AstraZeneca PLC
30 April 2021 07:00 BST

First quarter 2021 results
Robust performance supports continued investment for long-term sustainable growth

AstraZeneca delivered robust revenue growth of 15% (11% at CER[1]) in the quarter to $7,320m; excluding the contribution from the pandemic COVID-19 vaccine, revenue growth increased by 11% (7% at CER) to $7,045m. The overall results in the quarter further increased the Company's profitability and cash generation, while the pipeline demonstrated encouraging progress; the Company reiterates full-year 2021 guidance.

Pascal Soriot, Chief Executive Officer, commented:
"We delivered solid progress in the first quarter of 2021 and continued to advance our portfolio of life-changing medicines. Oncology grew 16% and New CVRM grew 15%. New medicines contributed over half of revenue and all regions delivered encouraging growth. This performance ensured another quarter of strong revenue and earnings progression, continued profitability, and cash-flow generation, despite the pandemic's ongoing negative impact on the diagnosis and treatment of many conditions. Given the performance in the first quarter, in line with our expectations, we reiterate our full-year guidance. We expect the impact of COVID to reduce and anticipate a performance acceleration in the second half of 2021.

Further significant pipeline advances were achieved as we continued to invest for long-term sustainable growth, including the OlympiA Phase III trial demonstrating *Lynparza's* benefit for certain forms of early breast cancer. This sustained pipeline progress and accelerating business performance underlines our commitment to patients and delivering our growth potential, which will be further complemented by the proposed acquisition of Alexion."

Table 1: Q1 2021 - Financial summary

	$m	Actual % change	CER % change
- Product Sales	7,257	15	11
- Collaboration Revenue	63	43	42
Total revenue	7,320	15	11
- Less pandemic COVID-19 vaccine	275	n/m[2]	n/m
Total revenue ex. pandemic vaccine[3]	7,045	11	7
Reported[4] EPS[5]	$1.19	100	97
Core[6] EPS	$1.63	55	53
Impact of pandemic vaccine on EPS	$(0.03)	n/m	n/m

Highlights of Total Revenue in the quarter included:

- An increase in Product Sales of 15% (11% at CER) to $7,257m. New medicines[7] Total Revenue improved by 30% (26% at CER) in the quarter to $3,891m, including growth in Emerging Markets of 33% (30% at CER) to $874m. Globally, new medicines represented 53% of Total Revenue (Q1 2020: 47%). Q1 2020 benefitted from a low-to-mid single-digit percentage increase in sales following short-term inventory increases in the distribution channel, an indirect effect of the COVID-19 pandemic

- Oncology growth of 20% (16% at CER) to $3,024m, an increase in New CVRM[8] of 19% (15% at CER) to $1,306m. Respiratory & Immunology (R&I), however, declined by 1% (4% at CER) to $1,546m, predominately reflecting the impact of stocking of an authorised generic version of *Symbicort* in the US during Q1 2020 and phasing of COVID-19 impacts

- An increase in Emerging Markets of 14% (10% at CER) to $2,592m, with China growth of 19% (10% at CER) to $1,679m. In the US, Total Revenue increased by 10% to $2,310m and in Europe by 28% (18% at CER) to $1,546m

Guidance
The Company reiterates 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 the pandemic COVID-19 vaccine. Similarly, the guidance excludes the proposed acquisition of Alexion Pharmaceuticals, Inc. (Alexion) which is intended to become AstraZeneca's rare disease unit and area of expertise. The acquisition is 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 April to December 2021 were to remain at the average of rates seen in the quarter, 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 15% in the quarter (11% at CER) to $7,320m. Product Sales grew by 15% (11% at CER) to $7,257m, driven primarily by the performances of new medicines across Oncology and BioPharmaceuticals, including *Tagrisso* and *Farxiga*. Total Revenue included $275m of pandemic COVID-19 vaccine sales

- The Reported Gross Profit Margin[9] declined by three percentage points to 74.3%, and the Core Gross Profit[9] Margin declined by three percentage points in the quarter to 74.6%. The performance predominantly reflected the significant impact of equitable supply, at no profit to AstraZeneca, of the pandemic COVID-19 vaccine, together with an increasing contribution from profit-sharing arrangements, primarily *Lynparza*, and the impact of the Chinese National Reimbursement Drug List (NRDL) and the volume-based procurement (VBP) patient-access programmes. A higher proportion of Oncology sales and increasing patient access in China partially offsets these impacts. These variations in gross margin performance between quarters can be expected to continue

- Reported Total Operating Expense increased by 13% (9% at CER) in the quarter to $4,741m and represented 65% of Total Revenue (Q1 2020: 66%). Core Total Operating Expense increased by 15% (11% at CER) to $4,136m and comprised 57% of Total Revenue (Q1 2020: 57%)

- Reported and Core R&D Expense increased by 24% (19% at CER) in the quarter to $1,713m and by 23% (18% at CER) to $1,638m, respectively. The increases primarily reflected the investment in Phase III and the advancement to Phase II of several clinical development programmes, particularly in BioPharmaceuticals. The Company continued to invest in its COVID-19 vaccine and potential medicines to prevent and treat COVID-19

- Reported SG&A Expense increased by 8% (4% at CER) in the quarter to $2,929m; Core SG&A Expense increased by 10% (7% at CER) to $2,399m, representing 33% of Total Revenue (Q1 2020: 34%)

- Reported Other Operating Income and Expense[10] grew by 146% (145% at CER) in the quarter to $1,180m. Core Other Operating Income and Expense increased by 147% (146% at CER) to $1,180m during the period. The growth predominately reflected the $776m of income from divestment of AstraZeneca's 26.7% share of Viela Bio, Inc. (Viela) as part of the acquisition by Horizon Therapeutics plc

- The Reported Operating Profit Margin increased by seven percentage points in the quarter (eight at CER) to 26%; the Core Operating Profit Margin increased by five percentage points (six at CER) to 34%. The performance predominately reflected the aforementioned one-time benefit from Other Operating Income and Expense[10]

- Reported EPS of $1.19 in the quarter represented an increase of 100% (97% at CER). Core EPS grew by 55% (53% at CER) to $1.63. EPS benefitted from a lower tax rate as a result of a non-taxable gain from the divestment of AstraZeneca's share of Viela

Commercial summary

Oncology
Total Revenue increased by 20% in the quarter (16% at CER) to $3,024m.

Table 2: Q1 2021 - Select Oncology medicine Total Revenue performances

Medicine	$m	Actual % change	CER % change
Tagrisso	1,149	17	13
Imfinzi	556	20	17
Lynparza	543	37	33
Calquence	209	n/m	n/m
Enhertu	40	n/m	n/m

New CVRM
Total Revenue increased by 19% in the quarter (15% at CER) to $1,306m.

Table 3: Q1 2021 - Select New CVRM medicine Total Revenue performances

Medicine	$m	Actual % change	CER % change
Farxiga	625	54	50
Brilinta	374	(8)	(11)
Bydureon	103	3	1
Roxadustat	41	n/m	n/m
Lokelma	33	n/m	n/m

Respiratory & Immunology
Total Revenue declined by 1% in the quarter (4% at CER) to $1,546m.

Table 4: Q1 2021 - Select R&I medicine Total Revenue performances

Medicine	$m	Actual % change	CER % change
Symbicort	691	(13)	(15)
Pulmicort	330	(13)	(18)
Fasenra	260	31	27
Breztri	27	n/m	n/m

COVID-19
Total Revenue increased sequentially from $2m in Q4 2020 to $275m in the first quarter of 2021.

Table 5: Q1 2021 - Pandemic COVID-19 vaccine performance

Medicine	$m	Actual % change	CER % change
Pandemic COVID-19 vaccine	275	n/m	n/m

Emerging Markets
Total Revenue increased by 14% in the quarter (10% at CER) to $2,592m, however, the performance was offset by the decline of *Pulmicort*, which included an adverse impact of four percentage points (four at CER) and suppressed the overall Total Revenue growth in the quarter.

China increased 19% (10% at CER) to $1,679m in the quarter and comprised 65% of Emerging Markets Total Revenue. New medicines, primarily driven by *Tagrisso* in Oncology and *Forxiga* in New CVRM, delivered particularly encouraging growth. The Total Revenue growth in the quarter, however, included an adverse impact of five percentage points (four at CER) from the reduced sales of *Pulmicort* which, restricted overall revenue growth in the quarter. Ex-China Total Revenue increased 6% (11% at CER) to $913m, with a particularly strong performance in Middle East and Africa.

Business development

Acquisition of Acerta Pharma B.V. (Acerta) shares
In December 2015, the Company agreed to acquire 55% of the entire issued share capital of Acerta for an upfront payment of $2.5bn, which was paid in 2016. A further amount of $1.5bn was paid in 2017 on receipt of the first US regulatory approval for *Calquence*. The agreement included options that, if exercised, provided the opportunity for Acerta shareholders to sell, and AstraZeneca to buy, the remaining 45% of shares in Acerta. The final condition for these options to be exercised was satisfied in November 2020 when *Calquence* received EU marketing authorisation. AstraZeneca exercised its option to acquire the remaining 45% of shares in Acerta in April 2021.

The agreement initially provided that the remaining 45% of shares in Acerta would be acquired at a price of approximately $3bn net of certain costs and payments incurred by AstraZeneca and net of agreed future adjusting items, using a pre-agreed pricing mechanism. In October 2019, an amendment agreement came into effect which was disclosed as part of year-to-date and Q3 2019 results, changing the timing of payments and reducing the maximum consideration required to be made to acquire the remaining outstanding shares of Acerta if the options were exercised. The payments are to be made in similar annual instalments in 2022, 2023 and 2024. The changes to the terms were reflected in the assumptions that were used to calculate the amortised cost of the option liability as of 31 March 2021 of $2,336m.

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

a) Access to healthcare
AstraZeneca and its sublicensee, Serum Institute of India Pvt. Ltd. (SII), delivered over 48 million doses of its pandemic COVID-19 vaccine to more than 120 countries through COVAX[11], the multilateral facility co-led by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations, and the World Health Organization (WHO), with c.80% of the doses going to low and middle-income countries.

b) Environmental protection
During the period, the Company was recognised for its leadership in building sustainable business models, as one of the top 7% of companies on CDP's 2020 Supplier Engagement Rating Leaderboard. By working with suppliers to reduce their emissions, AstraZeneca is helping to drive science-based climate action across the value chain, a key component of the Company's Ambition Zero Carbon strategy.

c) Ethics and transparency

The Company released its seventh annual Sustainability Report and Sustainability Data Summary via its website and social media. The report was released in conjunction with the Annual Report and Form 20-F Information 2020. The report outlined progress and challenges and aims for the future.

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

Notes

The following notes refer to pages one to five.

1. Constant exchange rates. These are financial measures that are not accounted for according to generally accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.
2. Not meaningful.
3. *Total revenue ex. pandemic vaccine* is a non-GAAP measure, which excludes the revenue impact from sales of the pandemic COVID-19 vaccine during the pandemic period to help facilitate a comparison to guidance.
4. Reported financial measures are the financial results presented in accordance with UK and EU-adopted International Financial Reporting Standards (IFRSs), and IFRS as issued by the International Accounting Standards Board (IASB).
5. Earnings per share.
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. *Tagrisso*, *Imfinzi*, *Lynparza*, *Calquence*, *Enhertu*, *Koselugo*, *Farxiga*, *Brilinta*, *Lokelma*, roxadustat, *Fasenra*, *Bevespi* and *Breztri*. The new medicines are pillars in the three disease areas (formally referred to as Therapy Areas) of Oncology, Cardiovascular (CV), Renal & Metabolism (CVRM), and R&I and are important platforms for future growth.
8. New CVRM comprises *Brilinta*, Renal and Diabetes medicines.
9. Gross Profit is defined as Total Revenue minus Cost of Sales. The calculation of Reported and Core Gross Profit Margin excludes the impact of Collaboration Revenue and any associated costs, thereby reflecting the underlying performance of Product Sales.
10. 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.
11. 18.4 million doses of AstraZeneca's pandemic COVID-19 vaccine and 29.9 million of SII's Covidshield vaccine.
12. COVID-19 Vaccines Global Access (COVAX) is a coalition co-led by CEPI, the Coalition for Epidemic Preparedness Innovations, Gavi, the Vaccine Alliance (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.

Table 6: Pipeline highlights

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

Regulatory approval or other regulatory action	- *Tagrisso* - adjuvant NSCLC[13] (EGFRm[14]): approval (CN) - *Tagrisso* - adjuvant NSCLC (EGFRm): positive opinion (EU) - *Imfinzi* - bladder cancer (2nd line): indication voluntarily withdrawn (US) - *Koselugo* - NF1[15]: positive opinion (EU)
Regulatory submission acceptance and/or submission	- *Lynparza* - breast cancer (BRCAm[16]): submission voluntarily withdrawn (CN) - *Brilique* - CAD[17]/T2D[18] CVOT[19]: submission voluntarily withdrawn (EU, CN)
Major Phase III data readout or other significant development	- *Lynparza* - adjuvant breast cancer (BRCAm): Phase III primary endpoint met - *Farxiga* - COVID-19: Phase III primary endpoint not met - roxadustat - anaemia in CKD[20]: delay in regulatory decision due to convening of advisory committee (US) - nirsevimab - RSV[21]: Phase III primary endpoint met - COVID-19 vaccine - COVID-19: Phase III primary endpoint met (US trial)

[13] Non-small cell lung cancer.
[14] Epidermal growth factor receptor mutation.
[15] Neurofibromatosis type 1, a genetic condition causing tumours to grow along nerves in the skin, brain, and other parts of the body.
[16] Breast cancer susceptibility gene 1/2 mutation.
[17] Coronary artery disease.
[18] Type-2 diabetes.
[19] CV outcome trial.
[20] Chronic kidney disease.
[21] Respiratory syncytial virus.

