

AstraZeneca PLC
30 July 2020 07:00 BST

H1 2020 results

A strong performance during the pandemic; a leader in the fight against COVID-19

During the COVID-19 global pandemic, AstraZeneca's priority was and will continue to be the safe supply of medicines to millions of patients. In the first half, revenue, profit and cash-flow continued to grow. This performance was supported by successful launches of new medicines¹ and more encouraging progress from the pipeline. The Company's focus on growth through innovation is designed to support a continuation of these trends.

Pascal Soriot, Chief Executive Officer, commented:

"I want to thank my colleagues around the world for producing a strong performance in the first half of the year, delivering further revenue growth and another step forward in profitability and cash generation. I was particularly pleased with the robust growth in Emerging Markets and the success of our new medicines. We made further progress with our pipeline, highlighted by the overwhelming success of *Tagrisso* in the ADAURA trial and with *Farxiga*, which expanded its potential beyond diabetes. We are also pleased with our new collaboration with Daiichi Sankyo on DS-1062, which strengthens our growing Oncology portfolio.

Furthermore, our company has mounted a significant response to COVID-19, with capacity to deliver over two billion doses of AZD1222, the accelerated development of our monoclonal antibodies and new trials for the use of *Calquence* and *Farxiga* to treat patients affected by the virus.

Looking ahead, while we continue to anticipate variations in quarterly performance, the continuation of our strategy makes us confident about the future. We are retaining our full-year guidance that is underpinned by the focus on commercial execution and an exciting pipeline of new medicines."

Financial performance

Table 1: Financial summary

	H1 2020			Q2 2020		
	\$m	% change		\$m	% change	
		Actual	CER ²		Actual	CER
Total Revenue	12,629	12	14	6,275	8	11
<i>Product Sales</i>	12,359	11	13	6,048	6	9
<i>Collaboration Revenue</i>	270	<i>n/m</i> ³	<i>n/m</i>	227	<i>n/m</i>	<i>n/m</i>
Reported ⁴ EPS ⁵	\$1.17	<i>n/m</i>	<i>n/m</i>	\$0.58	<i>n/m</i>	<i>n/m</i>
Core ⁶ EPS	\$2.01	24	26	\$0.96	32	31

There was only a modest inventory-related benefit to Total Revenue, reflecting the effects of the ongoing COVID-19 pandemic, in the first half of the year.

Total Revenue increased by 12% (14% at CER) to \$12,629m in the half, with growth across all three therapy areas⁷ and in every region. Highlights of Total Revenue included:

- The performance of the new medicines, which improved by 42% (45% at CER) to \$6,353m, including new-medicine growth in Emerging Markets of 71% (79% at CER) to \$1,406m. These medicines represented 50% of global Total Revenue (H1 2019: 40%)
- Growth across all therapy areas: Oncology +28% (+31% at CER) to \$5,324m, New CVRM⁸ +8% (+11% at CER) to \$2,265m and Respiratory & Immunology +5% (+7% at CER) to \$2,676m. In the second quarter, Respiratory & Immunology Total Revenue of \$1,122m declined by 11% (8% at CER), reflecting the adverse impact of COVID-19 on sales of *Pulmicort* in China

- Growth in every region: an increase in Emerging Markets of 9% (15% at CER) to \$4,329m, with China growth of 10% (14% at CER) to \$2,659m. China increased by 7% in the second quarter (12% at CER) to \$1,243m. Total Revenue in the US increased by 13% in the half to \$4,177m and in Europe by 17% (20% at CER) to \$2,447m

COVID-19

In addition to the array of efforts listed in the [prior results announcement](#), the Company has mobilised research efforts to find new ways to help target the SARS-CoV-2 virus, reduce the cytokine storm⁹ and limit organ damage; for the latest AstraZeneca communications regarding COVID-19, please [click here](#).

AstraZeneca has prioritised broad and equitable supply of a vaccine throughout the world at no profit during the pandemic, details of which can be found in the sustainability section of this document. In July 2020, results from the ongoing Phase I/II COV001 trial, led by the University of Oxford, were published in [The Lancet](#) showing that recombinant adenovirus vaccine AZD1222 (ChAdOx1 nCoV-19) was tolerated and generated robust immune responses against the SARS-CoV-2 virus in evaluated participants. Late-stage trials are currently underway in the UK, Brazil and South Africa and are due to start in the US. These trials will determine how well the vaccine will protect from the COVID-19 disease and measure safety and immune responses in different age ranges, at various doses.

Further details of the Company's broad COVID-19 research and development programme and agreements to establish manufacturing capacity are shown later in this announcement.

Guidance

The Company provides guidance for FY 2020 at CER on:

- Total Revenue, comprising Product Sales and Collaboration Revenue
- Core EPS

Guidance partly reflects the changing nature and growing strategic impact of Collaboration Revenue which, over time, will primarily comprise potential income from various collaborations, including:

- A share of gross profits derived from sales of *Enhertu* in several markets, where those sales are recorded by Daiichi Sankyo Company, Limited (Daiichi Sankyo)
- A share of gross profits derived from sales of roxadustat in China recorded by FibroGen Inc. (FibroGen)¹⁰
- Milestone revenue from the MSD¹¹ collaboration on *Lynparza*
- Smaller amounts of milestone and royalty revenue from other marketed and pipeline medicines

Financial guidance for FY 2020 is unchanged. Total Revenue is expected to increase by a high single-digit to a low double-digit percentage and Core EPS is expected to increase by a mid- to high-teens percentage.

AstraZeneca recognises the heightened risks and uncertainties from the impact of COVID-19 referred to later in this announcement. Variations in performance between quarters can be expected to continue.

The Company is unable to provide guidance and indications on a Reported basis because AstraZeneca cannot reliably forecast material elements of the Reported result, including any fair-value adjustments arising on acquisition-related liabilities, intangible-asset impairment charges and legal-settlement provisions. Please refer to the cautionary-statements section regarding forward-looking statements at the end of this announcement.

Indications

The Company provides indications for FY 2020 at CER:

- The Company is focused on improving operating leverage

- A Core Tax Rate of 18-22%. Variations in the Core Tax Rate between quarters are anticipated to continue
- Capital Expenditure is expected to be broadly stable versus the prior year

Currency impact

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

Financial summary

- Total Revenue, comprising Product Sales and Collaboration Revenue, increased by 12% in the half (14% at CER) to \$12,629m. Product Sales increased by 11% (13% at CER) to \$12,359m, primarily driven by the performances of the new medicines within Emerging Markets and Oncology
- The Reported and Core Gross Profit Margins¹² were stable at 81%; the Core Gross Profit Margin declined by one percentage point at CER, partly reflecting the impact of a one-off change in estimate relating to Group inventory valuation and the growth in profit share from the collaboration with MSD in respect of *Lynparza*. The Core Gross Profit Margin increased in the second quarter by two percentage points (one at CER) to 84%, reflecting the mix of Product Sales and manufacturing efficiencies
- Reported Total Operating Expense increased by 1% in the half (3% at CER) to \$8,322m and represented 66% of Total Revenue (H1 2019: 73%). Core Total Operating Expense increased by 5% (7% at CER) to \$7,256m and represented 57% of Total Revenue (H1 2019: 61%). The increases partly reflected investment in the pipeline, including the development of *Enhertu* and the ending in 2019 of the release of the upfront funding of *Lynparza* development as part of the aforementioned [collaboration](#) with MSD; Core R&D Expense increased by 8% in the half (9% at CER) to \$2,712m. The increase in Core Total Operating Expense was also driven by additional SG&A investment in Oncology-medicine launches and AstraZeneca's further expansion in China; Core SG&A Expense increased in the half by 2% (5% at CER) to \$4,353m
- The Reported Operating Profit Margin increased in the half by six percentage points to 20%; the Core Operating Profit Margin increased by two percentage points to 29%
- Reported EPS of \$1.17 in the half, representing an increase of 108% (106% at CER). Core EPS increased by 24% (26% at CER) to \$2.01. This was despite an increase in the weighted-average number of shares to 1,312m (H1 2019: 1,289m)
- Net Cash Inflow from Operating Activities of \$1,179m in the half represented a year-on-year increase of \$688m, reflecting a \$914m improvement in Reported Operating Profit to \$2,504m
- An unchanged first interim dividend of \$0.90 per share

Commercial summary

Oncology

Total Revenue increased by 28% in the half (31% at CER) to \$5,324m.

