)	(13)
Disposal of non-current asset investments	1,381	18
Movement in short-term investments, fixed deposits and other investing instruments	745	194
Payments to associates and joint ventures	(8)	(74)
Interest received	47	124
Net cash outflow from investing activities	(285)	(657)
Net cash inflow before financing activities	4,514	2,312
Cash flows from financing activities		
Proceeds from issue of share capital	30	3,525
Issue of loans	2,968	500
Repayment of loans	(1,609)	(1,500)
Dividends paid	(3,572)	(3,592)
Hedge contracts relating to dividend payments	(101)	4
Repayment of obligations under leases	(207)	(186)
Movement in short-term borrowings	288	(516)
Net cash outflow from financing activities	(2,203)	(1,765)
Net increase in cash and cash equivalents in the period	2,311	547
Cash and cash equivalents at the beginning of the period	5,223	4,671
Exchange rate effects	12	5
Cash and cash equivalents at the end of the period	7,546	5,223
Cash and cash equivalents consist of:		
Cash and cash equivalents	7,832	5,369
Overdrafts	(286)	(146)
	7,546	5,223

Notes to the Condensed Financial Statements

1) Basis of preparation and accounting policies

The Condensed Consolidated Financial Statements for the year ended 31 December 2020 have been prepared in accordance with International Financial Reporting Standards (IFRSs) adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the EU and as issued by the International Accounting Standards Board (IASB). On 31 December 2020, EU-adopted IFRS was brought into UK law and became UK-adopted international accounting standards, with future changes to IFRS being subject to endorsement by the UK Endorsement Board. The Condensed Consolidated Financial Statements will transition to UK-adopted international accounting standards for financial periods beginning 1 January 2021.

These Condensed Consolidated Financial Statements comprise the financial results of AstraZeneca PLC for the years to 31 December 2020 and 2019 together with the Statement of financial position as at 31 December 2020 and 2019. The results for the year to 31 December 2020 have been extracted from the 31 December 2020 audited Consolidated Financial Statements which have been approved by the Board of Directors. These have not yet been delivered to the Registrar of Companies but are expected to be published on 15 February 2021 within the Annual Report and Form 20-F Information 2020.

The financial information set out above does not constitute the Group's statutory accounts for the years to 31 December 2020 or 2019 but is derived from those accounts. The auditors have reported on those accounts; their reports (i) were unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report and (iii) did not contain a statement under section 498 (2) or (3) of the Companies Act 2006 in respect of the accounts for the year to 31 December 2020 or 31 December 2019. Statutory accounts for the year to 31 December 2020 were approved by the Board of Directors for release on 11 February 2021.

Except as noted below, the Condensed Consolidated Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 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 result in 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

The replacement of benchmark interest rates, such as the London Inter-bank Offered Rate (LIBOR) and other interbank offered rates (IBORs) is a priority for global regulators and is expected to be largely completed in 2021. To prepare for this, the Group early adopted the Phase 1 amendments to IFRS 9 'Financial Instruments' and IFRS 7 'Financial Instruments: Disclosures' in 2019. These amendments provide relief from applying specific hedge accounting requirements to hedge relationships directly affected by IBOR reform and have the effect that the reform should generally not cause hedge accounting to terminate. There was no financial impact from the early adoption of these amendments. Further amendments (Phase 2) were issued on 27 August 2020 and the Group will apply these in 2021.

The Group has one IFRS 9 designated hedge relationship that is 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 have been assessed and the Group is currently preparing to move to the new benchmark rates in 2021.

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 under Trade

and other payables as deferred income and released to net off against the related expenditure when incurred. Each contract is assessed to determine whether there are both grant elements and supply of product which need to be separated. In each case, contracts set out the specified terms for the supply of the product and the provisions for funding for certain costs, primarily research and development associated with the IP. It is considered whether there are any conditions for the funding to be refunded. The consideration in the contract is allocated between the grant and supply elements. The standalone selling price for the supply of products is determined by reference to observed prices with other customers. The amount allocated as a government grant is determined by reference to the specific agreed costs and activities identified in the contract as being related to activities not directly attributable to the supply of product. Government grants are recorded as an offset to the relevant expense in the Income Statement and are capped to match the relevant costs incurred.

COVID-19

AstraZeneca has assessed the impact of the uncertainty presented by the COVID-19 pandemic on the Consolidated Financial Statements comprising the financial results to 31 December 2020 and the financial position as at 31 December 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 year ended 31 December 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 31 December 2020, the Group had $12.1bn in financial resources (cash and cash-equivalent balances of $7.8bn, $0.2bn of liquid fixed income securities and undrawn committed bank facilities of $4.1bn, of which $3.4bn is available until April 2024, $0.7bn is available until November 2021 (with a one-year extension option, exercisable by the Group), with only $2.4bn of borrowings due within one year). To support the financing of the acquisition of Alexion, the Group entered into committed bank facilities totalling $17.5bn during December 2020. The facilities are intended to cover the financing of the cash portion of the acquisition consideration and associated acquisition costs and to refinance the existing term loan and revolving credit facilities of Alexion. All facilities contain no financial covenants and were undrawn at 31 December 2020.