Table 7: Pipeline anticipated major news flow

Timing	News flow
H1 2021	- *Tagrisso* - adjuvant NSCLC (EGFRm): regulatory decision (EU) - *Imfinzi* +/- treme - NSCLC (1st line) (POSEIDON): data readout (OS[22]) - *Calquence* - CLL[23] (R/R[24]) (ELEVATE R/R): regulatory submission - *Koselugo* - NF1 regulatory decision (EU) - *Farxiga* - CKD: regulatory decision (US) - *Symbicort* - mild asthma: regulatory decision (EU) - *Fasenra* - nasal polyps[25]: regulatory submission - tezepelumab - severe asthma: regulatory submission - COVID-19 vaccine - COVID-19: regulatory submission (US, JP) - AZD7442 - SARS-CoV-2: data readout, regulatory submission
H2 2021	- *Imfinzi* - unresectable[26], Stage III NSCLC (PACIFIC-2): data readout, regulatory submission - *Imfinzi* - NSCLC (1st line) (PEARL): data readout - *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): regulatory decision (CN) - *Lynparza* - prostate cancer (1st line, castration-resistant): data readout, regulatory submission - *Enhertu* - breast cancer (2nd line, HER2+[27]): data readout[28], regulatory submission - *Forxiga* - CKD: regulatory decision (EU, JP, CN) - *Farxiga* - HF (HFpEF[29]): data readout - *Brilique* - stroke (THALES): regulatory decision (EU, CN) - roxadustat - anaemia in CKD: regulatory decision (US) - PT027 - asthma: data readout - anifrolumab - lupus (SLE[30]): regulatory decision (US, EU, JP) - nirsevimab - RSV (MEDLEY): data readout

[22] Overall survival.
[23] Chronic lymphocytic leukaemia, the most common type of leukaemia in adults.
[24] Relapsed/refractory.
[25] Benign soft growths inside the nose.
[26] The tumour cannot be removed completely through surgery.
[27] Human epidermal growth factor receptor 2 positive.
[28] Based on a planned interim analysis as communicated by Daiichi Sankyo in Q2 of their fiscal year 2021.
[29] HF with preserved ejection fraction.
[30] Systemic lupus erythematosus, a chronic autoimmune disease that causes inflammation in connective tissues throughout the body.

Timing	News flow
2022	- *Imfinzi* - NSCLC (1st line) (PEARL): regulatory submission - *Imfinzi* - ES-SCLC[31]: regulatory decision (CN) - *Imfinzi* - LS-SCLC[32]: 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): data readout, regulatory submission - *Enhertu* - breast cancer (HER2 low): data readout, regulatory submission - *Calquence* - CLL: regulatory submission (CN) - *Koselugo* - NF1: regulatory submission (JP, CN) - *Farxiga* - HF (HFpEF): regulatory submission - roxadustat - MDS[33]: data readout, regulatory submission - PT027 - asthma: regulatory submission - nirsevimab - RSV: regulatory submission

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

Reporting calendar
The Company intends to publish its half-year and second-quarter results on Thursday 29 July 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 in Oncology and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts
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[31] Extensive-stage small cell lung cancer.
[32] Limited-stage small cell lung cancer.
[33] Myelodysplastic syndrome.

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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 three-month period to 31 March 2021 (the quarter or Q1 2021) compared to the three-month period to 31 March 2020 (Q1 2020) respectively, unless stated otherwise.

Forward-looking statements in this announcement do not reflect the impact of the performance of AstraZeneca's COVID-19 vaccine 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 Interim Financial Statements. Management believes that these non-GAAP financial measures, when provided in combination with Reported results, will provide investors and analysts with helpful supplementary information to understand better the financial performance and position of the Group on a comparable basis from period to period. These non-GAAP financial measures are not a substitute for, or superior to, financial measures prepared in accordance with GAAP. Core financial measures are adjusted to exclude certain significant items, such as:

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

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

- Other specified items, principally comprising the Diabetes alliance[34], 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 84 of the Annual Report and Form 20-F Information 2020. Reference should be made to the Reconciliation of Reported to Core financial measures table included in the financial performance section in this announcement.

Total revenue ex. pandemic vaccine is a new non-GAAP financial measure introduced in the current period to enable management to explain the financial impact of the COVID-19 vaccine on the Group's Total revenue.

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 Interim Financial Statements in this announcement.

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

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

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

[34] 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.

Total Revenue

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

Table 8: Q1 2021 - Total Revenue by disease area

Specialty-care medicines comprise all Oncology medicines, *Brilinta*, *Lokelma*, roxadustat and *Fasenra*. At 51% of Total Revenue (Q1 2020: 49%), specialty-care medicines increased by 19% in the year (15% at CER) to $3,732m.

	$m	% of total	Actual % change	CER % change
Oncology	3,024	41	20	16
BioPharmaceuticals	2,852	39	7	4
- New CVRM	*1,306*	*18*	*19*	*15*
- R&I	*1,546*	*21*	*(1)*	*(4)*
Other medicines	1,169	16	(1)	(4)
COVID-19	275	4	n/m	n/m
Total Revenue	**7,320**	**100**	**15**	**11**
- Less pandemic COVID-19 vaccine	275	4	n/m	n/m
Total Revenue ex. pandemic vaccine	7,045	96	11	7

Table 9: Q1 2021 - Disease area and medicine performance

	$m	% of total	Actual % change	CER % change
Oncology	**2,981**	**41**	**19**	**15**
- Tagrisso	1,149	16	17	13
- Imfinzi	556	8	20	17
- Lynparza	543	7	37	33
- Calquence	209	3	n/m	n/m
- Koselugo	21	-	n/m	n/m
- Enhertu	1	-	n/m	n/m
- Zoladex[35]	221	3	(1)	(6)
- Faslodex[35]	122	2	(26)	(30)
- Iressa[35]	61	1	(21)	(26)
- Arimidex[35]	44	1	(12)	(15)
- Casodex[35]	42	1	-	(6)
- Others	12	-	(12)	(12)
BioPharmaceuticals: CVRM	**1,912**	**26**	**12**	**9**
- Farxiga	624	9	54	50
- Brilinta	374	5	(8)	(11)
- Bydureon	103	1	3	1
- Onglyza	101	1	(28)	(31)
- Byetta	16	-	(20)	(20)
- Other diabetes	13	-	3	(1)
- Roxadustat	39	1	n/m	n/m
- Lokelma	33	-	n/m	n/m
- Crestor[35]	274	4	(9)	(12)
- Seloken/Toprol-XL[35]	250	3	41	36
- Atacand[35]	34	-	(48)	(49)
- Others	51	1	(13)	(16)
BioPharmaceuticals: R&I	**1,541**	**21**	**(1)**	**(5)**
- Symbicort	691	9	(13)	(15)
- Pulmicort	330	5	(13)	(18)
- Fasenra	260	4	31	27
- Daliresp/Daxas	60	1	14	12

[35] Legacy medicine.

- *Breztri*	27	-	n/m	n/m
- *Bevespi*	13	-	8	5
- Others	160	2	42	33
Other medicines	**548**	**7**	**(2)**	**(5)**
- *Nexium*[35]	403	6	19	15
- *Synagis*[35]	24	-	(72)	(72)
- *Losec/Prilosec*[35]	54	1	1	(5)
- *Seroquel XR*/IR[35]	29	-	(20)	(22)
- *FluMist*[35]	2	-	n/m	n/m
- Others	36	-	(19)	(20)
COVID-19	**275**	**4**	**n/m**	**n/m**
Pandemic COVID-19 vaccine	275	4	n/m	n/m
Product Sales	**7,257**	**99**	**15**	**11**
Collaboration Revenue	**63**	**1**	**43**	**42**
Total Revenue	**7,320**	**100**	**15**	**11**
Total Revenue ex. pandemic vaccine	7,045	96	11	7

Table 10: Q1 2021 - Collaboration Revenue

	$m	**% of total**	**Actual % change**	**CER % change**
Enhertu: share of gross profits	38	60	n/m	n/m
Roxadustat: share of gross profits	2	3	(16)	(23)
Other Ongoing Collaboration Revenue	23	37	(19)	(20)
Total	**63**	**100**	**43**	**42**

Other Collaboration Revenue included *Zoladex*, *Farxiga*, *Eklira*, *Nexium* OTC[36] and other royalties. No Initial Collaboration Revenue was recorded in the quarter.

Total Revenue summary

Oncology

Total Revenue of $3,024m in the quarter; an increase of 20% (16% at CER). Oncology represented 41% of overall Total Revenue (Q1 2020: 40%).

Tagrisso
Tagrisso has received regulatory approval in 17 countries, including the US and China, for use as an adjuvant treatment of EGFRm NSCLC patients, with four 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 89 countries, including the US, China, in the EU and Japan. To date, 43 reimbursements have been granted in this setting, with further decisions anticipated. These developments followed *Tagrisso*'s regulatory approval in 91 countries, including the US, China, in the EU and Japan, to treat patients with EGFR T790M[37] NSCLC, an indication in which 67 reimbursements have been granted.

Total Revenue, entirely comprising Product Sales, amounted to $1,149m in the quarter and represented growth of 17% (13% at CER). Sales in the US increased by 12% to $415m following the US Food and Drug Administration (FDA) approval in 2020 for the adjuvant treatment of Stage IB to IIIA EGFRm NSCLC patients, despite the decrease in lung cancer diagnoses observed due to the impact of the COVID-19 pandemic.

Tagrisso sales in Emerging Markets increased by 9% in the quarter (5% at CER) to $306m; the performance was adversely impacted, however, due to the one-time effects of admission to the China NRDL in March 2021 for the 1st-line setting and the renewal in the 2nd-line setting, respectively. Japan increased by 12% (7% at

[36] Over the counter.
[37] Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.

CER) to $172m. In Europe, sales of $225m in the quarter represented an increase of 39% (26% at CER), driven by greater adoption in the 1st-line setting, as more reimbursements were granted.

Imfinzi
Imfinzi has received regulatory approval in 71 countries, including the US, China, in the European Union (EU) and Japan, with 34 reimbursements granted. *Imfinzi* is approved to treat patients with unresectable Stage III NSCLC, whose disease has not progressed following platinum-based chemoradiation therapy (CRT). *Imfinzi* has also been approved to treat ES-SCLC patients in 53 countries, with eight reimbursements granted.

Total Revenue, entirely comprising Product Sales, amounted to $556m in the quarter and represented growth of 20% (17% at CER), predominantly for the treatment of unresectable, Stage III NSCLC patients. The US increased by 2% to $292m, despite the COVID-19 related decrease in lung cancer diagnosis. In Japan, growth of 46% (39% at CER) represented sales of $82m. Europe increased by 46% (32% at CER) to $109m, reflecting a growing number of reimbursements. Sales in Emerging Markets increased to $58m, representing a growth of 74% (69% at CER) following recent regulatory approvals and launches, including in China.

Lynparza
Lynparza has received regulatory approval in 81 countries for the treatment of ovarian cancer; it has also been approved in 79 countries for the treatment of metastatic breast cancer, and in 59 countries for the treatment of pancreatic cancer. *Lynparza* has received regulatory approval in 55 countries for the 2nd-line treatment of certain prostate-cancer patients.

Total Revenue, entirely comprising Product Sales in the quarter, amounted to $543m, reflecting growth of 37% (33% at CER). The strong performance was geographically spread, with further launches across multiple cancer types continuing globally. US Product Sales increased by 28% to $253m, as the launches in prostate cancer and 1st-line HRD+ ovarian cancer continued to take effect. *Lynparza* remained the leading medicine in the poly ADP ribose polymerase-inhibitor (PARPi) class, as measured by total prescription volumes. Product Sales in Europe increased by 46% (33% at CER) to $149m, reflecting additional reimbursements and increasing BRCAm-testing rates, as well as successful recent 1st-line BRCAm ovarian and homologous recombination repair gene mutation (HRRm) prostate cancer launches.

Japan Product Sales of *Lynparza* amounted to $42m, representing growth of 23% (17% at CER). Emerging Markets Product Sales were $87m, up by 54%. In China, *Lynparza* was admitted to the NRDL as a 1st-line treatment for BRCAm ovarian cancer patients with effect from March 2021.

Enhertu
Total Revenue, predominately comprising Collaboration Revenue recorded, amounted to $40m in the quarter. Global sales amounted to $81m in the quarter (ex. Japan). US sales, recorded by Daiichi Sankyo Company Limited (Daiichi Sankyo), amounted to $73m. *Enhertu* was approved at the end of 2019 by the US FDA to treat 3rd-line HER2+ breast cancer.

Calquence
Total Revenue, entirely comprising Product Sales, amounted to $209m in the quarter and represented growth of 138% (137% at CER), with the overwhelming majority of sales in the US; the performance benefitted from increased front-line use. The US FDA approved *Calquence* for the treatment of CLL in November 2019. In total, *Calquence* has received regulatory approvals for this indication in 61 countries and 28 countries for the treatment of patients with R/R mantle cell lymphoma.

Koselugo
Total Revenue, entirely comprising Product Sales in the US, amounted to $21m in the quarter, following its launch during the second quarter of 2020 to treat the rare disease NF1 in paediatric patients aged two years and older who have symptomatic, inoperable plexiform neurofibromas (PN).

Zoladex
Total Revenue, predominantly comprising Product Sales, amounted to $226m in the quarter and represented a decrease of 1% (5% at CER).

Emerging Markets Product Sales of *Zoladex* decreased by 8% (11% at CER) to $136m. Product Sales in Europe increased by 6% (declined by 2% at CER) to $37m while, in the Established Rest of World (RoW) region, Product Sales increased by 11% (4% at CER) to $43m.

Faslodex
Total Revenue, entirely comprising Product Sales, amounted to $122m in the quarter and represented a decline of 26% (30% at CER) following the launch of several generic versions of the medicine.

Emerging Markets fell by 12% (13% at CER) to $43m, while US sales declined by 60% to $9m; in Europe, sales fell by 35% (41% at CER) to $41m. In Japan, sales declined by 3% (8% at CER) to $28m, driven by a mandated price reduction in 2020.

Iressa
Total Revenue, entirely comprising Product Sales, amounted to $61m in the quarter and represented a decline of 21% (26% at CER). Emerging Markets fell by 15% (20% at CER) to $53m, driven by the impact of *Iressa*'s inclusion in China's VBP programme and subsequent price reduction.

BioPharmaceuticals: CVRM

Total Revenue increased by 12% in the quarter (9% at CER) to $1,916m and represented 26% of Total Revenue (Q1 2020: 27%).

New CVRM Total Revenue, which excludes *Crestor* and other legacy medicines' sales, increased by 19% in the year (15% at CER) to $1,306m, mainly reflecting the strong performance of *Farxiga*. New CVRM represented 68% of overall CVRM Total Revenue in the quarter (Q1 2020: 65%).