Table 2: Select Oncology medicine performances

	H1 2020			Q2 2020		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
<i>Tagrisso</i> : Product Sales	2,016	43	45	1,034	32	35
<i>Imfinzi</i> : Product Sales	954	51	52	492	46	48
<i>Lynparza</i> : Product Sales	816	57	60	419	48	52

<i>Calquence</i> : Product Sales	195	n/m	n/m	107	n/m	n/m
<i>Enhertu</i> : Collaboration Revenue	36	n/m	n/m	22	n/m	n/m

New CVRM

Total Revenue increased by 8% in the half (11% at CER) to \$2,265m.

Table 3: Select New CVRM medicine performances

	H1 2020			Q2 2020		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
<i>Farxiga</i> : Product Sales	848	17	21	443	17	23
<i>Brilinta</i> : Product Sales	845	15	17	437	12	16
<i>Bydureon</i> : Product Sales	216	(24)	(23)	116	(18)	(17)
<i>Lokelma</i> : Product Sales	28	n/m	n/m	17	n/m	n/m
Roxadustat: Collaboration Revenue	11	n/m	n/m	9	n/m	n/m

Respiratory & Immunology

Total Revenue increased by 5% in the half (7% at CER) to \$2,676m.

Table 4: Select Respiratory & Immunology medicine performances

	H1 2020			Q2 2020		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
<i>Symbicort</i> : Product Sales	1,442	23	26	653	12	15
<i>Pulmicort</i> : Product Sales	477	(33)	(32)	97	(71)	(69)
<i>Fasenra</i> : Product Sales	426	44	45	227	36	37

Sales of *Pulmicort*, of which the majority were in China, were adversely impacted in the half by the effects of COVID-19. *Pulmicort* sales in Emerging Markets declined by 36% (34% at CER) to \$371m in the first half and by 78% (76% at CER) to \$58m in the second quarter.

Emerging Markets

As the Company's largest region, at 34% of Total Revenue, Emerging Markets increased by 9% in the half (15% at CER) to \$4,329m, including:

- A China increase of 10% in the half (14% at CER) to \$2,659m; the performance was adversely impacted by the aforementioned effects of COVID-19 on sales of *Pulmicort*. Q2 2020 Total Revenue increased by 7% (12% at CER) to \$1,243m
- An ex-China increase of 8% in the half (15% at CER) to \$1,671m. Q2 2020 Total Revenue increased by 4% (15% at CER) to \$813m

Sustainability summary

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

a) Access to healthcare

During the period, AstraZeneca advanced its commitment to broad and equitable global access to the University of Oxford's COVID-19 vaccine, AZD1222, following landmark agreements with the US Biomedical Advanced Research and Development Authority (BARDA) for the development, production and delivery of the vaccine and parallel agreements with the [UK Government](#), [Europe's Inclusive Vaccine Alliance \(IVA\)](#), the [Coalition for Epidemic Preparedness Innovations \(CEPI\)](#) and [Gavi, The Vaccine Alliance \(GAVI\)](#). In addition, the Company reached a licensing agreement with Serum Institute of India (SII) to supply low-and-middle-income countries and agreements with R-Pharm in Russia and SK Biopharmaceuticals Co., Ltd in the Republic of Korea to manufacture and export for other global markets. Across the world, these parallel agreements helped to provide total manufacturing capacity of over two billion doses of the vaccine to support broad and equitable access, at no profit to AstraZeneca during the pandemic.

b) Environmental protection

Pascal Soriot was one of 176¹³ business leaders from member companies of the [Science-Based Targets](#) initiative that signed a recent [statement](#) urging governments around the world to align their COVID-19 economic aid and recovery efforts with the latest climate science, which was [announced](#) by the UN Global Compact (UNGC) in May 2020.

c) Ethics and transparency

Highlighting the Company's continued commitment to inclusion and diversity, AstraZeneca was recognised by [DiversityInc](#) as one of the [2020 Top 50 Companies for Diversity](#); the Company was also named by DiversityInc as a Top Company for lesbian, gay, bisexual, and transgender (LGBT) employees.

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

Notes

The following notes refer to pages one to five.

1. *Tagrisso, Imfinzi, Lynparza, Calquence, Enhertu, Koselugo, Farxiga, Brilinta, Lokelma*, roxadustat, *Fasenra, Bevespi* and *Breztri*. The new medicines are pillars in the three therapy areas of Oncology, Cardiovascular (CV), Renal & Metabolism (CVRM), and Respiratory & Immunology and are important platforms for future growth. The Total Revenue of *Enhertu* and roxadustat in the half entirely reflected Ongoing Collaboration Revenue.
2. Constant exchange rates. These are financial measures that are not accounted for according to generally accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.
3. Not meaningful.
4. Reported financial measures are the financial results presented in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board and adopted by the EU. The UK is in the process of establishing its post-Brexit IFRS-adoption authority, which is expected to be operational later in 2020, but for the current time, will follow the EU approval process.
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 Interim Financial Statements. See the operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
7. Defined here as Oncology, New CVRM and Respiratory & Immunology.
8. New CVRM comprises *Brilinta*, Renal and Diabetes medicines.
9. A severe immune reaction in which the body releases too many cytokines into the blood too quickly. Cytokines are cell signalling proteins that aid communication in innate and adaptive immune responses, stimulating cell movement towards sites of inflammation and infection.
10. FibroGen and AstraZeneca are collaborating on the development and commercialisation of roxadustat in the US, China, and other global markets. FibroGen and Astellas Pharma Inc. (Astellas) are collaborating on the development and commercialisation of roxadustat in territories including Japan, Europe, the Commonwealth of Independent States, the Middle East and South Africa.
11. Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.
12. 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.
13. As of 1 July 2020.

Table 5: Pipeline highlights

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

Regulatory approvals	<ul style="list-style-type: none"> - <i>Lynparza</i> - ovarian cancer (1st line, HRD+¹¹) (PAOLA-1) (US) - <i>Lynparza</i> - pancreatic cancer (1st line, BRCAm¹²) (EU) - <i>Lynparza</i> - prostate cancer (2nd line, HRRm¹³) (US) - <i>Farxiga</i> - HF¹⁴ CVOT¹⁵ (US) - <i>Brilinta</i> - CAD¹⁶/T2D¹⁷ CVOT (US) - <i>Bevespi</i> - COPD¹⁸ (CN) - <i>Breztri</i> - COPD (US)
Regulatory submission acceptances and/or submissions	<ul style="list-style-type: none"> - <i>Enhertu</i> - breast cancer (3rd line, HER2+¹⁹) (EU) - <i>Enhertu</i> - gastric cancer (3rd line, HER2+) (JP) - <i>Brilinta/Brilique</i> - stroke (THALES) (US, EU)
Major Phase III data readouts or other significant developments	<ul style="list-style-type: none"> - <i>Imfinzi</i> - ES²⁰-SCLC²¹: positive opinion (EU) - <i>Enhertu</i> - breast cancer (3rd line, HER2+): accelerated assessment (EU) - <i>Enhertu</i> - gastric cancer (HER2+): Orphan Drug Designation, Breakthrough Therapy Designation (US) - <i>Enhertu</i> - NSCLC²² (2nd line, HER2m²³): Breakthrough Therapy Designation (US) - <i>Calquence</i> - CLL²⁴: positive opinion (EU) - selumetinib - NF1²⁵: orphan drug designation (JP) - <i>Farxiga</i> - CKD²⁶: primary, all secondary endpoints met - <i>Brilinta</i> - stroke (THALES): Priority Review (US)

Table 6: Pipeline - anticipated major news flow

Innovation is critical to addressing unmet patient needs and is at the heart of the Company's growth strategy. The focus on research and development is designed to yield strong and sustainable results from the pipeline.