The directors have considered the impact of COVID-19 on AstraZeneca's operations (including the effects of any governmental or regulatory response to the pandemic), and mitigations to these risks. Overall the impact of these items would heighten certain risks, such as those relating to the delivery of the pipeline or launch of new medicines, the execution of AstraZeneca's commercial strategy, the manufacturing and supply of medicines and reliance on third-party goods and services. The Company is continuously monitoring and mitigating where possible impacts of these risks.

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.

Accordingly, the going-concern basis has been adopted in these Condensed 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 net impairment charge of $240m being recorded against intangible assets during the year ended 31 December 2020 (2019: $1,033m).

Impairment charges in respect of launched products totalled $350m (2019: $425m), including *Duaklir* ($200m, revised carrying amount of $210m), *Bydureon* ($102m, revised carrying amount of $581m), and other launched products totalling $48m. If revenue projections for *Bydureon* were to fall by 15% over the forecast period, this would result in a further impairment charge of c.$110m. Impairment charges recorded against products in development totalled $55m (2019: $609m).

The impairments recorded on launched products were a consequence of revised market volume, share and price assumptions. Impairments recorded on products in development were a consequence of failed or poor performing trials, with the individual assets being fully impaired.

The Group has performed an assessment on assets which have had impairments recorded in previous periods to determine if any reversals of impairments were required. Impairment reversals of $165m were recorded in 2020 in respect of launched products (2019: $3m in respect of products in development), including *FluMist* ($147m, revised carrying amount of $300m, driven by expanded vaccination efforts increasing global demand), and other launched products of $18m.

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 43: Net Debt

	At 1 Jan 2020 $m	Cash flow $m	Non-cash & other $m	Exchange movements $m	At 31 Dec 2020 $m
Non-current instalments of loans	(15,730)	(2,968)	1,394	(201)	(17,505)
Non-current instalments of leases	(487)	-	11	(13)	(489)
Total long-term debt	**(16,217)**	**(2,968)**	**1,405**	**(214)**	**(17,994)**
Current instalments of loans	(1,597)	1,609	(1,411)	(137)	(1,536)
Current instalments of leases	(188)	226	(225)	(5)	(192)
Bank collateral	(71)	(217)	-	-	(288)
Other short-term borrowings excluding overdrafts	(8)	(71)	-	(5)	(84)
Overdraft	(146)	(138)	-	(2)	(286)
Total current debt	**(2,010)**	**1,409**	**(1,636)**	**(149)**	**(2,386)**
Gross borrowings	**(18,227)**	**(1,559)**	**(231)**	**(363)**	**(20,380)**
Net derivative financial instruments	43	101	134	-	278
Net borrowings	**(18,184)**	**(1,458)**	**(97)**	**(363)**	**(20,102)**
Cash and cash equivalents	5,369	2,449	-	14	7,832
Other investments - current	849	(745)	61	(5)	160
Other investments - non-current	62	-	(62)	-	-
Cash and investments	**6,280**	**1,704**	**(1)**	**9**	**7,992**
Net Debt	**(11,904)**	**246**	**(98)**	**(354)**	**(12,110)**

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

Other investments - non-current are included within the balance of $1,108m (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 $2,297m (31 December 2019: $2,146m), shown in non-current other payables.

Net Debt increased by $206m in the year to $12,110m. Details of the committed undrawn bank facilities are disclosed within the going-concern section of Note 1.

During the year to 31 December 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 $128m at 31 December 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 year ended 31 December 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 year ended 31 December 2020 are Level 1 fair-value measurements.

Financial instruments measured at fair value include $1,268m of other investments, $6,602m held in money-market funds, $339m of loans designated at fair value through profit or loss, $371m of loans designated in a fair-value hedge relationship and $278m of derivatives as at 31 December 2020. The total fair value of interest-bearing loans and borrowings at 31 December 2020, which have a carrying value of $20,380m in the Condensed consolidated statement of financial position, was $23,825m. 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 44: 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	(546)	(276)	(822)	(709)
Revaluations	(51)	(221)	(272)	(614)
Discount unwind	229	49	278	356
At 31 December	**2,932**	**391**	**3,323**	**4,139**

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 $2,932m (31 December 2019: $3,300m) would increase/decline by $293m with an increase/decline in sales of 10%, as compared with the current estimates.

5) Legal proceedings and contingent liabilities

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property (IP) 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, H1 2020 and Q3 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, the majority of claims involve highly complex issues. Often these issues are subject to substantial uncertainties and, therefore, the probability of a loss, if any, being sustained and/or an estimate of the amount of any loss is difficult to ascertain.

Unless specifically identified below that a provision has been taken, AstraZeneca considers each of the claims to represent a contingent liability and discloses information with respect to the nature and facts of the cases in accordance with IAS 37.

In cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed and which are not subject to appeal, or where a loss is probable and we are able to make a reasonable estimate of the loss, AstraZeneca records the loss absorbed or makes a provision for its best estimate of the expected loss. The position could change over time and the estimates that the Company made, and upon which the Company have relied in calculating these provisions are inherently imprecise. There can, therefore, be no assurance that any losses that result from the outcome of any legal proceedings will not exceed the amount of the provisions that have been booked in the accounts. The major factors causing this uncertainty are described more fully in the Disclosures and herein.

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

Matters disclosed in respect of the fourth quarter of 2020 and to 11 February 2021

Patent litigation

Enhertu
US patent proceedings
As previously disclosed, in October 2020, Seagen Inc. (Seagen) filed a complaint against Daiichi Sankyo in the US District Court for the Eastern District of Texas alleging that *Enhertu* infringes US Patent No 10,808,039 (the '039 patent). AstraZeneca Pharmaceuticals LP co-commercialises *Enhertu* with Daiichi Sankyo, Inc. in the US. A claim construction hearing has been scheduled for August 2021 and a trial has been scheduled for April 2022.

In November 2020, AstraZeneca, Daiichi Sankyo and Daiichi Sankyo Inc. filed a complaint against Seagen in the US District Court for the District of Delaware seeking a declaratory judgment that plaintiffs do not infringe the '039 patent. On 18 December 2020, Seagen filed a motion seeking to stay or dismiss this action.

On 23 December 2020, AstraZeneca and Daiichi Sankyo Inc. filed a post grant review petition with the US Patent and Trademark Office alleging, *inter alia*, that the '039 patent is invalid for lack of written description and entablement. In January 2021, AstraZeneca and Daiichi Sankyo, Inc. filed a second post grant review petition with the US Patent and Trademark Office extending its challenge to additional claims in the '039 patent. A decision on institution of these petitions is expected in July 2021.

Symbicort
US patent proceedings
As previously disclosed, AstraZeneca has Abbreviated New Drug Application litigation pending against Mylan Pharmaceuticals Inc. and Kindeva Drug Delivery L.P. in the US District Court for the Northern District of West Virginia. The trial of the matter was held in October 2020 and closing argument was held on 12 January 2021. A decision is awaited.

Movantik
US patent proceedings
As previously disclosed, in March 2020, Aether Therapeutics, Inc. filed a patent infringement lawsuit in the US District Court for the District of Delaware against AstraZeneca, Nektar Therapeutics and Daiichi Sankyo, Inc., relating to *Movantik*. A trial has been set for March 2023.

Forxiga
Patent Proceedings outside the US
In Canada, in January 2021, Sandoz Canada Inc. served three Notices of Allegation on AstraZeneca alleging invalidity and/or non-infringement of all three patents listed on the Canadian Patent Register in relation to *Forxiga*. AstraZeneca is considering its response.

Product liability litigation

***Farxiga* and *Xigduo* XR**
As previously disclosed, in several jurisdictions in the US, AstraZeneca has been named as a defendant in lawsuits involving plaintiffs claiming physical injury, including diabetic ketoacidosis and kidney failure, from treatment with *Farxiga* and/or *Xigduo* XR. In April 2017, the Judicial Panel on Multidistrict Litigation ordered transfer of any currently pending cases as well as of any similar, subsequently filed cases to a co-ordinated and

consolidated pre-trial multidistrict litigation proceeding in the US District Court for the Southern District of New York. All of these claims have been resolved or dismissed, and the multidistrict litigation has been administratively closed.

In addition, in several jurisdictions in the US, AstraZeneca has been named as a defendant in lawsuits involving plaintiffs claiming physical injury, including Fournier's Gangrene and necrotising fasciitis, from treatment with *Farxiga* and/or *Xigduo* XR. A majority of these claims are filed in Delaware State Court and remain pending.

Bydureon/Byetta
As previously disclosed in the US, Amylin Pharmaceuticals, LLC, a wholly owned subsidiary of AstraZeneca, and/or AstraZeneca are among multiple defendants in various lawsuits filed in federal and state courts involving claims of physical injury from treatment with *Bydureon* and/or *Byetta*. The lawsuits allege several types of injuries including pancreatitis, pancreatic cancer, thyroid cancer, and kidney cancer. A multidistrict litigation was established in the US District Court for the Southern District of California (the District Court) in regard to the alleged pancreatic cancer cases in federal courts. Further, a coordinated proceeding has been established in Los Angeles (the California Court), California in regard to the various lawsuits in California state courts. In November 2015, the District Court granted the defendants' motion for summary judgment and dismissed all claims alleging pancreatic cancer that accrued prior to 11 September 2015. In November 2017, the US Court of Appeals for the Ninth Circuit vacated the District Court's order and remanded for further discovery. In November 2018, the Court of Appeal for the State of California annulled the judgment from the California state coordinated proceeding and remanded for further discovery. In October and December 2020, the District Court and the California Court jointly heard oral argument on a renewed motion filed by Defendants seeking summary judgment and dismissal of all claims. That motion remains pending.

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. In November 2020, the Court decided in AstraZeneca's favour and subsequently entered a Final Judgment as to all pending claims in favour of AstraZeneca. In December 2020, the plaintiffs filed an appeal to the Delaware Supreme Court.