Farxiga
Total Revenue, predominantly comprising Product Sales, amounted to $625m in the quarter and represented growth of 54% (50% at CER), reflecting volume growth across the regions; *Farxiga* grew faster than the overall SGLT2 class in the majority of markets.

Emerging Market sales increased by 84% (85% at CER) to $260m in the quarter. The performance reflected the addition of *Forxiga* to the Chinese NRDL in 2020; the initial price impact has been more than offset by increased access for patients.

In the US, Product Sales increased by 16% to $131m, benefitting from the recent regulatory approval to treat patients with heart failure with reduced ejection fraction (HFrEF) with and without T2D.

Product Sales in Europe increased by 50% (36% at CER) to $174m in the quarter, partly reflecting growth in the sodium-glucose co-transporter-2 inhibitor class, the beneficial addition of CVOT data to the label and the recent HFrEF regulatory approval in November 2020. In Japan, sales to collaborator Ono Pharmaceutical Co., Ltd, which records in-market sales, increased by 152% (140% at CER) to $32m.

Brilinta
Total Revenue, entirely comprising Product Sales, amounted to $374m in the quarter, representing a decline of 8% (11% at CER). Global demand continued to be adversely impacted by COVID-19, reflected in fewer acute coronary syndrome hospital admissions and lower demand, particularly in China. The performance in China, was also affected following VBP in 2020, where the Company chose not to participate further in the bidding process.

Emerging Markets sales declined by 22% (23% at CER) to $105m, driven by the aforementioned VBP impact. In the US, sales increased by 1% to $166m with an increase in the average weighted duration of treatment partly offset by the adverse effects of COVID-19, reflected in fewer elective procedures. Sales of *Brilique* in Europe declined by 6% (14% at CER) to $88m in the quarter, with the performance similarly impacted by COVID-19.

Onglyza
Total Revenue, entirely comprising Product Sales, amounted to $101m in the quarter and represented a decline of 28% (31% at CER). Sales in Emerging Markets, however, increased by 22% (19% at CER) to $58m, driven by China's performance and the growing domestic DPP-4[38] class. US sales of *Onglyza* fell by 72% in the year

[38] Dipeptidyl peptidase 4.

to $19m, while Europe sales increased by 1% (declined by 8% at CER) to $15m, highlighting the shift away from the class.

Bydureon
Total Revenue, entirely comprising Product Sales, amounted to $103m in the quarter, representing a growth of 3% (1% at CER).

US sales of $85m reflected an increase of 1% in the quarter. Sales in Europe increased by 24% (14% at CER) to $15m.

Lokelma
Total Revenue, comprising Product Sales, amounted to $33m in the quarter (Q1 2020: $11m), an increase of 204% (200% at CER), despite the adverse impact of COVID-19 on market growth. 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 countries to treat hyperkalaemia, including in the EU, China and Japan, with further launches anticipated.

Roxadustat
Total Revenue in China, predominantly comprising Product Sales, amounted to $41m in the quarter. From January 2021, AstraZeneca started recognising the overwhelming majority of China's revenue as Product Sales following an amendment to the existing licence agreement entered into in July 2020.

Crestor
Total Revenue, primarily comprising Product Sales, amounted to $274m in the quarter and represented a decline of 9% (12% at CER).

In Emerging Markets, sales fell by 1% (4% at CER) to $189m. The performance continued to be adversely impacted by China's VBP programme's ongoing effects. US sales declined by 22% to $22m. In Europe, sales decreased by 39% (43% at CER) to $21m while, in Japan, where AstraZeneca collaborates with Shionogi Co., Ltd, sales declined by 9% (13% at CER) to $31m.

In February 2021, AstraZeneca announced that it had completed an agreement to sell the rights to *Crestor* in over 30 countries in Europe except the UK and Spain to Grünenthal GmbH (Grünenthal).

BioPharmaceuticals: Respiratory & Immunology

Total Revenue, which included Ongoing Collaboration Revenue of $5m from *Duaklir*, *Eklira* and other medicines, declined by 1% in the quarter (4% at CER) to $1,546m and represented 21% of Total Revenue (Q1 2020: 24%). The adverse impact of the decline of *Pulmicort* sales reduced Respiratory & Immunology Total Revenue growth by four percentage points. In addition, stocking of respiratory medicines due to COVID-19 and an inventory build for the authorised generic version of *Symbicort* in the US by the Company's collaborator Prasco LLC (Prasco) in Q1 2020, both adversely impacted the performance comparison in the quarter.

Symbicort
Total Revenue, entirely comprising Product Sales, amounted to $691m in the quarter and represented a decrease of 13% (15% at CER). The performance relative to Q1 2020 predominately reflected the aforementioned impact of stocking of an authorised generic version of *Symbicort* in the US during Q1 2020 and phasing of COVID-19 impacts. *Symbicort* remains the global market-volume and value leader within the inhaled corticosteroid (ICS) / long-acting beta-agonist (LABA) class. The global ICS/LABA class growth developed slower, particularly in the US, due to the impact of COVID-19 on the diagnosis of respiratory diseases, lower levels of respiratory symptoms, and reduced use of medicines.

US sales fell by 14% in the quarter to $266m due to the stocking effects. In March 2021, the US District Court for the Northern District of West Virginia decided in favour of AstraZeneca and determined that the asserted patent claims by Mylan Pharmaceuticals Inc. (Mylan) and Kindeva Drug Delivery L.P., were not invalid or unenforceable.

Emerging Markets sales increased by 6% (3% at CER) to $165m. In Europe, sales decreased by 14% (21% at CER) in the quarter to $168m. Sales in Japan declined by 44% (47% at CER) to $31m in the quarter, the

performance predominately reflected the ongoing adverse impact of generic competition and an unfavourable price comparison due to the termination of the co-promotion agreement by Astellas Pharma Inc.

Pulmicort
Total Revenue, entirely comprising Product Sales, amounted to $330m in the quarter and represented a decline of 13% (18% at CER), as the continued effects of COVID-19 impacted the hospital treatment of respiratory patients.

Emerging Markets, where *Pulmicort* sales fell by 9% (14% at CER) in the quarter to $286m, represented 87% of the global total. Alongside the effects of COVID-19, the performance in China continued to be impacted by a reduction in the number of paediatric patients attending outpatient nebulisation rooms and an increasing number of generic versions of *Pulmicort*.

Sales in the US declined by 25% in the quarter to $17m, due to the fall in the use of *Pulmicort Respules*. In Japan, sales declined by 47% (49% at CER) to $5m as a result of generic competition and fell in Europe by 37% (43% at CER) to $16m.

Fasenra
Total Revenue, entirely comprising Product Sales, increased by 31% (27% at CER) to $260m in the quarter. The performance reflected growing demand, despite the impact of COVID-19 on the level of new-patient starts in several countries. *Fasenra* remained the leading novel biologic in most markets in the new-to-brand prescription share for patients with severe, uncontrolled asthma.

Sales in the US grew by 30% in the quarter to $156m due to increased demand and patient adherence seen using the *Fasenra Pen* home administration device. This performance, however, was again partly offset by the continuing and adverse effect of COVID-19. In Europe, sales of $63m represented an increase of 37% (25% at CER); the benefit of ongoing launches and additional reimbursement was offset by a decline in the dynamic market due to COVID-19 restrictions. Sales in Japan increased by 25% (19% at CER) to $26m due to increased demand and a partial recovery in the treatment naïve market. in Emerging Markets, sales decreased 51% (47% at CER) to $3m.

Daliresp/Daxas
Total Revenue, entirely comprising Product Sales, amounted to $60m in the quarter and represented an increase of 14% (12% at CER). US sales increased by 20% to $54m.

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 nine countries.

Total Revenue, entirely comprising Product Sales, amounted to $27m in the quarter (Q1 2020: $4m). Sales in the US amounted to $12m (Q1 2020: $nil), with an encouraging 20% market share in new patient starts. Sales in Japan amounted to $5m (Q1 2020: $1m). In Europe, under the name *Trixeo*, sales amounted to $1m in the quarter (Q1 2020: $nil). Emerging Markets sales amounted to $9m in the quarter (Q1 2020: $4m). Following inclusion into the China NRDL with effect from March 2021, the number of patients that have access to *Breztri* in China has significantly increased.

Other medicines (outside the main disease areas)

Total Revenue, primarily comprising Product Sales, amounted to $559m in the quarter, a decline of 3% (6% at CER). Other medicines Total Revenue represented 8% of overall Total Revenue (Q1 2020: 9%).

Nexium
Total Revenue, predominantly comprising Product Sales, amounted to $409m in the quarter, an increase of 18% (13% at CER). Emerging Markets Product Sales of *Nexium* increased by 25% (21% at CER) to $234m in the quarter, reflecting an increase in *Nexium* initiation in the hospital setting in China, as patients underwent colonoscopy procedures that had been delayed by the pandemic.

China concluded another round of the VBP-programme in February 2021, including *Nexium* (oral). The Company, however, having submitted an initial price, chose not to participate further in the bidding process and consequently accepted a mandatory price reduction of 10%.

In Japan, where AstraZeneca collaborates with Daiichi Sankyo, Product Sales increased by 37% (30% at CER) to $103m, due to phasing of orders from Daiichi Sankyo, while Product Sales in the US declined by 20% to $32m. In Europe, Product Sales decreased by 18% (26% at CER) to $18m.

In March 2021, AstraZeneca and Daiichi Sankyo announced that the two companies will end the joint sales promotion of *Nexium* in Japan on the 14 September 2021, after which date AstraZeneca will market, distribute, and promote *Nexium*.

Synagis
Total Revenue, entirely comprising Product Sales, amounted to $24m in the quarter, representing a decrease of 72%. Sales in Europe, wholly comprising sales to AbbVie Inc. (AbbVie) made under the current supply agreement for markets outside the US, amounted to $22m in the quarter, a decrease of 69% reflecting low levels of RSV infections globally due to the impact of COVID-19, the phasing of orders from AbbVie and preparations for the reversion of commercial rights outside the US, held by AbbVie since 1997, to AstraZeneca upon the expiry of the current agreement on 30 June 2021.

COVID-19

COVID-19 vaccine
Total Revenue, entirely comprised of Product Sales, amounted to $275m in the quarter, reflecting the delivery of c.68 million[39] doses worldwide. Sales in Europe were $224m, Emerging Markets sales were $43m, and in Established RoW sales amounted to $8m.

Regional Total Revenue

A geographical split of Product Sales is shown in Note 7. For additional details, refer to Table 47: Ongoing Collaboration **Revenue** for Collaboration Revenue recognised during Q1 2021 and Q1 2020.

Table 11: Q1 2021 - Regional Total Revenue

	$m	% of total	Actual % change	CER % change
Emerging Markets	**2,592**	**35**	**14**	**10**
- China	*1,679*	*23*	*19*	*10*
- Ex-China	*913*	*12*	*6*	*11*
US	**2,310**	**32**	**10**	**10**
Europe	**1,546**	**21**	**28**	**18**
Established RoW	**872**	**12**	**11**	**5**
- Japan	*620*	*8*	*12*	*7*
- Canada	*156*	*2*	*-*	*(4)*
- Other Established RoW	*96*	*1*	*23*	*6*
Total	**7,320**	**100**	**15**	**11**

The performance in Europe benefitted from $224m of sales from the pandemic COVID-19 vaccine.

[39] The EU received c.30 million doses, the UK c.26 million doses, and Gavi and other countries received approximately seven and five million doses, respectively.

Table 12: Q1 2021 - Emerging Markets Total Revenue disease-area performance

	$m	% of total	Actual % change	CER % change
Oncology	**762**	**29**	**7**	**4**
BioPharmaceuticals	**1,014**	**39**	**16**	**13**
- New CVRM	*472*	*18*	*43*	*41*
- R&I	*542*	*21*	*-*	*(4)*
Other medicines	**773**	**30**	**12**	**8**
COVID-19	**43**	**2**	**n/m**	**n/m**
Total	**2,592**	**100**	**14**	**10**

Emerging Markets Total Revenue grew by 14% (10% at CER) to $2,592m in the quarter. New medicines represented 34% of Emerging Markets Total Revenue in the quarter (Q1 2020: 29%). Speciality-care medicines increased by 7% (3% at CER) to $912m and comprised 35% of Emerging Markets Total Revenue in the quarter (Q1 2020: 38%).

Table 13: Q1 2021 - Notable new medicine Total Revenue performances in Emerging Markets

	$m	% of total	Actual % change	CER % change
Tagrisso	306	12	9	5
Forxiga	260	10	84	85
Brilinta	105	4	(22)	(23)
Lynparza	87	3	54	54

China comprised 65% of Emerging Markets Total Revenue in the quarter and increased by 19% (10% at CER) to $1,679m. New medicines, primarily driven by *Tagrisso* in Oncology and *Forxiga* in New CVRM, delivered particularly encouraging growth and represented 31% of China Total Revenue (Q1 2020: 27%); strong sales of *Seloken*, *Nexium* and *Symbicort* supplemented this performance. The Total Revenue growth in the quarter, however, included an adverse impact of five percentage points (four at CER) from the reduced sales of *Pulmicort* which, restricted overall revenue growth in the quarter.

Table 14: Q1 2021 - Ex-China Emerging Markets Total Revenue

	$m	Actual % change	CER % change
Ex-China Emerging Markets	**913**	**6**	**11**
- Russia	77	(9)	7
- Brazil	79	(11)	12
- Ex-Brazil Latin America	107	(1)	8
- Ex-China Asia Pacific	324	4	-
- Middle East and Africa	326	23	26

Ex-China Emerging Markets Total Revenue, primarily comprising Product Sales, increased by 6% in the quarter (11% at CER) to $913m. New medicines represented 39% of ex-China Emerging Markets Total Revenue (Q1 2020: 32%), increasing by 26% (33% at CER) to $352m.