¹¹ Homologous recombination deficiency positive.

¹² Breast cancer susceptibility gene 1/2 mutation.

¹³ Homologous recombination repair mutation.

¹⁴ Heart failure.

¹⁵ CV outcomes trial.

¹⁶ Coronary artery disease.

¹⁷ Type-2 diabetes.

¹⁸ Chronic obstructive pulmonary disease.

¹⁹ Human epidermal growth factor receptor 2 positive.

²⁰ Extensive stage.

²¹ Small cell lung cancer.

²² Non-small cell lung cancer.

²³ HER2 mutation.

²⁴ Chronic lymphocytic leukaemia.

²⁵ Neurofibromatosis type 1, a genetic condition causing tumours to grow along nerves in the skin, brain and other parts of the body.

²⁶ Chronic kidney disease

Timing	News flow
H2 2020	<ul style="list-style-type: none"> - <i>Tagrisso</i> - adjuvant NSCLC (EGFRm²⁷): regulatory submission - <i>Imfinzi</i> - unresectable²⁸, Stage III NSCLC (PACIFIC-2): data readout - <i>Imfinzi</i> - ES-SCLC: regulatory decision (EU, JP) - <i>Imfinzi</i> +/- tremelimumab²⁹ - liver cancer (1st line): data readout, regulatory submission - <i>Lynparza</i> - ovarian cancer (1st line) (PAOLA-1): regulatory decision (EU, JP) - <i>Lynparza</i> - ovarian cancer (3rd line, BRCAm): regulatory submission - <i>Lynparza</i> - breast cancer (BRCAm): regulatory decision (CN) - <i>Lynparza</i> - prostate cancer (2nd line): regulatory decision (EU) - <i>Enhertu</i> - breast cancer (3rd line, HER2+): regulatory decision (EU) - <i>Enhertu</i> - gastric cancer (3rd line, HER2+): regulatory decision (JP) - <i>Calquence</i> - CLL: regulatory decision (EU) - <i>Forxiga</i> - T2D CVOT: regulatory decision (CN) - <i>Forxiga</i> - HF CVOT: regulatory decision (EU, JP) - <i>Farxiga</i> - CKD: regulatory submission - <i>Brilinta</i> - stroke (THALES): regulatory decision (US) - <i>Brilinta</i> - stroke (THALES): regulatory submission (CN) - roxadustat - anaemia in CKD: regulatory decision (US) - <i>Symbicort</i> - mild asthma: regulatory decision (CN) - <i>Symbicort</i> - mild asthma: regulatory submission (EU) - <i>Fasenra</i> - nasal polyposis³⁰: data readout - PT010 - COPD: regulatory decision (EU) - tezepelumab - severe asthma: data readout - anifrolumab - lupus (SLE³¹): regulatory submission - AZD1222 - SARS-CoV-2: data readout, regulatory submission
H1 2021	<ul style="list-style-type: none"> - <i>Imfinzi</i> - unresectable, Stage III NSCLC (PACIFIC-2): regulatory submission - <i>Imfinzi</i> - NSCLC (1st line) (PEARL): data readout - <i>Imfinzi</i> +/- tremelimumab - head & neck cancer (1st line): data readout, regulatory submission - <i>Lynparza</i> - pancreatic cancer (1st line, BRCAm): regulatory decision (JP) - <i>Lynparza</i> - prostate cancer (2nd line): regulatory decision (JP) - <i>Lynparza</i> - adjuvant breast cancer: data readout - <i>Calquence</i> - CLL: regulatory decision (JP) - <i>Koselugo</i> - NF1 regulatory decision (EU) - <i>Forxiga</i> - HF CVOT: regulatory decision (CN) - <i>Brilique/Brilinta</i> - CAD/T2D CVOT: regulatory decision (EU, JP, CN) - <i>Brilique</i> - stroke (THALES): regulatory decision (EU) - <i>Fasenra</i> - nasal polyposis: regulatory submission - tezepelumab - severe asthma: regulatory submission

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²⁷ Epidermal growth factor receptor-mutated.

²⁸ The tumour cannot be removed completely through surgery.

²⁹ Tremelimumab.

³⁰ Painless, benign soft growths inside the nose.

³¹ Systemic lupus erythematosus, a chronic autoimmune disease that causes inflammation in connective tissues throughout the body.

Timing	News flow
H2 2021	<ul style="list-style-type: none"> - <i>Imfinzi</i> - NSCLC (1st line) (PEARL): regulatory submission - <i>Imfinzi</i> - adjuvant bladder cancer: data readout - <i>Imfinzi</i> - liver cancer (locoregional): data readout, regulatory submission - <i>Imfinzi</i> - biliary tract cancer: data readout - <i>Imfinzi</i> +/- tremelimumab - NSCLC (1st line) (POSEIDON): data readout (OS), regulatory submission - <i>Lynparza</i> - adjuvant breast cancer: regulatory submission - <i>Lynparza</i> - prostate cancer (1st line, castration-resistant): data readout, regulatory submission - <i>Enhertu</i> - breast cancer (3rd line, HER2+) (Phase III): data readout - <i>Enhertu</i> - breast cancer (2nd line, HER2+): data readout, regulatory submission - <i>Enhertu</i> - breast cancer (HER2 low³²): data readout - <i>Calquence</i> - CLL (2nd line) (ELEVATE R/R): data readout, regulatory submission - <i>Farxiga</i> - HF (HFpEF³³): data readout, regulatory submission - PT027 - asthma: data readout, regulatory submission

Conference call

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

Report calendar

The Company intends to publish its year-to-date and third-quarter results on Thursday, 5 November 2020.

AstraZeneca

AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, CVRM, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information, please visit astrazeneca.com and follow the Company on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

Contacts

For details on how to contact the Investor Relations Team, please [click here](#). For Media contacts, [click here](#).

Operating and financial review

All narrative on growth and results in this section is based on actual exchange rates, and financial figures are in US\$ millions (\$m), unless stated otherwise. The performance shown in this announcement covers the six-month period to 30 June 2020 (the half or H1 2020) and the three-month period to 30 June 2020 (the second quarter or Q2 2020) compared to the six-month period to 30 June 2019 (H1 2019) and three-month period to 30 June 2019 (Q2 2019) respectively, unless stated otherwise.

Core financial measures, EBITDA, Net Debt, Initial Collaboration Revenue and Ongoing Collaboration Revenue are non-GAAP financial measures because they cannot be derived directly from the Group's Interim Financial Statements. Management believes that these non-GAAP financial measures, when provided in combination with Reported results, will provide investors and analysts with helpful supplementary information to understand better the financial performance and position of the Group on a comparable basis from period to period. These non-GAAP financial measures are not a substitute for, or superior to, financial measures prepared in accordance with GAAP. Core financial measures are adjusted to exclude certain significant items, such as:

³² HER2 immunohistochemistry (IHC) 1+ or 2+ with fluorescence in situ hybridisation (ISH) test-result negative.

³³ HF with preserved ejection fraction.