Definiens
As previously disclosed, 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 c.$140m in earn-outs under the SPA; AstraZeneca disputes the claims of the Sellers. The arbitration tribunal has scheduled an oral hearing in July 2022.

AZD1222 Securities Litigation
In January 2021, putative securities class action lawsuits were filed in the US District Court for the Southern District of New York against AstraZeneca PLC and certain officers, on behalf of purchasers of AstraZeneca publicly traded securities during the period 21 May 2020 through 20 November 2020. The complaints allege that defendants made materially false and misleading statements in connection with the development of AZD1222 (otherwise known as *C19VAZ*), a potential recombinant adenovirus vaccine for the prevention of COVID-19, and assert claims under sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5.

Government investigations/proceedings

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 (the Supreme Court) to review the decision of the Appellate Court and reinstate the Trial Court's summary judgment ruling. In December 2020, the Supreme Court granted AstraZeneca's petition and agreed to review the Appellate Court's decision. AstraZeneca filed its opening appellate brief with the Supreme Court in January 2021. A decision on the merits of the appeal remains pending.

Crestor

Qui tam litigation

In the US, in January and February 2014, AstraZeneca was served with lawsuits filed in the US District Court for the District of Delaware under the qui tam provisions of the federal False Claims Act and related state statutes, alleging that AstraZeneca directed certain employees to promote *Crestor* off-label and provided unlawful remuneration to physicians in connection with the promotion of *Crestor*. The Department of Justice and all US states declined to intervene in the lawsuits. In March 2019, AstraZeneca filed a motion to dismiss the complaint. In February 2020, the District Court partially granted AstraZeneca's motion to dismiss. This matter was resolved and is now concluded.

US 340B Litigations and Proceedings

AstraZeneca is involved in several matters relating to its policy with regard to contract pharmacy recognition under the 340B Drug Pricing Program in the United States. In October and November 2020, two lawsuits, one in the US District Court for the District of Columbia and one in the US District Court for the Northern District of California, were filed by covered entities and advocacy groups against the US Department of Health and Human Services, the US Health Resources and Services Administration as well as other US government agencies and their officials. The complaints allege, among other things, that these agencies should enforce an interpretation of the governing statute for the 340B Drug Pricing Program that would require drug manufacturers participating in the program to offer their drugs for purchase at statutorily capped rates by an unlimited number of contract pharmacies. AstraZeneca has sought to intervene in the lawsuits. Administrative Dispute Resolution proceedings have also been initiated against AstraZeneca before the US Health Resources and Services Administration. In addition, in January 2021 AstraZeneca filed a separate lawsuit in federal court in Delaware alleging that a recent Advisory Opinion issued by the Department of Health and Human Services violates the Administrative Procedure Act.

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 and significant estimates 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 $287m (31 December 2019: $140m) reflected the progress in those tax audits and reviews during the year 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 $251m, including associated interest (31 December 2019: $76m). The total net accrual to cover the worldwide tax exposure for other tax contingencies of $727m (31 December 2019: $887m) reflected the progress in those tax audits and reviews during the year and expiry of statute of limitations. AstraZeneca estimates the potential for reasonably possible additional liabilities above and beyond the amount provided to be up to $517m, including associated interest (31 December 2019: $327m). The Company believes 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.

6) Subsequent Events

In December 2020, AstraZeneca and Alexion announced that they had entered into a definitive agreement for AstraZeneca to acquire Alexion for a total consideration of $39bn, partly funded in cash and partly in AstraZeneca American Depository Shares. The boards of directors of both companies have unanimously approved the acquisition. Subject to receipt of regulatory clearances and approval by shareholders of both companies, the acquisition is expected to close in the third quarter of 2021, and upon completion, Alexion shareholders will own c.15% of the combined company. In conjunction with the acquisition, AstraZeneca has entered into committed bank facilities of $17.5bn.

In February 2021, AstraZeneca agreed to divest, subject to certain limited exceptions, its 26.7% ownership in Viela Bio, Inc. (Viela), as part of the proposed acquisition of Viela by Horizon Therapeutics plc. AstraZeneca anticipates receiving cash proceeds and profit of c.$760-780m upon closing for the sale of the holding, which will be recorded in Reported and Core Other Operating Income and Expense in the Company's financial statements. The divestment is expected to complete by the end of the first quarter of 2021.

In February 2021, AstraZeneca completed its sale of rights to *Crestor* and associated medicines in certain European countries to Grünenthal for an upfront payment of $320m, which will be recorded within Other operating income and expense. At 31 December 2020, there were no intangible or other assets on the balance sheet relating to the disposal.

7) Table 45: Product Sales year-on-year analysis - FY 2020[97]

The CER information in respect of FY 2020 included in the Consolidated Financial Information has not been audited by PricewaterhouseCoopers LLP.