Financial performance

Table 15: Reported Profit and Loss

	Q1 2021 $m	Q1 2020 $m	Actual % change	CER % change
Total Revenue	**7,320**	**6,354**	**15**	**11**
- Product Sales	7,257	6,311	15	11
- Collaboration Revenue	63	43	43	42
Cost of Sales	(1,864)	(1,420)	31	25
Gross Profit	**5,456**	**4,934**	**11**	**7**
Gross Margin	*74.3%*	*77.5%*	*-3*	*-3*
Distribution Expense	(99)	(87)	14	8
% Total Revenue	*1.4%*	*1.4%*	-	-
R&D Expense	(1,713)	(1,388)	24	19
% Total Revenue	*23.4%*	*21.8%*	*-2*	*-2*
SG&A Expense	(2,929)	(2,719)	8	4
% Total Revenue	*40.0%*	*42.8%*	*+3*	*+3*
Other Operating Income & Expense	1,180	480	n/m	n/m
% Total Revenue	*16.1%*	*7.6%*	*+9*	*+9*
Operating Profit	**1,895**	**1,220**	**55**	**54**
Operating Profit Margin	*25.9%*	*19.2%*	*+7*	*+8*
Net Finance Expense	(283)	(281)	1	(1)
Joint Ventures and Associates	(4)	(4)	6	(1)
Profit Before Tax	**1,608**	**935**	**72**	**69**
Taxation	(46)	(185)	(75)	(76)
Tax Rate	3%	20%		
Profit After Tax	**1,562**	**750**	**n/m**	**n/m**
EPS	**$1.19**	**$0.59**	**100**	**97**

Table 16: Reconciliation of Reported Profit Before Tax to EBITDA

	Q1 2021 $m	Q1 2020 $m	Actual % change	CER % change
Reported Profit Before Tax	**1,608**	**935**	**72**	**69**
Net Finance Expense	283	281	1	(1)
Joint Venture and Associates	4	4	6	(1)
Depreciation, Amortisation and Impairment	797	841	(5)	(10)
EBITDA	**2,692**	**2,061**	**31**	**29**

Table 17: Reconciliation of Reported to Core financial measures

Q1 2021	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other	Core[40]	Core % change	
	$m	$m	$m	$m	$m	$m	Actual	CER
Gross Profit	**5,456**	**7**	**17**	**-**	**-**	**5,480**	**10**	**7**
Gross Profit Margin	*74.3%*					*74.6%*	*(3)*	*(3)*
Distribution Expense	(99)	-	-	-	-	(99)	14	8
R&D Expense	(1,713)	13	63	-	(1)	(1,638)	23	18
SG&A Expense	(2,929)	30	383	99	18	(2,399)	10	7
Total Operating Expense	(4,741)	43	446	99	17	(4,136)	15	11
Other Operating Income & Expense	1,180	-	1	-	(1)	1,180	n/m	n/m
Operating Profit	**1,895**	**50**	**464**	**99**	**16**	**2,524**	**36**	**34**
Operating Profit Margin	*25.9%*					*34.5%*	*+5*	*+6*
Net Finance Expense	(283)	-	-	49	47	(187)	11	16
Taxation	(46)	(10)	(101)	(31)	(2)	(190)	(43)	(44)
EPS	**$1.19**	**$0.03**	**$0.27**	**$0.09**	**$0.05**	**$1.63**	**55**	**53**

Profit and Loss summary

a) Gross Profit

The increases in Reported and Core Gross Profit by 11% (7% at CER) and 10% (7% at CER), respectively, reflected the 15% (11% at CER) growth in Product Sales. The Reported Gross Profit Margin declined by three percentage points to 74.3%, and the Core Gross Profit Margin declined by three percentage points in the quarter to 74.6%. The performance predominantly reflected the significant impact of equitable supply, at no profit to AstraZeneca, of the pandemic COVID-19 vaccine, together with an increasing contribution from profit-sharing arrangements, primarily *Lynparza*, and the impact of the Chinese National Reimbursement Drug List (NRDL) and the volume-based procurement (VBP) patient-access programmes. A higher proportion of Oncology sales and increasing patient access in China partially offsets these impacts. These variations in gross margin performance between quarters can be expected to continue.

b) Total Operating Expense

Reported Total Operating Expense increased by 13% (9% at CER) to $4,741m and represented 65% of Total Revenue (Q1 2020: 66%). Core Total Operating Expense increased by 15% (11% at CER) to $4,136m and comprised 57% of Total Revenue (Q1 2020: 57%).

The increases in Reported and Core R&D Expense primarily reflected investment in Phase III and the advancement to Phase II of several clinical development programmes, particularly in BioPharmaceuticals. The Company continued to invest in its COVID-19 vaccine and potential medicines for the prevention and treatment of COVID-19, including other related costs, such as personal protective equipment and colleague COVID-19 testing across the Company. In the quarter, grant income of $270m has been recognised, of which $209m has been offset against the US Clinical trial costs for AZD1222.

[40] 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.

Reported and Core SG&A Expense grew primarily due to additional select investment in new medicine launches and the Company's continued expansion in China.

c) Other Operating Income and Expense

Reported and Core Other Operating Income and Expense of $1,180m reflected an increase of 146% (145% at CER) and 147% (146% at CER), respectively and included:

- Income from the divestment of AstraZeneca's 26.7% share of Viela as part of the acquisition by Horizon Therapeutics plc. AstraZeneca received cash proceeds and profit of $776m upon closing with the profit being recorded as other operating income

- $309m of income from an agreement with Grünenthal to divest commercial rights to *Crestor* in over 30 countries in Europe, except in the UK and Spain

d) Net Finance Expense

Reported Net Finance Expense increased by 1% (declined 1% at CER) in the quarter to $283m reflecting lower interest rates on cash, cash equivalents and other current investments and was partially offset by lower discount unwind costs on acquisition-related liabilities, including the Diabetes Alliance. The 11% (16% at CER) increase in Core Finance Expense was driven by the aforementioned lower interest rates.

e) Taxation

The Reported Tax Rate for the quarter was 3% (Q1 2020: 20%), and the Core Tax Rate was 8% (Q1 2020: 20%). These tax rates benefitted from the following one-off favourable impacts:

- Non-taxable gain on the divestment of the investment in Viela

- Reduction of tax liabilities arising from updates to estimates of prior period tax liabilities following settlements with tax authorities

Excluding these benefits, the Reported and Core Tax Rates would have been c.20%, within the indication provided for 2021.

The net cash tax paid for the quarter was $332m (Q1 2020: $477m), representing 21% of Reported Profit Before Tax (Q1 2020: 51%).

In its Spring Budget, the UK Government has announced that UK Corporation Tax will increase from 19% to 25% from 1 April 2023. It is anticipated that this will be substantively enacted during Q2 2021, which will result in a tax charge during that quarter arising from the recalculation of deferred tax balances to the 25% tax rate.

f) EPS

Reported EPS of $1.19 in the quarter represented an increase of 100% (97% at CER); Core EPS increased by 55% (53% at CER) to $1.63.

Table 18: Cash Flow

	Q1 2021 $m	Q1 2020 $m	Change $m
Reported Operating Profit	1,895	1,220	675
Depreciation, Amortisation and Impairment	797	841	(44)
Decrease/(increase) in Working Capital and Short-Term Provisions	1,210	(445)	1,655
Gains on Disposal of Intangible Assets	(310)	(358)	48
Gains on Disposal of Investments in Associates and Joint Ventures	(776)	-	(776)
Non-Cash and Other Movements	(363)	(462)	99
Interest Paid	(187)	(180)	(7)
Taxation Paid	(332)	(477)	145
Net Cash Inflow from Operating Activities	**1,934**	**139**	**1,795**
Net Cash Inflow before Financing Activities	**2,489**	**148**	**2,341**
Net Cash Outflow from Financing Activities	**(2,731)**	**(2,362)**	**(369)**

The increase in Net Cash Inflow from Operating Activities of $1,795m was primarily driven by the decrease in working capital, of which $996m related to the movement in pandemic COVID-19 vaccine working capital balances within trade and other payables, trade and other receivables and inventories.

The increase in Net Cash Inflow before Financing Activities of $2,341m was a result of the aforementioned improvement in Net Cash Inflow from Operating Activities, as well as cash proceeds received of $776m from the divestment of AstraZeneca's 26.7% shareholding in Viela.

Capital Expenditure
Capital Expenditure amounted to $220m in the quarter, compared to $186m in Q1 2020. 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 several limited-sized projects.

Table 19: Net Debt summary

	At 31 Mar 2021 $m	At 31 Dec 2020 $m	At 31 Mar 2020 $m
Cash and cash equivalents	7,636	7,832	3,413
Other investments	129	160	804
Cash and investments	**7,765**	**7,992**	**4,217**
Overdrafts and short-term borrowings	(581)	(658)	(691)
Lease liabilities	(680)	(681)	(653)
Current instalments of loans	(1,461)	(1,536)	(1,598)
Non-current instalments of loans	(17,410)	(17,505)	(15,634)
Interest-bearing loans and borrowings (Gross Debt)	**(20,132)**	**(20,380)**	**(18,576)**
Net derivatives	162	278	(54)
Net Debt	**(12,205)**	**(12,110)**	**(14,413)**

Net Debt of $12,205m represented an increase of $95m in the year to date.

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

During the three months, 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 20: Currency sensitivities

The Company provides the following currency-sensitivity information:

		Average Exchange Rates versus USD			Annual Impact of 5% Strengthening in Exchange Rate versus USD ($m)[41]	
Currency	**Primary Relevance**	**FY 2020[42]**	**YTD 2021[43]**	**% change**	**Product Sales**	**Core Operating Profit**
CNY	Product Sales	6.90	6.48	6	312	186
EUR	Product Sales	0.88	0.83	5	189	58
JPY	Product Sales	106.74	105.98	1	140	91
Other[44]					239	108
GBP	Operating Expense	0.78	0.73	7	31	(84)
SEK	Operating Expense	9.20	8.39	9	5	(59)

[41] Based on currency assumptions disclosed in the full-year 2020 results announcement.
[42] Based on average daily spot rates in FY 2020.
[43] Based on average daily spot rates from 1 January 2021 to 31 March 2021.
[44] Other currencies include AUD, BRL, CAD, KRW and RUB.

Sustainability

AstraZeneca's sustainability approach has three priority areas[45], aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

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

a) Access to healthcare

AstraZeneca and its sublicensees, including SII, delivered over 48 million doses of its pandemic COVID-19 vaccine to more than 110 countries through COVAX, the multilateral facility co-led by Gavi, the Coalition for Epidemic Preparedness Innovations, and the World Health Organization (WHO), with c.80% of the doses going to low and middle-income countries.

In April 2021, Chief Executive Officer Pascal Soriot joined Heads of State, Ministers and global leaders at the Gavi COVAX Advance Market Commitment investment opportunity to highlight AstraZeneca's commitment to broad and equitable access, and its collaboration with COVAX.

Following the Company's launch in November 2020 of the Partnership for Health System Sustainability and Resilience (PHSSR) 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. AstraZeneca co-led the first virtual PHSSR Summit held between 15-19 March 2021, which brought together over 50 leading experts from eight pilot countries, including Germany, France, the UK, Italy, Spain, Vietnam, Russia and Poland. Participants also included representatives from bodies such as The Organisation for Economic Co-operation and Development, the WHO, the World Heart Federation, and the International Society of Nephrology to discuss the future of health in a post-COVID-19 world. Over 1,200 people registered from more than 65 countries.

During the period, the Company's Healthy Heart Africa (HHA) programme expanded into the Republic of Côte d'Ivoire, its first French-speaking country of operation, signing a memorandum of understanding with the country's Ministry of Health. Since the programme launched in 2015, HHA has conducted over 17 million blood pressure screenings, identified over three million elevated readings, activated over 900 sites and trained over 7,600 healthcare workers and volunteers.

In March 2021, the Company's Young Health Programme (YHP) released its annual report. The report noted that in 2020, the programme directly delivered health information to more than one million youth, trained 55,000 peer educators and health professionals, engaged more than 1,300 employees as volunteers and expanded into six new countries. It also showcased the immediate contribution of its latest partner, UNICEF, and its focus on advocacy and policy change. Independent external evaluations of YHP completed in 2020 in Brazil, Indonesia, and Kenya found YHP's community-based delivery model and peer educator approach leads to sustained behaviour change among youth. The assessment also confirmed that when health services are more accessible to young people, they will use them more often and be more satisfied. Two new learning modules developed by UNICEF were launched, including substance abuse and air pollution, respectively.

b) Environmental protection

In April 2021, AstraZeneca launched an interactive EcoPharmacoVigiliance dashboard measuring potential environmental risks associated with patient use of the Company's life-saving medicines. The dashboard is part of the AstraZeneca's commitment to lead in the environmental safety of its medicines and respond to stakeholder concerns associated with pharmaceuticals in the environment. The dashboard collates published measured environmental concentrations of the active ingredients in AstraZeneca's products and presents data based on potential risk.

[45] 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'.

During the period, the Company was recognised for its leadership in building sustainable business models, as one of the top 7% of companies on CDP's 2020 Supplier Engagement Rating Leaderboard. By working with suppliers to reduce their emissions, AstraZeneca is helping to drive science-based climate action across the value chain, a key component of the Company's Ambition Zero Carbon strategy.

In March 2021, AstraZeneca published its first voluntary disclosure in line with the recommendations of the Taskforce on Climate-related Financial Disclosures (TCFD), describing its progress and actions as at 31 December 2020. All the Company's business operations worldwide are in scope unless otherwise stated. Full TCFD disclosure will be provided according to the UK's Financial Conduct Authority's enhanced listing rules, which promote better climate-related financial disclosures for UK premium-listed companies. The rule will apply for accounting periods beginning on or after 1 January 2021, meaning that AstraZeneca's first annual financial report to include TCFD would be published in spring 2022.

During the period, the Innovative Medicines Initiative (IMI) PREMIER project, in which the Company is a leading participant, launched a novel database and digital assessment system for characterising the environmental risks of medicines and making environmental data more visible and accessible to industry, academia, regulators and the public.

The company joined a new UK collaboration with CPI in the Medicines Manufacturing Innovation Centre that aims to revolutionise the development of new manufacturing processes for oligonucleotides (short DNA or RNA molecules) to achieve sustainable large scale manufacturing.

The Company was recognised by the UK Government in March 2021 as one of 30 FTSE 100 companies to have signed up to the United Nation's Race to Zero campaign – the largest ever global alliance committed to achieving net zero carbon emissions by 2050 at the latest - leading the way in the world's transition to a low carbon economy, as well as committing to align with UK government ambitions and eliminate their contribution to climate change by 2050.

In March 2021, the Company was also recognised in the BloombergNEF (BNEF) net zero research tool as achieving the top score for its Ambition Zero Carbon strategy, out of 400 of the largest corporations in heavy-emitting industries.

c) Ethics and transparency

The Company released its seventh annual Sustainability Report and Sustainability Data Summary via its website and social media. The report was released in conjunction with the Annual Report and Form 20-F Information 2020. The report outlined progress and challenges and aims for the future.