- Amortisation and impairment of intangible assets, including impairment reversals but excluding any charges relating to IT assets
- Charges and provisions related to restructuring programmes, which includes charges that relate to the impact of restructuring programmes on capitalised IT assets
- Other specified items, principally comprising acquisition-related costs, which include fair-value adjustments and the imputed finance charge relating to contingent consideration on business combinations and legal settlements

Details on the nature of Core financial measures are provided on page 80 of the [Annual Report and Form 20-F Information 2019](#). Reference should be made to the Reconciliation of Reported to Core financial measures table included in the financial performance section of this announcement.

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

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

Table 7: Total Revenue by therapy area

Specialty-care medicines comprise all Oncology medicines, *Brilinta*, *Lokelma*, roxadustat and *Fasenra*. At 53% of Total Revenue (H1 2019: 46%), specialty-care medicines increased by 28% in the half (30% at CER) to \$6,634m.

	H1 2020				Q2 2020			
	\$m	% of total	% change		\$m	% of total	% change	
			Actual	CER			Actual	CER
Oncology	5,324	42	28	31	2,806	45	25	28
BioPharmaceuticals	4,941	39	7	9	2,285	36	(1)	2
<i>New CVRM</i>	2,265	18	8	11	1,163	19	10	13
<i>Respiratory & Immunology</i>	2,676	21	5	7	1,122	18	(11)	(8)
Other medicines	2,364	19	(7)	(4)	1,184	19	(6)	(2)
Total	12,629	100	12	14	6,275	100	8	11

Table 8: Top-ten medicines by Total Revenue

Medicine	Therapy Area	H1 2020				Q2 2020		
		\$m	% of total	% change		\$m	% change	
				Actual	CER		Actual	CER
<i>Tagrisso</i>	Oncology	2,016	16	43	45	1,034	32	35
<i>Symbicort</i>	Respiratory & Immunology	1,442	11	23	26	653	12	15
<i>Imfinzi</i>	Oncology	954	8	51	52	492	46	48
<i>Lynparza</i>	Oncology	951	8	64	66	554	62	65
<i>Farxiga</i>	CVRM	850	7	17	21	444	17	23
<i>Brilinta</i>	CVRM	845	7	15	17	437	12	16
<i>Nexium</i>	Other medicines	731	6	(5)	(3)	384	(4)	(1)
<i>Crestor</i>	CVRM	583	5	(10)	(7)	282	(9)	(6)
<i>Zoladex</i>	Oncology	484	4	22	27	257	28	34
<i>Pulmicort</i>	Respiratory & Immunology	477	4	(33)	(32)	97	(71)	(69)
Total		9,333	74	20	22	4,634	14	17

Table 9: Collaboration Revenue

Other Ongoing Collaboration Revenue included *Zoladex*, *Farxiga*, *Eklira*, *Nexium OTC*³⁴ and other royalties. No Initial Collaboration Revenue was recorded in the half.

	H1 2020				Q2 2020		
	\$m	% of total	% change		\$m	% change	
			Actual	CER		Actual	CER
<i>Lynparza</i> : regulatory milestone revenue	135	50	n/m	n/m	135	n/m	n/m
<i>Enhertu</i> : profit share	36	13	n/m	n/m	22	n/m	n/m
Roxadustat: profit share	11	4	n/m	n/m	9	n/m	n/m
Other Collaboration Revenue	88	33	24	25	61	36	36
Total	270	100	n/m	n/m	227	n/m	n/m

Total Revenue

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

Table 10: Therapy area and medicine performance - H1 2020

³⁴ Over the counter.

Product Sales: therapy area	Medicine	H1 2020			
		\$m	% of total Product Sales	Actual	CER
Oncology	<i>Tagrisso</i>	2,016	16	43	45
	<i>Imfinzi</i>	954	8	51	52
	<i>Lynparza</i>	816	7	57	60
	<i>Calquence</i>	195	2	n/m	n/m
	<i>Koselugo</i>	7	-	n/m	n/m
	<i>Zoladex</i>	442	4	13	18
	<i>Faslodex</i>	312	3	(40)	(38)
	<i>Iressa</i>	147	1	(42)	(40)
	<i>Arimidex</i>	107	1	(3)	-
	<i>Casodex</i>	89	1	(15)	(13)
	Others	26	-	(50)	(47)
	Total Oncology	5,111	41	26	28
BioPharmaceuticals: CVRM	<i>Farxiga</i>	848	7	17	21
	<i>Brilinta</i>	845	7	15	17
	<i>Onglyza</i>	256	2	(5)	(3)
	<i>Bydureon</i>	216	2	(24)	(23)
	<i>Byetta</i>	35	-	(36)	(35)
	Other diabetes	23	-	3	6
	<i>Lokelma</i>	28	-	n/m	n/m
	<i>Crestor</i>	582	5	(10)	(8)
	<i>Seloken/Toprol-XL</i>	395	3	-	6
	<i>Atacand</i>	126	1	19	25
	Others	106	1	(20)	(18)
BioPharmaceuticals: total CVRM	3,460	28	3	6	
BioPharmaceuticals: Respiratory & Immunology	<i>Symbicort</i>	1,442	12	23	26
	<i>Pulmicort</i>	477	4	(33)	(32)
	<i>Fasenra</i>	426	3	44	45
	<i>Daliresp/Daxas</i>	106	1	1	2

Product Sales: therapy area	Medicine	H1 2020			
		\$m	% of total Product Sales	Actual	CER
	<i>Bevespi</i>	22	-	10	10
	<i>Breztri</i>	11	-	n/m	n/m
	Others	184	1	(20)	(18)
	BioPharmaceuticals: total Respiratory & Immunology	2,668	22	5	7
Other medicines	<i>Nexium</i>	714	6	(5)	(3)
	<i>Synagis</i>	176	1	18	18
	<i>Losec/Prilosec</i>	99	1	(32)	(30)
	<i>Seroquel XR/IR</i>	63	1	(9)	(8)
	Others	68	1	(32)	(31)
	Total other medicines	1,120	9	(8)	(6)
	Total Product Sales	12,359	100	11	13
	Total Collaboration Revenue	270		n/m	n/m
	Total Revenue	12,629		12	14

Table 11: Therapy area and medicine performance - Q2 2020

Product Sales: therapy area	Medicine	Q2 2020			
		\$m	% of total Product Sales	Actual	CER
Oncology	<i>Tagrisso</i>	1,034	17	32	35
	<i>Imfinzi</i>	492	8	46	48
	<i>Lynparza</i>	419	7	48	52
	<i>Calquence</i>	107	2	n/m	n/m
	<i>Koselugo</i>	7	-	n/m	n/m
	<i>Zoladex</i>	217	4	10	17
	<i>Faslodex</i>	146	2	(45)	(43)
	<i>Iressa</i>	70	1	(41)	(38)
	<i>Arimidex</i>	58	1	(4)	-

Product Sales: therapy area	Medicine	Q2 2020			
		\$m	% of total Product Sales	Actual	CER
Product Sales: therapy area	<i>Casodex</i>	47	1	(17)	(15)
	Others	12	-	(59)	(55)
	Total Oncology	2,609	43	20	24
BioPharmaceuticals: CVRM	<i>Farxiga</i>	443	7	17	23
	<i>Brilinta</i>	437	7	12	16
	<i>Onglyza</i>	115	2	(1)	3
	<i>Bydureon</i>	116	2	(18)	(17)
	<i>Byetta</i>	15	-	(42)	(41)
	Other diabetes	10	-	(9)	(5)
	<i>Lokelma</i>	17	-	n/m	n/m
	<i>Crestor</i>	281	5	(10)	(6)
	<i>Seloken/Toprol-XL</i>	218	4	29	38
	<i>Atacand</i>	59	1	6	14
	Others	48	1	(23)	(20)
	BioPharmaceuticals: total CVRM	1,759	29	6	10
BioPharmaceuticals: Respiratory & Immunology	<i>Symbicort</i>	653	11	12	15
	<i>Pulmicort</i>	97	2	(71)	(69)
	<i>Fasenra</i>	227	4	36	37
	<i>Daliresp/Daxas</i>	53	1	(7)	(7)
	<i>Bevespi</i>	10	-	(1)	(3)
	<i>Breztri</i>	7	-	n/m	n/m
	Others	70	1	(30)	(28)
	BioPharmaceuticals: total Respiratory & Immunology	1,117	18	(11)	(8)
Other medicines	<i>Nexium</i>	377	6	(4)	(1)
	<i>Synagis</i>	90	1	(5)	(5)