	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	4,328	36	36	1,208	59	63	1,566	24	748	58	56	806	18	16
Imfinzi	2,042	39	39	158	n/m	n/m	1,185	14	370	n/m	n/m	329	51	49
Lynparza	1,776	48	49	264	98	n/m	876	40	435	52	51	201	32	32
Calquence	522	n/m	n/m	6	n/m	n/m	511	n/m	2	n/m	n/m	3	n/m	n/m
Koselugo	38	n/m	n/m	-	-	-	38	n/m	-	-	-	-	-	-
*Zoladex**	888	9	13	561	14	20	5	(22)	140	4	4	182	1	1
*Faslodex**	580	(35)	(34)	180	(9)	(4)	55	(83)	221	(3)	(3)	124	(10)	(11)
*Iressa**	268	(37)	(36)	221	(23)	(22)	14	(21)	12	(82)	(82)	21	(57)	(57)
*Arimidex**	185	(18)	(16)	147	(3)	1	-	-	3	(88)	(88)	35	(23)	(24)
*Casodex**	172	(14)	(14)	133	4	6	-	-	3	(83)	(83)	36	(37)	(38)
Others	51	(47)	(46)	28	(1)	1	-	-	4	(41)	(40)	19	(69)	(69)
Total Oncology	**10,850**	**25**	**26**	**2,906**	**31**	**36**	**4,250**	**23**	**1,938**	**36**	**35**	**1,756**	**11**	**10**
BioPharmaceuticals: CVRM														
Farxiga	1,959	27	30	686	46	55	569	6	507	36	35	197	21	21
Brilinta	1,593	1	2	461	-	4	732	3	342	(3)	(3)	58	-	2
Onglyza	470	(11)	(10)	201	14	18	166	(28)	58	(16)	(17)	45	(12)	(11)
Bydureon	448	(18)	(18)	4	(62)	(59)	382	(17)	53	(20)	(20)	9	(32)	(31)
Byetta	68	(37)	(36)	8	(35)	(23)	37	(45)	14	(24)	(24)	9	(18)	(17)
Other diabetes	47	(10)	(10)	7	n/m	n/m	25	(37)	13	38	38	2	26	28
Lokelma	76	n/m	n/m	5	n/m	n/m	57	n/m	4	n/m	n/m	10	n/m	n/m
*Crestor**	1,180	(8)	(7)	748	(7)	(5)	92	(11)	129	(13)	(15)	211	(4)	(5)
*Seloken/Toprol-XL**	821	8	12	782	14	18	13	(66)	16	(35)	(35)	10	(11)	(10)
*Atacand**	243	10	15	175	9	17	10	(12)	35	17	17	23	15	15
Others	191	(30)	(30)	126	(35)	(34)	-	n/m	57	(5)	(4)	8	(60)	(61)
BioPharmaceuticals: total CVRM	**7,096**	**3**	**5**	**3,203**	**8**	**12**	**2,083**	**(6)**	**1,228**	**7**	**6**	**582**	**2**	**2**
BioPharmaceuticals: Respiratory & Immunology														
Symbicort	2,721	9	10	567	4	9	1,022	23	694	2	2	438	(1)	-
Pulmicort	996	(32)	(32)	798	(33)	(33)	71	(35)	73	(10)	(10)	54	(37)	(37)
Fasenra	949	35	34	12	n/m	n/m	603	25	203	72	70	131	33	32
Daliresp/Daxas	217	1	1	4	(9)	(8)	190	3	22	(14)	(13)	1	(10)	(8)
Bevespi	48	16	15	1	n/m	n/m	44	7	3	n/m	n/m	-	-	-
Breztri	28	n/m	n/m	14	n/m	n/m	5	n/m	-	-	-	9	n/m	n/m
Others	398	(15)	(15)	203	(15)	(16)	6	(12)	176	(14)	(15)	13	(15)	(7)
BioPharmaceuticals: total Respiratory & Immunology	**5,357**	**(1)**	**-**	**1,599**	**(20)**	**(18)**	**1,941**	**17**	**1,171**	**6**	**5**	**646**	**-**	**1**
Other medicines														
*Nexium**	1,492	1	2	757	1	4	169	(22)	71	12	10	495	9	8
*Synagis**	372	4	4	-	-	-	47	2	325	4	4	-	-	-
*FluMist**	295	n/m	n/m	1	n/m	n/m	70	n/m	219	n/m	n/m	5	n/m	n/m
*Losec/Prilosec**	183	(30)	(30)	152	(15)	(14)	6	(44)	20	(59)	(59)	5	(78)	(79)
*Seroquel XR/IR**	117	(39)	(37)	55	11	14	17	(48)	29	(67)	(67)	16	(19)	(18)
Others	128	(33)	(34)	6	(51)	(44)	55	(50)	58	(7)	(8)	9	6	(5)
Total other medicines	**2,587**	**(1)**	**-**	**971**	**(2)**	**1**	**364**	**(17)**	**722**	**8**	**7**	**530**	**5**	**3**
Total Product Sales	**25,890**	**10**	**11**	**8,679**	**6**	**10**	**8,638**	**12**	**5,059**	**16**	**15**	**3,514**	**6**	**6**

[97] 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 46: Product Sales year-on-year analysis - Q4 2020[98]

The Q4 2020 information in respect of the three months ended 31 December 2020 included in the Consolidated Financial Information has not been audited by PricewaterhouseCoopers LLP.