For more details on AstraZeneca's sustainability ambition, approach and targets, please refer to the latest Sustainability Report 2020 and Sustainability Data Summary 2020. Additional information is available within AstraZeneca's analyst interactive reporting centre or alternatively at astrazeneca.com/sustainability.

Research and development

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

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 21**: 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[46] - capivasertib - breast, prostate cancer - monalizumab - head & neck cancer - camizestrant - breast cancer - datopotamab deruxtecan - lung cancer **CVRM** - *Farxiga* - multiple indications - roxadustat - anaemia in CKD **Respiratory & Immunology** - *Fasenra* - multiple indications - *Breztri/Trixeo* - asthma - tezepelumab - severe asthma - PT027 - asthma - anifrolumab - lupus (SLE) - brazikumab - inflammatory bowel disease **Other** - nirsevimab - RSV **COVID-19** - COVID-19 vaccine - COVID-19 - AZD7442 - SARS-CoV-2
Total projects in clinical development	146	
Total projects in total pipeline	166	

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

Oncology

AstraZeneca shared an update on its innovative early oncology pipeline, across multiple strategic platforms, during the virtual American Association of Cancer Research Annual Meeting in early April 2021. Highlights included five presentations for AZD5305, a next-generation PARP1-selective inhibitor. Additionally, the Company also highlighted research across multiple presentations that showcased novel technologies, including myeloid gene expression. These technologies enable early detection of disease recurrence to inform earlier interventions for patients who are more likely to benefit from treatment.

a) *Tagrisso*

In April 2021, *Tagrisso* was recommended for marketing authorisation in the EU for the adjuvant treatment of adult patients with early-stage (IB, II and IIIA) EGFRm NSCLC after complete tumour resection with curative intent. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) based its positive opinion on results from the ADAURA Phase III trial.

During the period, *Tagrisso* received Chinese regulatory approval for the adjuvant treatment of patients with early-stage (IB, II and IIIA) EGFRm NSCLC after tumour resection with curative intent. The approval was based on the positive results from the ADAURA Phase III trial.

Table 22: Key *Tagrisso* Phase III trials

Trial (population)	Design	Timeline	Status
NeoADAURA (neo-adjuvant EGFRm NSCLC)	Placebo or *Tagrisso*	FPCD[47]: Q1 2021 First data anticipated: 2022+	Recruitment ongoing
ADAURA (adjuvant EGFRm NSCLC)	Placebo or *Tagrisso*	FPCD: Q4 2015 LPCD[48]: Q1 2019	Trial unblinded early due to overwhelming efficacy Regulatory approval (US, CN)
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

b) *Imfinzi*

In February 2021, in consultation with the US FDA, AstraZeneca announced the voluntary withdrawal of the *Imfinzi* indication in the US for previously treated adult patients with locally advanced or metastatic bladder cancer as the DANUBE Phase III trial did not confirm the efficacy observed from Study 1108, a single-arm Phase I/II trial, the basis for the US accelerated approval.

Table 23: Key *Imfinzi* Phase III trials in lung cancer

Trial (population)	Design	Timeline	Status
AEGEAN (neo-adjuvant NSCLC)	SoC[49] chemotherapy +/- *Imfinzi*, followed by surgery, followed by placebo or *Imfinzi*	FPCD: Q1 2019 First data anticipated: 2022+	Recruitment ongoing
ADJUVANT BR.31[50] (Stage IB-IIIA resected NSCLC)	Placebo or *Imfinzi*	FPCD: Q1 2015 LPCD: Q1 2020 First data anticipated: 2022+	Recruitment completed

[47] First patient commenced dosing.
[48] Last patient commenced dosing.
[49] Standard of Care.
[50] Conducted by the Canadian Cancer Trials Group.

Trial (population)	Design	Timeline	Status
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: H2 2021	Recruitment completed
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: H2 2021	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[51] 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 24: 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[52] or SoC BCG + *Imfinzi*	FPCD: Q4 2018 LPCD: Q3 2020 First data anticipated: 2022+	Recruitment completed
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[53])	TACE[54] 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

[51] Progression-free survival.
[52] Bacillus Calmette-Guerin.
[53] Hepatocellular carcinoma.
[54] Transarterial chemoembolisation.

Trial (population)	Design	Timeline	Status
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
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[55] (US)
TOPAZ-1 (Stage IV, 1st-line biliary-tract cancer)	Gemcitabine and cisplatin SoC chemotherapy or SoC + *Imfinzi*	FPCD: Q2 2019 LPCD: Q4 2020 First data anticipated: 2022	Recruitment completed

c) *Lynparza*

During the period, the Company announced that the OlympiA Phase III trial of *Lynparza* had demonstrated early efficacy. An independent data monitoring committee (IDMC) concluded that the trial crossed the superiority boundary for invasive disease-free survival versus placebo. The initial results demonstrated a sustainable, clinically relevant treatment effect for *Lynparza* versus placebo in patients with germline BRCA-mutated HER2-negative early breast cancer. As a result, the IDMC intends to move forward with an earlier than anticipated primary analysis. In China, the Company decided to voluntarily withdraw the *Lynparza* regulatory submission for BRCAm advanced breast cancer due to insufficient regional data from the OlympiAD Phase III trial.

Table 25: 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	Recruitment completed Early efficacy readout
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
DuO-O (advanced 1st-line ovarian cancer)	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + *Imfinzi* +/- *Lynparza* maintenance	FPCD: Q1 2019 First data anticipated: 2022+	Recruitment ongoing

[55] 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.

Trial (population)	Design	Timeline	Status
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

d) *Enhertu*

Table 26: Key *Enhertu* trials

Trial (population)	Design	Timeline	Status
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: 2022	Recruitment completed
DESTINY-Breast03-U302, Phase III (Stage IV, HER2+ 2nd-line 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 2nd-line breast cancer)	SoC chemotherapy or *Enhertu*	FPCD: Q4 2018 LPCD: Q4 2020 First data anticipated: 2022	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
DESTINY-Breast09, Phase III (Stage IV, HER2+ 1st-line breast cancer)	SoC chemotherapy trastuzumab + pertuzumab or *Enhertu* + pertuzumab or *Enhertu*	First data anticipated 2022+	Initiating
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-Gastric02, Phase II (Stage IV, HER2+ gastric cancer)	*Enhertu*	FPCD: Q4 2019 First data anticipated: H2 2021	Recruitment ongoing

During the period, the timelines for first data from the DESTINY-Breast02 and DESTINY-Breast04 Phase III trials, were updated from H2 2021 to 2022, respectively. These changes followed a conversion from initial event rate assumptions to actual observed event rates in the trials.

e) Camizestrant

Table 27: Camizestrant Phase III trials

Trial (population)	Design	Timeline	Status
SERENA-4 (ER+, HER2-, advanced breast cancer)	Palbociclib + anastrazole or palbociclib + camizestrant	FPCD: Q1 2021 First data anticipated: 2022+	Recruitment ongoing

f) Datopotamab deruxtecan

Table 28: Datopotamab deruxtecan Phase III trials

Trial (population)	Design	Timeline	Status
TROPION-LUNG01 (Stage IV, 2nd-line NSCLC)	SoC chemotherapy or datopotamab deruxtecan	First data anticipated: 2022+	Initiating

g) *Koselugo*

In April 2021, selumetinib was recommended for conditional marketing authorisation in the EU for the treatment of symptomatic, inoperable PN in paediatric patients with NF1 aged three years and above. The CHMP of the EMA based its positive opinion on results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Stratum 1 Phase II trial.

CVRM

a) *Brilinta*

During the period, AstraZeneca withdrew *Brilique*'s regulatory submissions, based on the THEMIS Phase III trial, for CAD in Europe and China to prevent against first heart attack or stroke. The THEMIS Phase III trial showed a statistically significant reduction in the primary composite endpoint of major adverse CV events at 36 months with aspirin plus *Brilinta* 60mg versus aspirin alone in patients with CAD and type-2 diabetes (T2D) at high risk of a first heart attack or stroke. The primary composite endpoint was driven by a reduction in heart attack and stroke, but these benefits were accompanied by an increased risk of bleeding. The US FDA approved *Brilinta* in June 2020 for the treatment of CAD based on the positive results from the THEMIS Phase III trial.

b) *Farxiga*

In April 2021, AstraZeneca and Saint Luke's Mid America Heart Institute announced high-level results of the primary analysis from the DARE-19 Phase III trial, which assessed the potential of the medicine to treat patients hospitalised with COVID-19 who are at risk of developing serious complications. The trial did not achieve statistical significance for the primary endpoint of prevention measuring organ dysfunction and all-cause mortality, and the primary endpoint of recovery measuring a change in clinical status (from early recovery to death), at 30 days. The safety and tolerability profile observed in the trial was consistent with the known safety profile of the medicine. The results will be presented at the American College of Cardiology Scientific Sessions in May 2021.

Table 29: Key large CVRM Phase III outcomes trials

Trial (population)	Design	Timeline	Status
Brilinta			
THALES (c.11,000 patients with acute ischaemic stroke[56] or transient ischaemic attack)	Aspirin plus placebo or aspirin plus *Brilinta* 90mg BID	FPCD: Q1 2018 LPCD: Q4 2019	Primary endpoint met Regulatory approval (US)
Farxiga			
DELIVER (c.6,300 patients with HF (HFpEF) with and without T2D)	Placebo or *Farxiga* 10mg QD	FPCD: Q4 2018 LPCD: Q4 2020 First data anticipated: H2 2021	Recruitment completed Fast Track[57] designation (US)
DAPA-CKD (c.4,300 patients with CKD, with and without T2D)	Placebo or *Farxiga* 10mg QD	FPCD: Q1 2017 LPCD: Q1 2020	Trial stopped early based on recommendation from an IDMC Primary endpoint and secondary endpoints met Breakthrough Therapy Designation, Priority Review (US)
DAPA-MI (c.6,400 patients with confirmed MI, either STEMI or NSTEMI, within the preceding 7 days)	Placebo or *Farxiga* 10mg QD	FPCD: Q4 2020 First data anticipated: 2022+	Recruitment ongoing

c) Roxadustat

During the period, FibroGen, Inc. (FibroGen) provided an update on certain prior disclosures relating to the US primary CV safety analyses from the roxadustat Phase III programme to treat anaemia of CKD.

In March 2021, AstraZeneca and FibroGen announced that the US FDA would convene a Cardiovascular and Renal Drugs Advisory Committee meeting to review the new drug application for roxadustat. The meeting has been tentatively scheduled for 15 July 2021. Roxadustat is approved in China, Japan, and Chile to treat anaemia in CKD in non-dialysis dependent and dialysis-dependent adult patients and is under regulatory review in the EU.

Respiratory & Immunology

a) *Fasenra*

Table 30: Key *Fasenra* lifecycle management Phase III trials

During the period, the Company announced that the first patients had commenced dosing in three trials evaluating *Fasenra* in dermatological indications, in reference to the Phase III FJORD trial in bullous pemphigoid and two-Phase II trials in atopic dermatitis (HILLIER) and chronic spontaneous urticaria (ARROYO).

[56] Ischaemic strokes are the most common type of stroke.
[57] A process designed to facilitate the development and expedite the review of medicines to treat serious conditions that fill an unmet medical need.

Trial (population)	Design	Timeline	Status
OSTRO (severe bilateral nasal polyps)	Placebo or *Fasenra* 30mg Q8W[58] SC[59]	FPCD: Q1 2018 LPCD: Q2 2019	Co-primary endpoints met
RESOLUTE (moderate to very severe COPD with a history of exacerbations and elevated peripheral blood eosinophils)	Placebo or *Fasenra* 100mg Q8W SC	FPCD: Q4 2019 First data anticipated: 2022+	Recruitment ongoing
MANDARA (eosinophilic granulomatosis with polyangiitis[60])	Mepolizumab 3x100mg Q4W or *Fasenra* 30mg SC	FPCD: Q4 2019 First data anticipated: 2022+	Recruitment ongoing Orphan Drug Designation (US)
NATRON (hyper-eosinophilic syndrome[61]	Placebo or *Fasenra* 30mg Q4W SC	FPCD: Q3 2020 First data anticipated: 2022	Recruitment ongoing Orphan Drug Designation (US)
MESSINA (eosinophilic oesophagitis[62])	Placebo or *Fasenra* 30mg Q4W SC	FPCD: Q4 2020 First data anticipated: 2022	Recruitment ongoing Orphan Drug Designation (US)
FJORD (bullous pemphigoid[63])	Placebo or *Fasenra* 30mg Q4W SC	FPCD: Q2 2021 First data anticipated: 2022+	Recruitment ongoing

b) *Breztri*

Table 31: Key *Breztri* Phase III trials

Trial (population)	Design	Timeline	Status
KALOS (asthma)	Budesonide/formoterol or *Breztri*	FPCD: Q1 2021 First data anticipated: 2022+	Recruitment ongoing
LOGOS (asthma)	Budesonide/formoterol or *Breztri*	FPCD: Q1 2021 First data anticipated: 2022+	Recruitment ongoing

c) Anifrolumab

During the period, the Phase II trial of anifrolumab in lupus nephritis concluded. Although the primary endpoint was not met, the trial results provided valuable insights that have informed the Phase III programme, planned to start in the second half of 2021. The full results from the Phase II trial will be presented at a forthcoming medical meeting.

Table 32: Key anifrolumab Phase III trials

Trial (population)	Design	Timeline	Status
TULIP 1 (moderate to severely active SLE)	Placebo or anifrolumab 150mg or 300mg IV Q4W	FPCD: Q4 2015 LPCD: Q4 2017	Primary endpoint not met Fast Track designation (US)
TULIP 2 (moderate to severely active SLE)	Placebo or anifrolumab 300mg IV Q4W	FPCD: Q4 2015 LPCD: Q4 2017	Primary endpoint met Fast Track designation (US)

[58] Once every eight weeks.
[59] Subcutaneous injection.
[60] A rare autoimmune condition that causes inflammation of small and medium-sized blood vessels.
[61] A group of rare blood disorders.
[62] White blood cells gather in the lining of the oesophagus.
[63] A skin condition that causes large, itchy, fluid-filled blisters.