Product Sales: therapy area	Medicine	Q2 2020			
		\$m	% of total Product Sales	% change	
				Actual	CER
	<i>Losec/Prilosec</i>	45	1	(34)	(31)
	<i>Seroquel XR/IR</i>	27	-	(16)	(14)
	Others	24	-	(53)	(52)
	Total other medicines	563	9	(12)	(10)
	Total Product Sales	6,048	100	6	9
	Total Collaboration Revenue	227		n/m	n/m
	Total Revenue	6,275		8	11

Total Revenue summary

Oncology

Total Revenue of \$5,324m in the half; an increase of 28% (31% at CER). This included *Lynparza* Collaboration Revenue of \$135m. The performance of *Enhertu* was reflected entirely in Collaboration Revenue.

Oncology represented 42% of overall Total Revenue (H1 2019: 37%).

Tagrisso

Tagrisso has received regulatory approval in 86 countries, including the US, China, in the EU and Japan for the 1st-line treatment of patients with EGFRm NSCLC. To date, reimbursement has been granted in 28 countries in this setting, with further reimbursement decisions anticipated in the second half of the year. This followed *Tagrisso's* initial approval in 89 countries, including the US, China, in the EU and Japan for the treatment of patients with EGFR T790M³⁵-mutated NSCLC.

Total Revenue, entirely comprising Product Sales, amounted to \$2,016m in the half and represented growth of 43% (45% at CER). This was partly driven by the aforementioned regulatory approvals and reimbursements in the 1st-line setting. Continued growth was also delivered in the 2nd-line setting, for example, within Europe and Emerging Markets. Sales in the US increased by 30% to \$725m, despite adverse inventory movements in the second quarter. Demand growth continued as *Tagrisso* retained its position as the standard of care (SoC) in the 1st-line setting.

In Emerging Markets, *Tagrisso* sales increased by 81% in the half (89% at CER) to \$595m, with notable growth in China, following the admission in 2019 to the China National Drug Reimbursement List (NRDL) in the 2nd-line setting. *Tagrisso* Total Revenue in Japan increased by 17% (16% at CER) to \$340m. In Europe, sales of \$325m in the half represented an increase of 53% (58% at CER), driven by its use in the 1st-line setting, as more reimbursements were granted.

Imfinzi

Imfinzi has received regulatory approval in 62 countries, including the US, China, in the EU and Japan for the treatment of patients with unresectable, Stage III NSCLC whose disease has not progressed following platinum-based chemoradiation therapy (CRT). The number of reimbursements increased to 27 in the half. During the period, *Imfinzi* was also approved for the treatment of ES-SCLC patients in eight countries, including the US. It is already approved for the 2nd-line treatment of patients with locally advanced or metastatic urothelial carcinoma (bladder cancer) in 17 countries, including the US.

³⁵ Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.

Total Revenue, entirely comprising Product Sales, amounted to \$954m in the half and represented growth of 51% (52% at CER), predominantly for the treatment of unresectable, Stage III NSCLC. Total Revenue in the US increased by 21% to \$574m; in Japan, growth of 44% (43% at CER) represented sales of \$124m. Sales in Europe increased by 179% (188% at CER) to \$167m, reflecting a growing number of reimbursements, while sales in Emerging Markets increased by 428% (459% at CER) to \$63m, following recent regulatory approvals and launches.

Lynparza

Lynparza has received regulatory approval in 75 countries for the treatment of ovarian cancer; it has also been approved in 67 countries for the treatment of metastatic breast cancer, and in 38 countries, including the US, for the treatment of pancreatic cancer. Finally, it has also received regulatory approval in the US for the 2nd-line treatment of HRRm prostate cancer.

Total Revenue amounted to \$951m in the half and represented growth of 64% (66% at CER); \$135m of *Lynparza* Collaboration Revenue, reflecting regulatory-milestone receipts, was recorded in the half. The strong performance was geographically spread, with launches continuing in Emerging Markets and the Established Rest of World region (RoW).

US sales increased by 55%, driven by the launch in the 1st-line BRCAm ovarian cancer setting at the end of 2018. *Lynparza* continued to be the leading medicine in the poly ADP ribose polymerase (PARP)-inhibitor class, as measured by total prescription volumes in both ovarian and breast cancer. Sales in Europe increased by 51% (56% at CER) to \$198m, reflecting increasing levels of reimbursement and BRCAm-testing rates, as well as successful recent 1st-line ovarian cancer launches, including in the UK and Germany.

Japan sales of *Lynparza* amounted to \$77m, representing growth of 32% (31% at CER). Emerging Markets sales of \$120m, up by 104% (117% at CER), were a result of the regulatory approval of *Lynparza* as a 2nd-line maintenance treatment of patients with ovarian cancer by the China National Medical Products Administration (NMPA) in 2019. *Lynparza* was admitted to the China NRDL for the same indication, with effect from January 2020.

Enhertu

Global sales, recorded by Daiichi Sankyo, amounted to \$77m. This reflected sales predominantly in the US, where *Enhertu* was launched at the start of the year and where Daiichi Sankyo is the principal. *Enhertu* was approved by the US Food and Drug Administration (FDA) for the treatment of 3rd-line HER2+ breast cancer at the end of 2019. Total Revenue, entirely comprising Collaboration Revenue recorded by AstraZeneca, amounted to \$36m in the half.

Calquence

Total Revenue, entirely comprising Product Sales, amounted to \$195m in the half and represented growth of 204% (205% at CER), with the overwhelming majority of sales in the US. *Calquence* was approved by the US FDA for the treatment of CLL and small lymphocytic lymphoma in November 2019 and received regulatory approval in this indication in an additional 12 countries. *Calquence* has also received 17 other regulatory approvals for the treatment of patients with mantle cell lymphoma.

Koselugo

Total Revenue, entirely comprising Product Sales in the US, amounted to \$7m in the half, following its launch during the period. *Koselugo* was approved by the US FDA for the treatment of paediatric patients aged two years and older with NF1 who have symptomatic, inoperable plexiform neurofibromas.

Legacy: Zoladex

Total Revenue, predominantly comprising Product Sales, amounted to \$484m in the half and represented growth of 22% (27% at CER).

Emerging Markets sales of *Zoladex* increased by 22% (29% at CER) to \$288m reflecting increased use and access in prostate cancer. Sales in Europe increased by 5% (8% at CER) to \$68m. In the Established RoW region, sales declined by 7% (6% at CER) to \$81m, driven by the effects of increased competition.

Legacy: Faslodex

Total Revenue, entirely comprising Product Sales, amounted to \$312m in the half and represented a decline of 40% (38% at CER).

Emerging Markets sales of *Faslodex* increased by 4% (10% at CER) to \$100m. US sales, however, declined by 87% to \$34m, reflecting the launch in 2019 of multiple generic *Faslodex* medicines. In Europe, where generic competitor medicines are established, sales increased by 6% (9% at CER) to \$116m, while in Japan, sales declined by 5% (7% at CER) to \$58m, driven by a mandated price reduction in the second quarter.

Legacy: Iressa

Total Revenue, entirely comprising Product Sales, amounted to \$147m in the half and represented a decline of 42% (40% at CER). Sales in Emerging Markets declined by 27% (24% at CER) to \$120m, reflecting the growing impact of *Iressa*'s inclusion on the China volume-based procurement programme.