	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	1,157	31	28	258	23	23	422	18	245	80	69	232	29	25
Imfinzi	555	31	29	45	n/m	n/m	300	6	115	78	68	95	44	41
Lynparza	496	42	40	69	n/m	n/m	245	27	124	58	49	58	29	27
Calquence	182	n/m	n/m	2	n/m	n/m	176	n/m	2	n/m	n/m	2	n/m	n/m
Koselugo	17	n/m	n/m	-	-	-	17	n/m	-	-	-	-	-	-
*Zoladex**	216	11	13	134	20	27	(1)	n/m	36	2	(3)	47	-	(4)
*Faslodex**	130	(21)	(22)	39	(27)	(22)	10	(40)	50	(17)	(22)	31	(12)	(14)
*Iressa**	67	(16)	(19)	58	(2)	(6)	3	(7)	1	(88)	(89)	5	(41)	(43)
*Arimidex**	36	(29)	(30)	26	(22)	(23)	-	-	1	(87)	(88)	9	(9)	(13)
*Casodex**	39	(10)	(13)	29	3	(1)	-	-	1	(80)	(80)	9	(16)	(22)
Others	13	(53)	(52)	8	25	19	-	-	-	(86)	(87)	5	(74)	(74)
Total Oncology	**2,908**	**28**	**26**	**668**	**22**	**24**	**1,172**	**29**	**575**	**45**	**37**	**493**	**17**	**14**
BioPharmaceuticals: CVRM														
Farxiga	586	40	40	198	50	57	184	31	144	45	36	60	27	24
Brilinta	363	(15)	(15)	69	(39)	(36)	195	(7)	85	(5)	(10)	14	(6)	(7)
Onglyza	105	(20)	(21)	47	3	4	32	(44)	15	(6)	(12)	11	(18)	(16)
Bydureon	122	(12)	(12)	1	(26)	(18)	105	(12)	14	(7)	(11)	2	(42)	(49)
Byetta	19	(31)	(30)	-	n/m	(85)	13	(18)	4	(16)	(21)	2	(15)	(18)
Other diabetes	12	(23)	(22)	2	n/m	n/m	6	(53)	4	45	38	-	(43)	6
Lokelma	28	n/m	n/m	1	n/m	n/m	20	n/m	2	n/m	n/m	5	n/m	n/m
*Crestor**	298	1	(1)	189	2	1	21	33	34	(7)	(13)	54	(8)	(11)
*Seloken/Toprol-XL**	200	6	7	190	10	11	3	(52)	4	(32)	(32)	3	(7)	(18)
*Atacand**	63	5	9	42	(2)	4	3	(16)	13	63	63	5	(7)	(15)
Others	46	(38)	(40)	33	(40)	(43)	-	n/m	12	(14)	(12)	1	(73)	(79)
BioPharmaceuticals: total CVRM	**1,842**	**3**	**3**	**772**	**3**	**5**	**582**	**(1)**	**331**	**13**	**7**	**157**	**3**	**-**
BioPharmaceuticals: Respiratory & Immunology														
Symbicort	680	(5)	(5)	145	(1)	3	267	9	173	1	(4)	95	(37)	(38)
Pulmicort	368	(11)	(14)	319	(8)	(11)	18	(14)	18	(17)	(20)	13	(49)	(50)
Fasenra	283	38	35	2	24	37	180	30	63	72	61	38	31	27
Daliresp/Daxas	54	(6)	(7)	1	-	(6)	49	(3)	4	(35)	(37)	-	-	-
Bevespi	12	8	4	-	-	-	11	(5)	1	n/m	n/m	-	-	-
Breztri	6	n/m	n/m	(1)	n/m	n/m	2	n/m	-	-	-	5	n/m	n/m
Others	125	(8)	(12)	81	10	4	(2)	n/m	44	(19)	(24)	2	(48)	(20)
BioPharmaceuticals: total Respiratory & Immunology	**1,528**	**(1)**	**(2)**	**547**	**(4)**	**(5)**	**525**	**12**	**303**	**5**	**(1)**	**153**	**(27)**	**(28)**
Other medicines														
*Nexium**	377	7	6	193	11	11	42	(2)	12	(18)	(25)	130	6	3
*Synagis**	78	24	24	-	-	-	-	n/m	78	46	47	-	-	-
*FluMist**	179	92	85	1	n/m	n/m	5	n/m	170	83	76	3	n/m	n/m
*Losec/Prilosec**	39	(15)	(18)	33	(2)	(6)	2	(26)	4	(16)	(12)	-	(96)	(95)
*Seroquel XR/IR**	19	(53)	(49)	15	68	77	(5)	n/m	7	(65)	(63)	2	(58)	(55)
Others	41	(30)	(31)	-	n/m	(90)	17	(42)	20	15	9	4	12	(17)
Total other medicines	**733**	**12**	**10**	**242**	**8**	**8**	**61**	**(33)**	**291**	**43**	**39**	**139**	**3**	**-**
Total Product Sales	**7,011**	**12**	**11**	**2,229**	**7**	**7**	**2,340**	**14**	**1,500**	**27**	**21**	**942**	**2**	**-**