Trial (population)	Design	Timeline	Status
TULIP LTE (moderate to severely active SLE)	Placebo or anifrolumab 300mg IV Q4W	FPCD: Q2 2016 LPCD: Q4 2018 First data anticipated: 2022	Recruitment completed Fast Track designation (US)

d) Tezepelumab (severe asthma)

During the period, AstraZeneca and Amgen Inc. presented positive results from the NAVIGATOR Phase III trial for tezepelumab at the American Academy of Allergy Asthma and Immunology Virtual Annual Meeting, held between 26 February and 1 March 2021.

When added to SoC[64], tezepelumab achieved a 56% reduction (p<0.001) in annualised asthma exacerbation rate (AAER) over 52 weeks when compared to placebo. In a pre-planned subgroup analysis, in patients with baseline eosinophil counts less than 300 cells per microlitre, tezepelumab achieved a statistically significant and clinically meaningful 41% reduction (p<0.001) in AAER. Importantly, clinically meaningful AAER reductions were observed in two additional subgroups; 39% reduction in patients with baseline eosinophil counts less than 150 cells per microlitre; 70% reduction in patients with greater than or equal to 300 cells per microlitre.

Clinically meaningful AAER reductions were also observed in the tezepelumab-treated patients, compared to placebo, irrespective of allergy status and fractional exhaled nitric oxide level[65]. The NAVIGATOR Phase III trial will form the basis of regulatory submissions for tezepelumab in severe asthma in H1 2021.

Table 33: Key tezepelumab Phase III trials

Trial (population)	Design	Timeline	Status
NAVIGATOR (severe asthma)	Placebo or tezepelumab 210mg Q4W SC	FPCD: Q1 2018 LPCD: Q3 2019	Primary endpoint met Breakthrough Therapy Designation (US)
WAYPOINT (chronic rhinosinusitis with nasal polyps)	Placebo or tezepelumab 210mg Q4W SC	First data anticipated 2022+	Initiating

e) PT027 (asthma)

Table 34: Key PT027 Phase III trials

Trial	Design	Timeline	Status
TYREE (asthma with exercise induced broncho constriction)	Placebo or PT027 160/180 µg, single dose	FPCD: Q1 2020 LPCD: Q3 2020	Primary endpoint met
MANDALA (moderate to severe asthma)	Albuterol or PT027 80/180 µg or PT027 160/180 µg (all 'as needed')	FPCD: Q4 2018 First data anticipated: H2 2021	Recruitment ongoing
DENALI (mild to moderate asthma)	Placebo or albuterol 180 µg or budesonide 160 µg or PT027 80/180 µg or PT027 160/180 µg QID	FPCD: Q2 2019 LPCD: Q2 2021 First data anticipated: H2 2021	Recruitment completed

Other

a) Nirsevimab (respiratory syncytial virus)

In April 2021, AstraZeneca announced that the MELODY Phase III trial for nirsevimab had met its primary endpoint of a statistically significant reduction in the incidence of medically attended lower respiratory tract

[64] Medium- or high-dose ICS plus at least one additional controller medication with or without OCS.
[65] A biomarker used by clinicians to inform treatment options.

infections caused by RSV compared to placebo in healthy late preterm and term infants (35 weeks or more) during their first RSV season. Nirsevimab becomes the first potential immunisation to show protection against RSV in the general infant population in a Phase III trial. Preliminary analysis of the safety profile for nirsevimab was consistent with previous trial data. No clinically meaningful differences in safety results between the nirsevimab and placebo groups have been seen. The trial is ongoing to collect additional safety data. Results from the MELODY trial will be presented at a forthcoming medical meeting.

Nirsevimab is also being evaluated in the MEDLEY Phase II/III trial which will assess the safety and tolerability of nirsevimab compared to *Synagis* (palivizumab) among preterm infants and children with chronic lung disease (CLD) and congenital heart disease (CHD) entering their first and second RSV seasons. The MEDLEY trial is also expected to read out earlier with first data anticipated in the second half of 2021. MELODY, MEDLEY and the Phase IIb trial will form the basis of AstraZeneca's regulatory submissions planned for 2022.

Table 35: Key nirsevimab trials

Trial	Design	Timeline	Status
MELODY (healthy late preterm and term infants)	Placebo or nirsevimab IM	FPCD: Q3 2019 LPCD: Q3 2020	Primary endpoint met
MEDLEY (high-risk children)	*Synagis* or nirsevimab IM	FPCD: Q3 2019 LPCD: Q4 2020 First data anticipated H2 2021	Recruitment completed

COVID-19

a) Pandemic COVID-19 vaccine

During the period, AstraZeneca announced positive high-level results from the US Phase III trial's primary analysis. The results confirmed that vaccine efficacy was consistent with the previously announced pre-specified interim analysis. The trial showed 76% (confidence interval (CI): 68% to 82%) vaccine efficacy at preventing symptomatic COVID-19, occurring 15 days or more after receiving two doses given four weeks apart. Importantly, these results were comparable across age groups, with vaccine efficacy of 85% (CI: 58% to 95%) in adults 65 years and older. A key secondary endpoint, preventing severe or critical disease and hospitalisation, demonstrated 100% efficacy. In the coming weeks, the Company will submit to the US FDA a regulatory submission for Emergency Use Authorisation, incorporating data from both the US and non-US Phase III clinical trial programme and emerging real-world data.

In March 2021, several regulatory agencies raised concerns about the potential risk of rare thrombotic events in people administered with the vaccine. Consequently, The Medicines and Healthcare products Regulatory Agency in the UK and the European Medicines Agency conducted several analyses that noted a potential causal link between the vaccine and these events. The agencies, however, reaffirmed that the vaccine's overall benefits continue to outweigh the potential risks. AstraZeneca will continue to work closely with health and regulatory authorities to ensure the appropriate use of the vaccine.

Table 36: Key vaccine trials in COVID-19

Trial	Design	Timeline	Status
COV002 (UK), Phase II/III (Protection against COVID-19 in participants aged 18-55, 55+)	MenACWY or COVID-19 vaccine	FPCD: Q2 2020 LPCD: Q4 2020	Initial data readout Regulatory authorisation (UK, EU)
COV003 (Brazil), Phase II/III (Protection against COVID-19 in participants aged 18-55)	MenACWY or COVID-19 vaccine	FPCD: Q2 2020 LPCD: Q4 2020	Initial data readout Regulatory authorisation (UK, EU)

Trial	Design	Timeline	Status
COV005 ChAdOx1 nCoV-19 ZA[66] (South Africa), Phase I/II (protection against COVID-19 in participants aged 18-65 HIV+[67] subgroup)	Placebo or COVID-19 vaccine	FPCD: Q2 2020 LPCD: Q4 2020	Initial data readout
D8110C00001 (US, global), Phase III (protection against COVID-19 in participants aged 18+	Placebo or COVID-19 vaccine	FPCD: Q3 2020 LPCD: Q1 2021	Initial data readout

b) AZD7442

The Company announced in March 2021 a modification to the existing agreement with the US Government to supply up to 500,000 additional doses of AZD7442, a long-acting antibody (LAAB) combination. AZD7442 is a potential new medicine in late-stage development for the prevention and treatment of COVID-19. The value of the extended agreement is $205m. It is contingent on AZD7442 receiving US FDA Emergency Use Authorisation in preventing COVID-19 in people who have confirmed exposure to the virus.

Total potential US supplies of AZD7442 under this and prior agreements with the US Government amount to 700,000; this includes 100,000 doses in 2020 and a further 600,000 doses in 2021.

Table 37: Key AZD7442 Phase II/III trials in COVID-19

Trial	Design	Timeline	Status
PROVENT (protection against COVID-19 (prophylaxis))	Placebo or AZD7442 300mg IM[68]	FPCD: Q4 2020 LPCD: Q1 2021 First data anticipated: H2 2021	Recruitment completed
STORM CHASER (protection against COVID-19 (post-exposure prophylaxis))	Placebo or AZD7442 300mg IM	FPCD: Q4 2020 LPCD: Q1 2021 First data anticipated: H1 2021	Recruitment completed
TACKLE (COVID-19 (outpatient treatment))	Placebo or AZD7442 600mg IM	FPCD: Q1 2021 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.

[66] Conducted by University of Witwatersrand, South Africa.
[67] Human immunodeficiency virus-positive.
[68] Intramuscular.

Table 38: **Q1 2021 - Condensed consolidated statement of comprehensive income**

For the **quarter** ended 31 March	**2021 $m**	**2020 $m**
Total Revenue	7,320	6,354
Product Sales	*7,257*	*6,311*
Collaboration Revenue	*63*	*43*
Cost of Sales	(1,864)	(1,420)
Gross Profit	5,456	4,934
Distribution costs	(99)	(87)
Research and development expense	(1,713)	(1,388)
Selling, general and administrative costs	(2,929)	(2,719)
Other operating income and expense	1,180	480
Operating Profit	1,895	1,220
Finance income	20	51
Finance expense	(303)	(332)
Share of after-tax losses in associates and joint ventures	(4)	(4)
Profit Before Tax	1,608	935
Taxation	(46)	(185)
Profit for the period	1,562	750
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	481	440
Net (losses)/gains on equity investments measured at fair value through other comprehensive income	(108)	171
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	1	21
Tax on items that will not be reclassified to profit or loss	(94)	(66)
	280	566
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(107)	(608)
Foreign exchange arising on designated borrowings in net investment hedges	(302)	(380)
Fair value movements on cash flow hedges	(86)	(187)
Fair value movements on cash flow hedges transferred to profit or loss	121	45
Fair value movements on derivatives designated in net investment hedges	13	60
Costs of hedging	(1)	(5)
Tax on items that may be reclassified subsequently to profit or loss	26	73
	(336)	(1,002)
Other comprehensive loss for the period, net of tax	(56)	(436)
Total comprehensive income for the period	1,506	314
Profit attributable to:		
Owners of the Parent	1,561	780
Non-controlling interests	1	(30)
	1,562	750
Total comprehensive income attributable to:		
Owners of the Parent	1,506	345
Non-controlling interests	-	(31)
	1,506	314
Basic earnings per $0.25 Ordinary Share	$1.19	$0.59
Diluted earnings per $0.25 Ordinary Share	$1.18	$0.59
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,312
Diluted weighted average number of Ordinary Shares in issue (millions)	1,319	1,313

Table 39: Condensed consolidated statement of financial position

	At 31 Mar 2021 $m	At 31 Dec 2020 $m	At 31 Mar 2020 $m
Assets			
Non-current assets			
Property, plant and equipment	8,189	8,251	7,347
Right-of-use assets	660	666	644
Goodwill	11,765	11,845	11,569
Intangible assets	20,347	20,947	19,718
Investments in associates and joint ventures	88	39	44
Other investments	972	1,108	1,476
Derivative financial instruments	115	171	104
Other receivables	549	720	527
Deferred tax assets	3,506	3,438	2,960
	46,191	47,185	44,389
Current assets			
Inventories	4,278	4,024	3,123
Trade and other receivables	6,281	7,022	5,080
Other investments	129	160	752
Derivative financial instruments	64	142	61
Income tax receivable	347	364	262
Cash and cash equivalents	7,636	7,832	3,413
Assets held for sale	-	-	131
	18,735	19,544	12,822
Total assets	64,926	66,729	57,211
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(2,042)	(2,194)	(2,289)
Lease liabilities	(216)	(192)	(181)
Trade and other payables	(17,370)	(15,785)	(12,633)
Derivative financial instruments	(16)	(33)	(31)
Provisions	(875)	(976)	(649)
Income tax payable	(994)	(1,127)	(1,260)
	(21,513)	(20,307)	(17,043)
Non-current liabilities			
Interest-bearing loans and borrowings	(17,410)	(17,505)	(15,634)
Lease liabilities	(464)	(489)	(472)
Derivative financial instruments	(1)	(2)	(188)
Deferred tax liabilities	(2,823)	(2,918)	(2,501)
Retirement benefit obligations	(2,545)	(3,202)	(2,129)
Provisions	(576)	(584)	(807)
Other payables	(5,148)	(6,084)	(6,221)
	(28,967)	(30,784)	(27,952)
Total liabilities	(50,480)	(51,091)	(44,995)
Net assets	14,446	15,638	12,216
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	328	328	328
Share premium account	7,976	7,971	7,946
Other reserves	2,037	2,024	2,056
Retained earnings	4,089	5,299	448
	14,430	15,622	10,778
Non-controlling interests	16	16	1,438
Total equity	14,446	15,638	12,216

Table 40: Condensed consolidated statement of changes in equity

	Share capital	Share premium account	Other reserves	Retained earnings	Total attributable to owners of the parent	Non-controlling interests	Total equity
	$m	$m	$m	$m	$m	$m	$m
At 1 Jan 2020	328	7,941	2,046	2,812	13,127	1,469	14,596
Profit for the period	-	-	-	780	780	(30)	750
Other comprehensive loss	-	-	-	(435)	(435)	(1)	(436)
Transfer to other reserves	-	-	10	(10)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,489)	(2,489)	-	(2,489)
Issue of Ordinary Shares	-	5	-	-	5	-	5
Share-based payments charge for the period	-	-	-	53	53	-	53
Settlement of share plan awards	-	-	-	(263)	(263)	-	(263)
Net movement	-	5	10	(2,364)	(2,349)	(31)	(2,380)
At 31 Mar 2020	**328**	**7,946**	**2,056**	**448**	**10,778**	**1,438**	**12,216**
At 1 Jan 2021	**328**	**7,971**	**2,024**	**5,299**	**15,622**	**16**	**15,638**
Profit for the period	-	-	-	1,561	1,561	1	1,562
Other comprehensive loss	-	-	-	(55)	(55)	(1)	(56)
Transfer to other reserves	-	-	13	(13)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,490)	(2,490)	-	(2,490)
Issue of Ordinary Shares	-	5	-	-	5	-	5
Share-based payments charge for the period	-	-	-	82	82	-	82
Settlement of share plan awards	-	-	-	(295)	(295)	-	(295)
Net movement	-	5	13	(1,210)	(1,192)	-	(1,192)
At 31 Mar 2021	**328**	**7,976**	**2,037**	**4,089**	**14,430**	**16**	**14,446**