BioPharmaceuticals: CVRM

Total Revenue increased by 3% in the first half (6% at CER) to \$3,478m and represented 28% of Total Revenue (H1 2019: 30%). This included roxadustat Ongoing Collaboration Revenue of \$11m, as well as sales of *Crestor* and other legacy medicines.

New CVRM Total Revenue, which excludes sales of *Crestor* and other legacy medicines, increased by 8% in the half (11% at CER) to \$2,265m, reflecting the performances of *Farxiga* and *Brilinta*. New CVRM represented 65% of overall CVRM Total Revenue in the half (H1 2019: 62%).

Farxiga

Total Revenue, predominantly comprising Product Sales, amounted to \$850m in the half and represented growth of 17% (21% at CER).

Emerging Markets sales increased by 49% (59% at CER) to \$306m. In China, *Farxiga* was admitted to the NRDL with effect from the start of 2020; as expected, this adversely impacted pricing. This effect, however, was more than offset by the volume benefit derived from the launch within the NRDL listing. The performance also reflected continued growth in the sodium-glucose layer transport protein 2 inhibitor class at the expense of the dipeptidyl-peptidase 4 (DPP-4) inhibitor class.

US sales declined by 12% to \$237m, reflecting the impact of competitive activity on pricing and the mix of channel sales that outweighed an encouraging level of volume growth. There were, however, favourable movements in the share of new-to-brand prescriptions, a result of a label update in Q3 2019 to reflect results from the DECLARE CVOT and the more recent HF (with reduced ejection fraction) label.

Sales in Europe increased by 25% (29% at CER) to \$223m, partly reflecting growth in the class and an acceleration of new-to-brand prescriptions, following a similar DECLARE-trial label update. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales, increased by 14% (12% at CER) to \$43m.

Brilinta

Total Revenue, entirely comprising Product Sales, amounted to \$845m in the half and represented growth of 15% (17% at CER). Patient uptake continued in the treatment of acute coronary syndrome and high-risk post-myocardial infarction (MI).

Emerging Markets sales increased by 34% (40% at CER) to \$291m. US sales, at \$351m, represented an increase of 9%, driven primarily by increasing levels of demand in both hospital and retail settings, as well as a lengthening in the average-weighted duration of treatment, reflecting the growing impact of 90-day prescriptions. Sales of *Brilique* in Europe increased by 2% in the half (5% at CER) to \$173m, mainly reflecting performances in Germany, France and Italy.

Onglyza

Total Revenue, entirely comprising Product Sales, amounted to \$256m in the half and represented a decline of 5% (3% at CER).

Sales in Emerging Markets increased by 15% (21% at CER) to \$100m, driven by the performance in China. US sales of *Onglyza* declined by 12% in the half to \$105m; Europe sales declined by 21% (18% at CER) to \$29m.

This highlighted the broader trend of a shift away from the DPP-4 inhibitor class. Given the significant future potential of *Farxiga*, the Company continues to prioritise commercial support over *Onglyza*.

Bydureon

Total Revenue, entirely comprising Product Sales, amounted to \$216m in the half and represented a decline of 24% (23% at CER).

US sales of \$185m reflected a decline of 21% in the half, resulting from competitive pressures and the impact of managed markets. Patients continue to transition from the dual-chamber pen to the *BCise* device. *Bydureon* sales in Europe fell by 29% (26% at CER) to \$24m. Reflecting the recent and potential performance of *Bydureon*, a \$102m intangible-asset impairment charge was recorded in the half.

Qternmet

During the period, the Company decided not to progress with the planned launch of *Qternmet* (a fixed-dose combination of metformin, *Farxiga* and *Onglyza*), reflecting adverse changes in the competitive landscape.

Lokelma

Total Revenue, entirely comprising Product Sales, amounted to \$28m in the half. Q2 2020 sales of \$17m reflected sequential growth of 56% (58% at CER) over Q1 2020.

The US represented the overwhelming majority of sales, following the recent launch of the medicine; *Lokelma* led new-to-brand prescription market share during the period. The medicine has received regulatory approval in a number of markets including in the EU, China and Japan and for the treatment of hyperkalaemia, with further launches in several markets anticipated soon.

Roxadustat

Total Revenue, entirely comprising Ongoing Collaboration Revenue, amounted to \$11m in the half. The period saw a continued focus on achieving hospital listings across China, with more than 40,000 patients being treated for anaemia in CKD with the medicine. The China NMPA approved roxadustat for the treatment of anaemia in CKD in dialysis-dependent (DD) and non-dialysis dependent (NDD) patients in December 2018 and August 2019, respectively. Roxadustat was admitted to the China NRDL with effect from January 2020.

In China, the Company currently records its share of roxadustat gross profit as Collaboration Revenue. During the period, FibroGen and AstraZeneca entered into an [amendment](#), effective 1 July 2020, to revise the existing licence, development and commercialisation agreement that was originally entered into on 30 July 2013, relating to the development and commercialisation of roxadustat in China. The amendment establishes a jointly owned entity that, once fully operational in 2021, will mean that FibroGen is expected to recognise revenue based on its sales to the entity, whereas AstraZeneca will likely recognise the overwhelming majority of its future revenue in China as Product Sales.

Legacy: Crestor

Total Revenue, predominantly comprising Product Sales, amounted to \$583m in the half and represented a decline of 10% (7% at CER).

Sales in Emerging Markets declined by 9% (6% at CER) to \$369m. The performance was adversely impacted by the effect of volume-based procurement in China. US sales declined by 17% to \$45m. In Europe, sales declined by 13% (12% at CER) to \$65m while in Japan, where AstraZeneca collaborates with Shionogi Co., Ltd, sales declined by 5% (6% at CER) to \$81m.

BioPharmaceuticals: Respiratory & Immunology

Total Revenue increased by 5% in the half (7% at CER) to \$2,676m and represented 21% of Total Revenue (H1 2019: 22%). This included Ongoing Collaboration Revenue of \$8m from *Duaklir*, *Eklira* and *Siliq*.

Symbicort

Total Revenue, entirely comprising Product Sales, amounted to \$1,442m in the half and represented growth of 23% (26% at CER).

US sales grew by 46% to \$558m in the half. An authorised-generic version of *Symbicort* was launched in the US by the Company's collaborator, Prasco, in January 2020. *Symbicort* also continued its global market-volume and value leadership within the inhaled corticosteroid / long-acting beta agonist (LABA) class. Emerging Markets

sales increased by 10% in the half (16% at CER) to \$290m, reflecting particularly strong performances in China and the Middle East & Africa.

In Europe, sales increased by 1% in the half (4% at CER) to \$356m. In Japan, sales increased by 53% (51% at CER) to \$102m, supported by the continued effect of AstraZeneca regaining full rights, following termination in 2019 of the Astellas co-promotion agreement; the increase was despite the market entry of a generic medicine.

Pulmicort

Total Revenue, entirely comprising Product Sales, amounted to \$477m in the half and represented a decline of 33% (32% at CER).

Emerging Markets, where *Pulmicort* sales declined by 36% in the half (34% at CER) at \$371m, represented 78% of global total. The performance in China continued to be impacted by COVID-19, with a significant reduction in the number of paediatric patients attending outpatient nebulisation rooms and adult elective procedures, where *Pulmicort* can be used in operative care when oral corticosteroids are unsuitable. This was particularly evident in the second quarter, when *Pulmicort* sales in Emerging Markets declined by 78% (76% at CER) to \$58m. The declines were also a reflection of a particularly benign influenza season in China, resulting in a significantly reduced number of asthma exacerbations.

Sales in the US declined by 36% to \$36m, while they fell in Europe by 8% (4% at CER) to \$40m.