[98] 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 47: Product Sales quarterly sequential analysis - FY 2020[99]

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

	Q1 2020			Q2 2020			Q3 2020			Q4 2020		
	$m	% change		$m	% change		$m	% change		$m	% change	
		Actual	CER		Actual	CER		Actual	CER		Actual	CER
Oncology												
Tagrisso	982	11	11	1,034	5	7	1,155	12	9	1,157	-	(1)
Imfinzi	462	9	9	492	6	8	533	8	6	555	4	3
Lynparza	397	13	13	419	5	7	464	11	8	496	7	6
Calquence	88	58	58	107	21	23	145	36	35	182	25	25
Koselugo	-	-	-	7	n/m	n/m	13	75	75	17	34	34
*Zoladex**	225	15	15	217	(3)	-	230	6	3	216	(6)	(7)
*Faslodex**	166	-	-	146	(12)	(9)	138	(5)	(8)	130	(6)	(7)
*Iressa**	77	(3)	(4)	70	(9)	(7)	54	(23)	(24)	67	24	19
*Arimidex**	50	(1)	(2)	58	17	16	42	(28)	(27)	36	(14)	(16)
*Casodex**	42	(2)	(3)	47	14	12	44	(7)	(8)	39	(11)	(14)
Others	13	(52)	(52)	12	(11)	(1)	13	4	3	13	2	2
Total Oncology	**2,502**	**10**	**10**	**2,609**	**4**	**6**	**2,831**	**8**	**6**	**2,908**	**3**	**2**
BioPharmaceuticals: CVRM												
Farxiga	405	(3)	(3)	443	9	13	525	19	16	586	11	10
Brilinta	408	(5)	(5)	437	7	9	385	(12)	(13)	363	(6)	(6)
Onglyza	141	8	8	115	(19)	(17)	110	(6)	(6)	105	(4)	(5)
Bydureon	100	(28)	(28)	116	16	17	109	(5)	(7)	122	12	11
Byetta	20	(24)	(24)	15	(28)	(28)	15	1	4	19	26	24
Other diabetes	13	(22)	(22)	10	(21)	(19)	11	9	6	12	11	15
Lokelma	11	42	42	17	56	58	21	22	26	28	37	28
*Crestor**	301	2	1	281	(7)	(4)	300	7	5	298	(1)	(4)
*Seloken/Toprol-XL**	177	(6)	(6)	218	23	27	225	4	3	200	(11)	(13)
*Atacand**	66	11	12	59	(11)	(5)	54	(9)	(12)	63	16	14
Others	59	(21)	(22)	48	(18)	(16)	39	(19)	(22)	46	18	17
BioPharmaceuticals: total CVRM	**1,701**	**(5)**	**(5)**	**1,759**	**3**	**6**	**1,794**	**2**	**-**	**1,842**	**3**	**1**
BioPharmaceuticals: Respiratory & Immunology												
Symbicort	790	11	11	653	(17)	(15)	599	(8)	(11)	680	13	13
Pulmicort	380	(8)	(9)	97	(74)	(73)	151	56	49	368	n/m	n/m
Fasenra	199	(3)	(3)	227	14	15	240	5	4	283	18	17
Daliresp/Daxas	53	(8)	(8)	53	(1)	(3)	57	8	11	54	(4)	(6)
Bevespi	12	9	9	10	(19)	(21)	14	47	46	12	(16)	(17)
Breztri	4	n/m	n/m	7	58	64	10	45	48	6	(39)	(38)
Others	113	(16)	(17)	70	(38)	(36)	90	27	22	125	39	35
BioPharmaceuticals: total Respiratory & Immunology	**1,551**	**1**	**1**	**1,117**	**(28)**	**(26)**	**1,161**	**4**	**1**	**1,528**	**32**	**29**
Other medicines												
*Nexium**	338	(4)	(4)	377	12	14	401	6	4	377	(6)	(7)
*Synagis**	85	35	35	90	6	7	118	31	29	78	(34)	(33)
*FluMist**	-	n/m	n/m	-	n/m	n/m	116	n/m	n/m	179	55	50
*Losec/Prilosec**	54	18	17	45	(15)	(15)	45	-	-	39	(15)	(18)
*Seroquel XR/IR**	36	(12)	(12)	27	(26)	(23)	35	32	29	19	(45)	(42)
Others	44	(71)	(70)	24	(46)	(42)	19	(17)	(19)	41	n/m	n/m
Total other medicines	**557**	**(15)**	**(15)**	**563**	**1**	**4**	**734**	**30**	**27**	**733**	**-**	**(2)**
Total Product Sales	**6,311**	**1**	**1**	**6,048**	**(4)**	**(2)**	**6,520**	**8**	**6**	**7,011**	**8**	**6**

[99] 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 48: Product Sales quarterly sequential analysis - FY 2019[100]

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

	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**

[100] 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.