Table 41: Condensed consolidated statement of cash flows

For the **quarter** ended 31 March	**2021 $m**	**2020 $m**
Cash flows from operating activities		
Profit Before Tax	1,608	935
Finance income and expense	283	281
Share of after-tax losses of associates and joint ventures	4	4
Depreciation, amortisation and impairment	797	841
Decrease/(increase) in working capital and short-term provisions	1,210	(445)
Gains on disposal of intangible assets	(310)	(358)
Gains on disposal of investments in associates and joint ventures	(776)	-
Fair value movements on contingent consideration arising from business combinations	-	(33)
Non-cash and other movements	(363)	(429)
Cash generated from operations	2,453	796
Interest paid	(187)	(180)
Tax paid	(332)	(477)
Net cash inflow from operating activities	1,934	139
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(171)	(167)
Purchase of property, plant and equipment	(220)	(186)
Disposal of property, plant and equipment	4	-
Purchase of intangible assets	(249)	(190)
Disposal of intangible assets	418	365
Purchase of non-current asset investments	-	(115)
Disposal of non-current asset investments	-	184
Movement in short-term investments, fixed deposits and other investing instruments	28	98
Payments to associates and joint ventures	(55)	(8)
Disposal of investments in associates and joint ventures	776	-
Interest received	24	28
Net cash inflow from investing activities	555	9
Net cash inflow before financing activities	2,489	148
Cash flows from financing activities		
Proceeds from issue of share capital	5	6
Repayment of loans	(4)	-
Dividends paid	(2,469)	(2,398)
Hedge contracts relating to dividend payments	(23)	(93)
Repayment of obligations under leases	(50)	(53)
Movement in short-term borrowings	(190)	176
Net cash outflow from financing activities	(2,731)	(2,362)
Net decrease in cash and cash equivalents in the period	(242)	(2,214)
Cash and cash equivalents at the beginning of the period	7,546	5,223
Exchange rate effects	(67)	(32)
Cash and cash equivalents at the end of the period	7,237	2,977
Cash and cash equivalents consist of:		
Cash and cash equivalents	7,636	3,413
Overdrafts	(399)	(436)
	7,237	2,977

Notes to the Interim Financial Statements

1) Basis of preparation and accounting policies

These unaudited Interim Financial Statements for the three months ended 31 March 2021 have been prepared in accordance with IAS 34 'Interim Financial Reporting' as issued by the International Accounting Standards Board (IASB) and as adopted by the UK and the EU. 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 Interim Financial Statements have transitioned to UK-adopted international accounting standards from financial periods beginning 1 January 2021.

The unaudited Interim Financial Statements for the three months ended 31 March 2021 were approved by the Board of Directors for publication on 30 April 2021.

The annual financial statements of the Group are prepared in accordance with IFRSs as issued by the IASB and as adopted by the UK and the EU. Except as noted below, the Interim Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2020.

IFRS 9 and IFRS 7

The replacement of benchmark interest rates, such as the London Inter-bank Offered Rate (LIBOR) and other interbank offered rates (IBORs) has been a priority for global regulators and is expected to be largely completed in 2021, although some benchmark rates will be continued to be published until mid-2023. To prepare for this, the Group adopted the Phase 1 amendments to IFRS 9 'Financial Instruments' and IFRS 7 'Financial Instruments: Disclosures' in 2019 and has adopted the Phase 2 amendments in 2021. 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.

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 working on moving to new benchmark rates in 2021.

COVID-19

AstraZeneca has assessed the impact of the uncertainty presented by the COVID-19 pandemic on the Interim Financial Statements comprising the financial results to 31 March 2021 and the financial position as at 31 March 2021, specifically considering the impact on key judgements and significant estimates as detailed on page 180 of the Annual Report and 20-F Information 2020 along with a several other areas of elevated risk during the pandemic period.

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 three-month period ended 31 March 2021.

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 March 2021, the Group had $11.8bn in financial resources (cash and cash-equivalent balances of $7.6bn, $0.1bn 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 $2.3bn of borrowings due within one year). Additionally, as at 31 March 2021, to support the financing of the acquisition of Alexion, the Group has committed bank facilities totalling $17.5bn, which are available unit at least December 2022. 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 March 2021.

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 Interim Financial Statements.

Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2020.

Financial information

The comparative figures for the financial year ended 31 December 2020 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 $55m being recorded against an intangible asset during the three months ended 31 March 2021 (Q1 2020: $117m). Net impairment charges in respect of launched products and products in development were $nil (Q1 2020: $84m) and $55m (Q1 2020: $33m) respectively. Impairments recorded on products in development were a consequence of failed or poor performing trials, with the individual assets being fully impaired.

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 2020. Net Debt is a non-GAAP financial measure.

Table 42: Net Debt

	At 1 Jan 2021 $m	Cash flow $m	Non-cash & other $m	Exchange movements $m	At 31 Mar 2021 $m
Non-current instalments of loans	(17,505)	-	1	94	(17,410)
Non-current instalments of leases	(489)	-	17	8	(464)
Total long-term debt	**(17,994)**	**-**	**18**	**102**	**(17,874)**
Current instalments of loans	(1,536)	4	-	71	(1,461)
Current instalments of leases	(192)	54	(83)	5	(216)
Bank collateral	(288)	114	-	-	(174)
Other short-term borrowings excluding overdrafts	(84)	76	-	-	(8)
Overdraft	(286)	(119)	-	6	(399)
Total current debt	**(2,386)**	**129**	**(83)**	**82**	**(2,258)**
Gross borrowings	**(20,380)**	**129**	**(65)**	**184**	**(20,132)**
Net derivative financial instruments	278	23	(139)	-	162
Net borrowings	**(20,102)**	**152**	**(204)**	**184**	**(19,970)**
Cash and cash equivalents	7,832	(123)	-	(73)	7,636
Other investments - current	160	(28)	-	(3)	129
Cash and investments	**7,992**	**(151)**	**-**	**(76)**	**7,765**
Net Debt	**(12,110)**	**1**	**(204)**	**108**	**(12,205)**

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

The Group has agreements with some bank counterparties whereby the parties agree to post cash collateral on financial derivatives, for the benefit of the other, equivalent to the market valuation of the derivative positions above a predetermined threshold. The carrying value of such cash collateral held by the Group was $174m (Q1 2020: $163m) and the carrying value of such cash collateral posted by the Group was $13m (Q1 2020: $190m). Cash collateral posted by the Group is presented within Cash and cash equivalents.

Other investments - non-current are included within the balance of $972m (31 December 2020: $1,108m) 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 $2,336m (31 December 2020: $2,297m), $874m of which is shown in current other payables and $1,462m is shown in non-current other payables. In April 2021, AstraZeneca exercised its option to acquire the remaining 45% of shares in Acerta, please refer to Note 6 for further information.

Net Debt increased by $95m in the year to date to $12,205m. Details of the committed undrawn bank facilities are disclosed within the going-concern section of Note 1.

During the three months to 31 March 2021, 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, lease liabilities and interest-bearing loans and borrowings. There have been no 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 2020.

The Group holds certain equity investments that are categorised as Level 3 in the fair-value hierarchy and for which fair-value gains of $nil (Q1 2020: $6m gain) have been recognised in the three months ended 31 March 2021. 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 three months ended 31 March 2021 are Level 1 fair-value measurements.

Financial instruments measured at fair value include $1,101m of other investments, $5,712m held in money-market funds, $333m of loans designated at fair value through profit or loss, $354m of loans designated in a fair-value hedge relationship and $162m of derivatives as at 31 March 2021. The total fair value of interest-

bearing loans and borrowings at 31 March 2021, which have a carrying value of $20,132m in the Condensed consolidated statement of financial position, was $22,437m. 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 43: Financial instruments - contingent consideration

	2021			2020
	Diabetes alliance $m	Other $m	Total $m	Total $m
At 1 January	2,932	391	3,323	4,139
Settlements	(166)	(5)	(171)	(167)
Revaluations	-	-	-	(33)
Discount unwind	49	6	55	73
At 31 March	**2,815**	**392**	**3,207**	**4,012**

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 $2,815m (31 December 2020: $2,932m) would increase/decline by $282m 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 2020 (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 first quarter of 2021 and to 30 April 2021

Patent litigation

Enhertu

US patent proceedings

As previously disclosed, in October 2020, Seagen Inc. (Seagen) filed a complaint against Daiichi Sankyo Company, Limited in the US District Court for the Eastern District of Texas alleging that *Enhertu* infringes US Patent No. 10,808,039 (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 Company, Limited and Daiichi Sankyo Inc. filed a complaint against Seagen in the US District Court for the District of Delaware (the District Court) seeking a declaratory judgment that plaintiffs do not infringe the '039 patent. In April 2021, the District Court stayed this proceeding for up to 90 days.

Faslodex

Patent Proceedings outside the US

In Japan, in April 2021, AstraZeneca received notice from the Japan Patent Office that Sandoz K.K. filed a Request for Invalidation Trial to seek invalidation of the *Faslodex* formulation patent. AstraZeneca is considering its response.

Farxiga

US patent proceedings

As previously disclosed, in 2018, in response to Paragraph IV notices, AstraZeneca initiated ANDA litigation against Zydus Pharmaceuticals (USA) Inc. (Zydus) in the US District Court for the District of Delaware. In the complaint, AstraZeneca alleged that Zydus' generic version of *Farxiga*, if approved and marketed, would infringe patents listed in the FDA Orange Book with reference to *Farxiga*. Proceedings are ongoing and trial is scheduled for May 2021.

Patent proceedings outside the US

As previously disclosed, 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 commenced litigation in response.

In Canada, in February 2021, Teva Canada Limited. served a Notice 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 commenced litigation in response.

Onglyza

Patent proceedings outside the US

As previously disclosed, in Canada, in November 2019, Sandoz Canada Inc. sent a Notice of Allegation to AstraZeneca challenging the validity of Canadian substance Patent No. 2402894 (expiry March 2021) (the '894 patent) and formulation Patent No. 2568391 (expiry May 2025) related to *Onglyza*. AstraZeneca commenced an action in response related to the '894 patent in January 2020. A trial date is set for May 2022.

Roxadustat

US Patent Proceedings

In April 2021, Akebia Therapeutics, Inc. and Otsuka America Pharmaceutical, Inc. served AstraZeneca with a complaint seeking a declaration of invalidity and noninfringement for several of FibroGen method of use patents (U.S. Patent Nos. 8318703, 8466172, 8614204, 9920011, 8629131, 8604012, 8609646, 8604013, 10626090, 10894774, 10882827, and 10927081) related to HIF prolylhydroxylase inhibitors. AstraZeneca is the exclusive licensee of FibroGen in the United States. AstraZeneca is considering its response.

Patent proceedings outside the US

As previously disclosed, in Canada, in May 2018, Akebia Therapeutics, Inc. filed an impeachment action in the Federal Court of Canada alleging invalidity of several of FibroGen's method of use patents (Canadian Patent Nos. 2467689; 2468083; and 2526496) related to HIF prolylhydroxylase inhibitors. AstraZeneca is the exclusive licensee of FibroGen in Canada. AstraZeneca and FibroGen were defending the action. The parties have settled the action.

Symbicort

US patent proceedings

As previously disclosed, in October 2018, AstraZeneca initiated ANDA litigation against Mylan and subsequently against 3M Company (3M) in the US District Court for the Northern District of West Virginia (the District Court). In the action, AstraZeneca alleges that the defendants' generic versions of *Symbicort*, if approved and marketed, would infringe various AstraZeneca patents. Mylan and 3M alleged that their proposed generic medicines do not infringe the asserted patents and/or that the asserted patents are invalid and/or unenforceable. In July 2020, AstraZeneca added Kindeva Drug Delivery L.P. (Kindeva) as a defendant in the case. In September 2020, Mylan, 3M and Kindeva stipulated to patent infringement to the extent that the asserted patent claims are found to be valid and enforceable, but reserved the right to seek a vacatur of the stipulation if the U.S. Court of Appeals for the Federal Circuit reverses or modifies the District Court's claim construction. In October 2020, following a stipulation by AstraZeneca, 3M and Kindeva, 3M was dismissed from the action. In

March 2021, the District Court decided in favour of AstraZeneca and determined that the asserted patent claims were not invalid or unenforceable. Mylan and Kindeva have appealed to the United States Court of Appeals for the Federal Circuit.

Product liability litigation

Byetta*/*Bydureon

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 *Byetta* and/or *Bydureon*. The lawsuits allege several types of injuries including pancreatic cancer and thyroid 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 October and December 2020, the District Court and the California Court jointly heard oral argument on renewed motions filed by Defendants seeking summary judgment and dismissal of all claims alleging pancreatic cancer. In March and April 2021, the District Court and the California State Court respectively granted the Defendants' motions, and dismissed all cases alleging pancreatic cancer with prejudice. The plaintiffs have provided notice that they intend to appeal. The other claims pending in both courts, including those alleging thyroid cancer, remains pending.

Nexium* and *Losec*/*Prilosec

US proceedings

As previously disclosed, in the US, AstraZeneca is defending various lawsuits brought in federal and state courts involving multiple plaintiffs claiming that they have been diagnosed with various injuries following treatment with proton pump inhibitors (PPIs), including *Nexium* and *Prilosec*. The vast majority of those lawsuits relate to allegations of kidney injuries. In particular, in May 2017, counsel for a group of such plaintiffs claiming that they have been diagnosed with kidney injuries filed a motion with the Judicial Panel on Multidistrict Litigation (JPML) seeking the transfer of any currently pending federal court cases as well as any similar, subsequently filed cases to a coordinated and consolidated pre-trial multidistrict litigation (MDL) proceeding. In August 2017, the JPML granted the motion and consolidated the pending federal court cases in an MDL proceeding in federal court in New Jersey for pre-trial purposes. A trial in the MDL has been rescheduled for January 2022. In addition to the MDL cases, there are cases filed in several state courts around the US; a trial in Delaware state court has been scheduled for February 2022.

In addition, AstraZeneca has been defending lawsuits involving allegations of gastric cancer following treatment with PPIs. All but one of these claims is filed in the MDL. One claim is filed in the US District Court for the Middle District of Louisiana, where the court has rescheduled a trial for August 2022.

Commercial litigation

Ocimum lawsuit

As previously disclosed, in the US, in December 2017, AstraZeneca was served with a complaint filed by Ocimum Biosciences, Ltd. (Ocimum) in the Superior Court for the State of Delaware (the Delaware Supreme Court) that alleged, among other things, breaches of contractual obligations and misappropriation of trade secrets, relating to a now terminated 2001 licensing agreement between AstraZeneca and Gene Logic, Inc. (Gene Logic), the rights to which Ocimum purports to have acquired from Gene Logic. In February 2021, the Delaware Supreme court affirmed the grant of AstraZeneca's motion for summary judgment. This matter is now concluded.