Fasenra

Fasenra has received regulatory approval in 58 countries, including in the US, the EU and Japan for the treatment of patients with severe, uncontrolled eosinophilic asthma. With further regulatory reviews ongoing, *Fasenra* has already achieved reimbursement in 41 countries. Total Revenue, entirely comprising Product Sales, amounted to \$426m in the half and represented growth of 44% (45% at CER).

Sales in the US increased by 31% in the half to \$272m, supported by an increase in the self-administration use as a result of COVID-19 restrictions. For the aforementioned treatment of patients, *Fasenra* ended the half as the leading novel biologic medicine in the US, as measured by new-to-brand prescriptions. In Europe, sales of \$88m in the half represented an increase of 96% (102% at CER), reflecting a number of successful launches. Sales in Japan increased by 21% (20% at CER) to \$46m. In its approved indication and among new patients, *Fasenra* obtained the leading market share of all novel biologic medicines in the 'top-five' European countries and in Japan. In Emerging Markets, sales amounted to \$7m in the half (H1 2019: \$1m).

Daliresp/Daxas

Total Revenue, entirely comprising Product Sales, amounted to \$106m in the half and represented an increase of 1% (2% at CER).

US sales, representing 85% of the global total, increased by 1% to \$90m, driven by higher demand.

Bevespi

Total Revenue, entirely comprising Product Sales, amounted to \$22m in the half and represented an increase of 10%.

Bevespi has been launched in the US, in a number of European countries and in Japan. The global LABA / long acting muscarinic antagonist class continued to grow more slowly than expected.

Breztri

Total Revenue, entirely comprising Product Sales, amounted to \$11m in the half (H1 2019: \$nil).

Following successful launches in Japan and China for the treatment of COPD, *Breztri* was recently approved in the US.

Other medicines (outside the three main therapy areas)

Total Revenue, primarily comprising Product Sales, amounted to \$1,151m in the half, representing a decline of 8% (6% at CER). The performance partly reflected the [divestment](#) of global rights to *Movantik*, excluding Europe, Canada and Israel, to RedHill Biopharma in April 2020. Other Total Revenue represented 9% of overall Total Revenue (H1 2019: 11%).

Nexium

Total Revenue, predominantly comprising Product Sales, amounted to \$731m in the half; a decline of 5% (3% at CER). Emerging Markets sales of *Nexium* were stable (increasing by 4% at CER) at \$370m. In Europe, sales increased by 20% (25% at CER) to \$38m, while sales in the US declined by 30% to \$89m and in Japan, where AstraZeneca collaborates with Daiichi Sankyo, they fell by 5% to \$204m.

Losec/Prilosec

Total Revenue, entirely comprising Product Sales, amounted to \$99m in the half, a decline of 32% (30% at CER). Sales in Emerging Markets declined by 15% (12% at CER) to \$81m. Sales in Europe fell by 68% to \$10m, while in Japan, they declined by 45% (46% at CER) to \$5m.

Synagis

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

Regional Total Revenue

Table 12: Regional Total Revenue

	H1 2020				Q2 2020		
	\$m	% of total	% change		\$m	% change	
			Actual	CER		Actual	CER
Emerging Markets	4,329	34	9	15	2,056	6	13
<i>China</i>	2,659	21	10	14	1,243	7	12
<i>Ex-China</i>	1,671	13	8	15	813	4	15
US	4,177	33	13	13	2,085	10	10
Europe	2,447	19	17	20	1,244	12	15
Established RoW	1,676	13	7	7	890	2	3
<i>Japan</i>	1,232	10	3	2	679	(2)	(3)
<i>Canada</i>	298	2	33	35	143	28	35
<i>Other Established RoW</i>	145	1	2	10	68	6	17
Total	12,629	100	12	14	6,275	8	11

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

	H1 2020				Q2 2020		
	\$m	% of total	% change		\$m	% change	
			Actual	CER		Actual	CER
Oncology	1,461	34	39	46	750	34	43
BioPharmaceuticals	1,480	34	-	5	608	(15)	(9)
<i>New CVRM</i>	719	17	38	46	387	37	48
<i>Respiratory & Immunology</i>	761	18	(20)	(17)	221	(49)	(45)
Other medicines	1,389	32	(3)	2	697	4	11

Total	4,329	100	9	15	2,056	6	13
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Table 14: Notable new-medicine performances in Emerging Markets - Total Revenue

	H1 2020				Q2 2020		
	\$m	% of total	% change		\$m	% change	
			Actual	CER		Actual	CER
<i>Tagrisso</i>	595	14	81	89	315	65	74
<i>Forxiga</i>	306	7	49	59	165	49	62
<i>Brilinta</i>	291	7	34	40	156	30	39
<i>Lynparza</i> ³⁶	120	3	n/m	n/m	64	95	n/m

The new medicines represented 32% of Emerging Markets Total Revenue (H1 2019: 20%). Total Revenue from specialty-care medicines increased by 40% (47% at CER) to \$1,771m and comprised 41% of Emerging Markets sales in the half (H1 2019: 32%).

China Total Revenue, which included \$11m of roxadustat Ongoing Collaboration Revenue, comprised 61% of Emerging Markets Total Revenue in the half and increased by 10% (14% at CER) to \$2,659m. New-medicine Total Revenue in China, primarily driven by *Tagrisso* and *Lynparza* in Oncology and *Brilinta* and *Forxiga* in New CVRM, delivered particularly encouraging growth and represented 31% of China Total Revenue (H1 2019: 17%). This performance was supplemented by strong sales of *Zoladex*, *Seloken* and *Symbicort*, despite the disappointing performance from *Pulmicort*.

Ex-China Emerging Markets, comprising entirely of Product Sales, increased by 8% in the half (15% at CER) to \$1,671m. The new medicines represented 34% of ex-China Emerging Markets Total Revenue in the half (H1 2019: 27%), increasing by 39% (48% at CER) to \$572m. The performance was underpinned by strong levels of growth across the following:

Table 15: Ex-China Emerging Markets: Total Revenue

	H1 2020			Q2 2020		
	\$m	% change		\$m	% change	
		Actual	CER		Actual	CER
Ex-China Asia Pacific	597	5	7	286	(1)	2
Middle East and Africa	530	10	12	266	9	12
Ex-Brazil Latin America	206	(2)	14	98	(10)	11
Russia	175	57	67	91	45	68
Brazil	161	(6)	16	72	(6)	28

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Table 16: Reported Profit and Loss - H1 2020

	H1 2020	H1 2019	% change	
	\$m	\$m	Actual	CER

³⁶ Here, excludes any Collaboration Revenue associated with the aforementioned collaboration with MSD.

Total Revenue	12,629	11,314	12	14
<i>Product Sales</i>	12,359	11,183	11	13
<i>Collaboration Revenue</i>	270	131	n/m	n/m
Cost of Sales	(2,404)	(2,192)	10	15
Gross Profit	10,225	9,122	12	14
<i>Gross Profit Margin</i>	80.5%	80.4%	-	-
Distribution Expense	(191)	(159)	20	25
<i>% Total Revenue</i>	1.5%	1.4%	-	-
R&D Expense	(2,777)	(2,622)	6	7
<i>% Total Revenue</i>	22.0%	23.2%	+1	+1
SG&A Expense	(5,354)	(5,457)	(2)	-
<i>% Total Revenue</i>	42.4%	48.2%	+6	+6
Other Operating Income & Expense	601	706	(15)	(13)
<i>% Total Revenue</i>	4.8%	6.2%	-1	-1
Operating Profit	2,504	1,590	57	58
<i>Operating Profit Margin</i>	19.8%	14.1%	+6	+6
Net Finance Expense	(588)	(632)	(7)	(7)
Joint Ventures and Associates	(20)	(59)	(66)	(63)
Profit Before Tax	1,896	899	n/m	n/m
Taxation	(408)	(229)	78	76
Tax Rate	22%	25%		
Profit After Tax	1,488	670	n/m	n/m
EPS	\$1.17	\$0.56	n/m	n/m