Table 49: Historic Collaboration Revenue

		FY 2020	FY 2019	FY 2018
		$m	$m	$m
Initial Collaboration Revenue	*Crestor* (Spain)	-	-	61
Ongoing Collaboration Revenue	*Lynparza*: regulatory milestones	160	60	140
	Lynparza: sales milestones	300	450	250
	Lynparza/*Koselugo*: option payments	-	100	400
	Crestor (Spain)	-	39	-
	Enhertu: share of gross profits	94	-	-
	Roxadustat: share of gross profits	30	-	-
	Royalty income	62	62	49
	Other Collaboration Revenue	81	108	141
	Total	**727**	**819**	**1,041**

Table 50: Other Operating Income and Expense

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

	FY 2020 $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	107	-	-
Inderal, *Tenormin*, *Seloken* and *Omepral* (Japan)	51	-	-
Synagis (US)	-	515	-
Losec (ex-China, Japan, US and Mexico)	-	243	-
Seroquel and Seroquel XR (US, Canada, Europe and Russia)	-	213	-
Arimidex and *Casodex* (various countries)	-	181	-
Nexium (Europe) and *Vimovo* (ex-US)	54	-	728
Seroquel	-	-	527
Legal settlement	-	-	346
Atacand	400	-	210
Anaesthetics	-	-	172
Alvesco, *Omnaris* and *Zetonna*	-	-	139
Other	446	389	405
Total	**1,528**	**1,541**	**2,527**

Shareholder information

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

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

Addresses for correspondence

Registered office	Registrar and transfer office	Swedish Central Securities Depository	US depositary Deutsche Bank Trust Company Americas
1 Francis Crick Avenue Cambridge Biomedical Campus Cambridge CB2 0AA	Equiniti Limited Aspect House Spencer Road Lancing West Sussex BN99 6DA	Euroclear Sweden AB PO Box 191 SE-101 23 Stockholm	American Stock Transfer 6201 15th Avenue Brooklyn NY 11219
United Kingdom	United Kingdom	Sweden	United States
+44 (0) 20 3749 5000	0800 389 1580 +44 (0) 121 415 7033	+46 (0) 8 402 9000	+1 (888) 697 8018 +1 (718) 921 8137 db@astfinancial.com

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 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, including following the Alexion transaction
- 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, including relating to the Alexion transaction
- 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
- 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
- the risk that a condition to the closing of the transaction with Alexion may not be satisfied, or that a regulatory approval that may be required for the transaction is delayed or is obtained subject to conditions that are not anticipated
- the risk that AstraZeneca is unable to achieve the synergies and value creation contemplated by the Alexion transaction, or that AstraZeneca is unable to promptly and effectively integrate Alexion's businesses
- and the risk that management's time and attention are diverted on transaction-related issues or that disruption from the Alexion transaction makes it more difficult to maintain business, contractual and operational relationships

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

Important additional information
In connection with the proposed transaction, the Group intends to file a registration statement on Form F-4 with the US Securities and Exchange Commission (SEC), which will include a document that serves as a prospectus of the Group and a proxy statement of Alexion (the proxy statement/prospectus), Alexion intends to file a proxy statement with the SEC (the proxy statement) and each party will file other documents regarding the proposed transaction with the SEC. Investors and security holders of Alexion are urged to carefully read the entire registration statement and proxy statement/prospectus or proxy statement and other relevant documents filed with the SEC when they become available, because they will contain important information. A definitive proxy statement/prospectus or a definitive proxy statement will be sent to Alexion's shareholders. Investors and security holders will be able to obtain the registration statement and the proxy statement/prospectus or the proxy statement free of charge from the SEC's website or from the Group or Alexion as described in the paragraphs below.

The documents filed by the Group with the SEC may be obtained free of charge at the SEC's website at www.sec.gov. These documents may also be obtained free of charge on the Group's website at http://www.astrazeneca.com under the tab 'Investors'.

The documents filed by Alexion with the SEC may be obtained free of charge at the SEC's website at www.sec.gov. These documents may also be obtained free of charge on Alexion's internet website at http://www.alexion.com under the tab, 'Investors' and under the heading 'SEC Filings or by contacting Alexion's Investor Relations Department at investorrelations@alexion.com.

Participants in the solicitation
Alexion, the Group and certain of their directors, executive officers and employees may be deemed participants in the solicitation of proxies from Alexion shareholders in connection with the proposed transaction. Information regarding the persons who may, under the rules of the SEC, be deemed participants in the solicitation of the shareholders of Alexion in connection with the proposed transaction, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the proxy statement/prospectus or proxy statement when it is filed with the SEC. Information about the directors and executive officers of Alexion and their ownership of Alexion shares is set forth in the definitive proxy statement for Alexion's 2020 special meeting of shareholders, as previously filed with the SEC on 26 March 2020. Free copies of these documents may be obtained as described in the paragraphs above.

- End of document -