AZD1222 securities litigation

As previously disclosed, 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 (pandemic COVID-19 vaccine), a potential recombinant adenovirus vaccine for the prevention of COVID-19. In March 2021, motions for consolidation of the pending lawsuits and appointment of a lead plaintiff and its counsel were filed and remain pending.

Alexion shareholder litigation

In March 2021, several shareholders of Alexion filed individual lawsuits against Alexion, its management, and/or AstraZeneca and affiliates in federal district court in New York. The complaints generally allege that the preliminary registration statement filed with the SEC on 19 February 2021, omitted certain allegedly material information in connection with AstraZeneca's proposed acquisition of Alexion (the Acquisition), and one of the

complaints further alleges that the Alexion directors breached their fiduciary duties in connection with the Acquisition and that AstraZeneca and the other entity defendants aided and abetted the alleged breaches.

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 (the State), 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. The Supreme Court heard oral argument on AstraZeneca's appeal in March 2021. In April 2021, prior to a decision from the Supreme Court, the State unilaterally moved to dismiss all of its claims with prejudice. That motion remains pending.

US 340B litigations and proceedings

As previously disclosed, AstraZeneca is involved in several matters relating to its policy with regard to contract pharmacy recognition under the 340B Drug Pricing Program in the US. 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 (ADR) 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. In February 2021, AstraZeneca received a Civil Investigative Subpoena from the Attorney General's Office for the State of Vermont seeking documents and information relating to AstraZeneca's policy regarding contract pharmacy recognition under the 340B Drug Pricing Program.

European Commission Claim Regarding AZD1222

In April 2021, the European Commission (acting on behalf of the European Union and its member states) initiated legal proceedings against AstraZeneca AB in the Court of First Instance in Brussels. The proceedings relate to an Advance Purchase Agreement (APA) between the parties dated 27 August 2020 for the supply of AZD1222. The allegations include claims that AstraZeneca has failed to meet certain of its obligations under the APA and the Commission is seeking, among other things, a Court order to compel AstraZeneca to supply a specified number of doses before the end of the second quarter of 2021.

6) Subsequent Events

In April 2021, AstraZeneca exercised its option to acquire the remaining 45% of shares in Acerta, following the final condition for exercising the option being satisfied in November 2020 when *Calquence* received EU marketing authorisation. Following the exercise of the option, payments to acquire the remaining outstanding shares of Acerta are to be made in similar annual instalments in 2022, 2023 and 2024. The associated cash flows will be disclosed as financing activities within the Consolidated Statement of Cash Flows.

7) Table 44: Q1 2021 - Product Sales year-on-year analysis[69]

		World		Emerging Markets			US		Europe			Established RoW		
		Actual	CER		Actual	CER		Actual		Actual	CER		Actual	CER
	$m	% change	% change	$m	% change	% change	$m	% change	$m	% change	% change	$m	% change	% change
Oncology	**2,981**	**19**	**15**	**762**	**7**	**4**	**1,193**	**23**	**575**	**29**	**17**	**451**	**20**	**14**
Tagrisso	1,149	17	13	306	9	5	415	12	225	39	26	203	20	14
Imfinzi	556	20	17	58	74	69	292	2	109	46	32	97	43	35
Lynparza	543	37	33	87	54	54	253	28	149	46	33	54	29	22
Calquence	209	n/m	n/m	2	n/m	n/m	195	n/m	9	n/m	n/m	3	n/m	n/m
Koselugo	21	n/m	n/m	-	-	-	21	n/m	-	-	-	-	-	-
Enhertu	1	n/m	n/m	1	n/m	n/m	-	-	-	-	-	-	-	-
*Zoladex**	221	(1)	(6)	136	(8)	(11)	5	n/m	37	6	(2)	43	11	4
*Faslodex**	122	(26)	(30)	43	(12)	(13)	9	(60)	41	(35)	(41)	29	(6)	(10)
*Iressa**	61	(21)	(26)	53	(15)	(20)	3	(22)	2	(70)	(72)	3	(47)	(50)
*Arimidex**	44	(12)	(15)	36	(13)	(17)	-	-	1	34	34	7	(10)	(14)
*Casodex**	42	-	(6)	33	-	(6)	-	-	1	(9)	(10)	8	-	6
Others	12	(12)	(12)	7	(10)	(11)	-	n/m	1	(14)	19	4	11	-
BioPharmaceuticals: CVRM	**1,912**	**12**	**9**	**945**	**22**	**20**	**463**	**(6)**	**364**	**18**	**9**	**140**	**9**	**3**
Farxiga	624	54	50	260	84	85	131	16	174	50	36	59	69	60
Brilinta	374	(8)	(11)	105	(22)	(23)	166	1	88	(6)	(14)	15	(5)	(12)
Bydureon	103	3	1	-	(62)	(53)	85	1	15	24	14	3	-	(12)
Onglyza	101	(28)	(31)	58	22	19	19	(72)	15	1	(8)	9	(19)	(23)
Byetta	16	(20)	(20)	4	35	50	8	(29)	2	(35)	(40)	2	(18)	(27)
Other diabetes	13	3	(1)	3	62	55	6	(24)	4	36	25	-	(34)	(42)
Lokelma	33	n/m	n/m	1	n/m	n/m	24	n/m	2	n/m	n/m	6	n/m	n/m
Roxadustat	39	n/m	n/m	39	n/m	n/m	-	-	-	-	-	-	n/m	n/m
*Crestor**	274	(9)	(12)	189	(1)	(4)	22	(22)	21	(40)	(43)	42	(11)	(15)
*Seloken/Toprol-XL**	250	41	36	244	47	42	-	(90)	3	(26)	(26)	3	(13)	(23)
*Atacand**	34	(48)	(49)	5	(89)	(89)	2	(15)	27	n/m	n/m	-	(97)	n/m
Others	51	(13)	(16)	37	-	(5)	-	-	13	(28)	(27)	1	(67)	(69)
BioPharmaceuticals: Respiratory & Immunology	**1,541**	**(1)**	**(5)**	**542**	**1**	**(4)**	**551**	**8**	**299**	**(7)**	**(15)**	**149**	**(17)**	**(22)**
Symbicort	691	(13)	(15)	165	6	3	266	(14)	168	(14)	(21)	92	(29)	(33)
Pulmicort	330	(13)	(18)	286	(9)	(14)	17	(25)	16	(37)	(43)	11	(42)	(47)
Fasenra	260	31	27	3	(51)	(47)	156	30	63	37	25	38	40	33
Daliresp/Daxas	60	14	12	1	13	13	54	20	5	(35)	(47)	-	-	-
Bevespi	13	8	5	1	n/m	n/m	10	(15)	2	n/m	n/m	-	-	-
Breztri	27	n/m	n/m	9	n/m	n/m	12	n/m	1	n/m	n/m	5	n/m	n/m
Others	160	42	33	77	30	20	36	n/m	44	(4)	(12)	3	(38)	(40)
Other medicines	**548**	**(2)**	**(5)**	**297**	**19**	**15**	**53**	**(39)**	**76**	**(38)**	**(40)**	**122**	**25**	**18**
*Nexium**	403	19	15	234	25	21	32	(20)	18	(18)	(26)	119	34	27
*Synagis**	24	(72)	(72)	-	n/m	n/m	2	(75)	22	(69)	(69)	-	-	-
*Seroquel XR/IR**	29	(20)	(22)	14	11	14	7	(46)	7	(3)	(8)	1	(66)	(89)
*Losec/Prilosec**	54	1	(5)	46	6	(2)	-	n/m	8	64	69	-	(95)	(95)
*FluMist**	2	n/m	n/m	-	-	-	-	n/m	2	n/m	n/m	-	-	-
Others	36	(19)	(20)	3	92	93	12	(51)	19	25	22	2	(37)	(40)
COVID-19	**275**	**n/m**	**n/m**	**43**	**n/m**	**n/m**	**-**	**-**	**224**	**n/m**	**n/m**	**8**	**n/m**	**n/m**
Pandemic COVID-19 vaccine	275	n/m	n/m	43	n/m	n/m	-	-	224	n/m	n/m	8	n/m	n/m
Total Product Sales	**7,257**	**15**	**11**	**2,589**	**14**	**10**	**2,260**	**10**	**1,538**	**28**	**18**	**870**	**11**	**5**

[69] 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 45: Q1 2021 - Product Sales quarterly sequential analysis[70]

	$m	Actual % change	CER % change
Oncology	**2,981**	**3**	**1**
Tagrisso	1,149	(1)	(3)
Imfinzi	556	-	(1)
Lynparza	543	9	8
Calquence	209	15	15
Koselugo	21	23	23
Enhertu	1	n/m	n/m
*Zoladex**	221	2	-
*Faslodex**	122	(6)	(8)
*Iressa**	61	(9)	(11)
*Arimidex**	44	22	18
*Casodex**	42	7	5
Others	12	(4)	(6)
BioPharmaceuticals: CVRM	**1,912**	**4**	**1**
Farxiga	624	6	4
Brilinta	374	3	1
Bydureon	103	(16)	(17)
Onglyza	101	(3)	(6)
Byetta	16	(14)	(15)
Other diabetes	13	7	1
Lokelma	33	16	18
Roxadustat	39	n/m	n/m
*Crestor**	274	(8)	(9)
*Seloken/Toprol-XL**	250	25	21
*Atacand**	34	(45)	(45)
Others	51	12	10
BioPharmaceuticals: Respiratory & Immunology	**1,541**	**1**	**(1)**
Symbicort	691	2	-
Pulmicort	330	(10)	(13)
Fasenra	260	(8)	(9)
Daliresp/Daxas	60	11	10
Bevespi	13	7	8
Breztri	27	n/m	n/m
Others	160	28	25
Other medicines	**548**	**(25)**	**(26)**
*Nexium**	403	7	5
*Synagis**	24	(69)	(69)
*Seroquel XR/IR**	29	51	38
*Losec/Prilosec**	54	39	36
*FluMist**	2	(99)	(99)
Others	36	(6)	(4)
COVID-19	**275**	**n/m**	**n/m**
Pandemic COVID-19 vaccine	275	n/m	n/m
Total Product Sales	**7,257**	**4**	**1**

[70] 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.

9) Table 46: FY 2020 - Product Sales quarterly sequential analysis[71]

	$m	Q1 2020 Actual % change	Q1 2020 CER % change	$m	Q2 2020 Actual % change	Q2 2020 CER % change	$m	Q3 2020 Actual % change	Q3 2020 CER % change	$m	Q4 2020 Actual % change	Q4 2020 CER % change
Oncology	**2,502**	**10**	**10**	**2,609**	**4**	**6**	**2,831**	**8**	**6**	**2,908**	**3**	**2**
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
BioPharmaceuticals: CVRM	**1,701**	**(5)**	**(5)**	**1,759**	**3**	**6**	**1,794**	**2**	**-**	**1,842**	**3**	**1**
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: Respiratory & Immunology	**1,551**	**1**	**1**	**1,117**	**(28)**	**(26)**	**1,161**	**4**	**1**	**1,528**	**32**	**29**
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
Other medicines	**557**	**(15)**	**(15)**	**563**	**1**	**4**	**734**	**30**	**27**	**733**	**-**	**(2)**
*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 Product Sales	**6,311**	**1**	**1**	**6,048**	**(4)**	**(2)**	**6,520**	**8**	**6**	**7,011**	**8**	**6**

[71] 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 47: Ongoing Collaboration Revenue

	Q1 2021 $m	Q1 2020 $m	FY 2020 $m	FY 2019 $m
Lynparza: regulatory milestones	-	-	160	60
Lynparza: sales milestones	-	-	300	450
Lynparza/*Koselugo*: option payments	-	-	-	100
Crestor (Spain)	-	-	-	39
Enhertu: share of gross profits	38	14	94	-
Roxadustat: share of gross profits	2	3	30	-
Royalty income	18	17	62	62
Other Collaboration Revenue	5	9	81	108
Total	**63**	**43**	**727**	**819**

Table 48: Other Operating Income and Expense

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

	Q1 2021 $m	Q1 2020 $m	FY 2020 $m	FY 2019 $m
Divestment of Viela Bio, Inc. shareholding	776	-	-	-
Crestor (Europe ex UK & Spain)	309	-	-	-
Hypertension medicines (ex-US, India and Japan)	-	350	350	-
Monetisation of an asset previously licensed	-	-	120	-
Brazikumab licence termination funding	26	-	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	-
Atacand	-	-	400	-
Other	69	130	446	389
Total	**1,180**	**480**	**1,528**	**1,541**

Financial calendar and other shareholder information

Annual general meeting	11 May 2021
Announcement of half-year and second-quarter results	29 July 2021
Announcement of year-to-date and third-quarter results	12 November 2021
Announcement of full-year and fourth-quarter results (tentative)	10 February 2022

Dividends are normally 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 first interim dividend for 2021, payable on 13 September 2021, will be 13 August 2021. The ex-dividend date will be 12 August 2021.

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Cautionary statements regarding forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act of 1995, AstraZeneca (hereafter 'the Group') provides the following cautionary statement:

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although the Group believes its expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and the Group undertakes no obligation to update these forward-looking statements. The Group identifies the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond the Group's control, include, among other things:

- the risk of failure or delay in delivery of pipeline or launch of new medicines
- the risk of failure to meet regulatory or ethical requirements for medicine development or approval
- the risk of failure to obtain, defend and enforce effective 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 completion of 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 filed a registration statement on Form F-4 (the Registration Statement), which has been declared effective by the United States Securities and Exchange Commission (SEC), and which includes a document that serves as a prospectus of the Group and a proxy statement of Alexion (the proxy statement/prospectus). Alexion filed the proxy statement/prospectus as a proxy statement and the Group filed the proxy statement/prospectus as a prospectus with the SEC on 12 April 2021, 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 and other relevant documents filed with the SEC when they become available, because they will contain important information. 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 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, is set forth in the proxy statement/prospectus filed with the SEC on 12 April 2021. Information about the directors and executive officers of Alexion and their ownership of Alexion shares is set forth in Alexion's Annual Report on Form 10-K/A, as previously filed with the SEC on 16 February 2021. Free copies of these documents may be obtained as described in the paragraphs above.

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