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Table 17: Reported Profit and Loss - Q2 2020

	Q2 2020	Q2 2019	% change	
	\$m	\$m	Actual	CER
Total Revenue	6,275	5,823	8	11
<i>Product Sales</i>	6,048	5,718	6	9
<i>Collaboration Revenue</i>	227	105	n/m	n/m
Cost of Sales	(984)	(1,063)	(7)	3
Gross Profit	5,291	4,760	11	13
<i>Gross Profit Margin</i>	83.7%	81.4%	+2	+1
Distribution Expense	(104)	(81)	29	37

% Total Revenue	1.7%	1.4%	-	-
R&D Expense	(1,389)	(1,356)	2	4
% Total Revenue	22.1%	23.3%	+1	+1
SG&A Expense	(2,635)	(2,943)	(10)	(8)
% Total Revenue	42.0%	50.6%	+9	+8
Other Operating Income & Expense	121	113	7	19
% Total Revenue	1.9%	2.0%	-	-
Operating Profit	1,284	493	n/m	n/m
Operating Profit Margin	20.5%	8.5%	+12	+11
Net Finance Expense	(307)	(320)	(4)	(5)
Joint Ventures and Associates	(16)	(32)	(50)	(45)
Profit Before Tax	961	141	n/m	n/m
Taxation	(223)	(34)	n/m	n/m
Tax Rate	23%	24%		
Profit After Tax	738	107	n/m	n/m
EPS	\$0.58	\$0.09	n/m	n/m

Table 18: Reconciliation of Reported Profit Before Tax to EBITDA - H1 2020

	H1 2020 \$m	H1 2019 \$m	% change	
			Actual	CER
Reported Profit Before Tax	1,896	899	n/m	n/m
Net Finance Expense	588	632	(7)	(7)
Joint Ventures and Associates	20	59	(66)	(63)
Depreciation, Amortisation and Impairment	1,551	1,403	11	12
EBITDA	4,055	2,993	35	37

Table 19: Reconciliation of Reported Profit Before Tax to EBITDA - Q2 2020

	Q2 2020 \$m	Q2 2019 \$m	% change	
			Actual	CER
Reported Profit Before Tax	961	141	n/m	n/m
Net Finance Expense	307	320	(4)	(5)
Joint Ventures and Associates	16	32	(50)	(45)
Depreciation, Amortisation and Impairment	710	727	(2)	-
EBITDA	1,994	1,220	63	63

Table 20: Reconciliation of Reported to Core financial measures - H1 2020³⁷

H1 2020	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other	Core	Core % change	
	\$m	\$m	\$m	\$m	\$m	\$m	Actual	CER
Gross Profit	10,225	35	33	-	5	10,298	12	13
<i>Gross Profit Margin</i>	80.5%					81.1%	-	-1
Distribution Expense	(191)	-	-	-	-	(191)	20	25
R&D Expense	(2,777)	16	49	-	-	(2,712)	8	9
SG&A Expense	(5,354)	45	809	152	(5)	(4,353)	2	5
Total Operating Expenses	(8,322)	61	858	152	(5)	(7,256)	5	7
Other Operating Income & Expense	601	2	1	-	-	604	(15)	(13)
Operating Profit	2,504	98	892	152	-	3,646	21	23
<i>Operating Profit Margin</i>	19.8%					28.9%	+2	+2
Net Finance Expense	(588)	-	-	115	104	(369)	(5)	(7)
Taxation	(408)	(20)	(183)	(60)	(1)	(672)	26	28
EPS	\$1.17	\$0.06	\$0.54	\$0.16	\$0.08	\$2.01	24	26

Table 21: Reconciliation of Reported to Core financial measures - Q2 2020³⁸

Q2 2020	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other	Core	Core % change	
	\$m	\$m	\$m	\$m	\$m	\$m	Actual	CER
Gross Profit	5,291	16	16	-	-	5,323	11	12
<i>Gross Profit Margin</i>	83.7%					84.3%	+2	+1

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

³⁸ 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.

Distribution Expense	(104)	-	-	-	-	(104)	29	37
R&D Expense	(1,389)	5	7	-	1	(1,376)	8	9
SG&A Expense	(2,635)	20	360	85	(6)	(2,176)	(1)	3
Total Operating Expenses	(4,128)	25	367	85	(5)	(3,656)	3	6
Other Operating Income & Expense	121	4	-	-	-	125	9	21
Operating Profit	1,284	45	383	85	(5)	1,792	32	31
Operating Profit Margin	20.5%					28.6%	+5	+4
Net Finance Expense	(307)	-	-	58	49	(200)	1	(3)
Taxation	(223)	(9)	(76)	(29)	(1)	(338)	68	68
EPS	\$0.58	\$0.03	\$0.23	\$0.09	\$0.03	\$0.96	32	31

Profit and Loss summary

a) Gross Profit

The increases in Reported and Core Gross Profit in the half reflected the growth in Product Sales. The Reported and Core Gross Profit Margins were stable at 81%; the Core Gross Profit Margin declined by one percentage point at CER, partly reflecting the impact of a one-off change in estimate relating to Group inventory valuation and the growth in profit share from the collaboration with MSD in respect of *Lynparza*. The Core Gross Profit Margin increased in the second quarter by two percentage points (one at CER) to 84%, reflecting the mix of Product Sales and manufacturing efficiencies.

b) Total Operating Expense

Reported Total Operating Expense increased by 1% in the half (3% at CER) to \$8,322m and represented 66% of Total Revenue (H1 2019: 73%). Reported SG&A Expense was adversely impacted by an increased level of intangible asset impairments, including a \$102m charge relating to *Bydureon*, and a \$96m charge relating to *Eklira/Tudorza* and *Duaklir*, partially offset by a \$95m impairment reversal in relation to *FluMist*. Core Total Operating Expense increased by 5% (7% at CER) to \$7,256m and represented 57% of Total Revenue (H1 2019: 61%).

The increases partly reflected investment in the pipeline, including the development of *Enhertu* and the ending in 2019 of the release of the upfront funding of *Lynparza* development as part of the [agreement](#) with MSD; Core R&D Expense increased in the half by 8% (9% at CER) to \$2,712m. The increase in Core Total Operating Expense was also driven by additional SG&A investment in Oncology-medicine launches and AstraZeneca's further expansion in China; Core SG&A Expense increased in the half by 2% (5% at CER) to \$4,353m.

c) Other Operating Income and Expense³⁹

Reported and Core Other Operating Income and Expense in the half included \$350m of income that reflected an [agreement](#) to divest commercial rights to a number of legacy hypertension medicines, as well as the divestment of the rights to *Inderal*, *Tenormin*, *Seloken* and *Omepral* in Japan for \$51m. Income from Allergan (part of AbbVie Inc) of \$23m was also received in the half in respect of the development of brazikumab.

³⁹ 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.

d) Net Finance Expense

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

e) Taxation

The Reported and Core Tax Rates for the half were 22% and 21% respectively (H1 2019: 25% and 21% respectively). The net cash tax paid for the half was \$792m, representing 42% of Reported Profit Before Tax (H1 2019: \$723m, 80%).

f) EPS

Reported EPS of \$1.17 in the half represented an increase of 108% (106% at CER); Core EPS increased by 24% (26% at CER) to \$2.01. This was despite an increase in the weighted-average number of shares to 1,312m (H1 2019: 1,289m).

g) Dividends

The Board has recommended an unchanged first interim dividend of \$0.90 (69.6 pence, 7.87 SEK) per Ordinary Share.

Table 22: Cash Flow

	H1 2020	H1 2019	Change
	\$m	\$m	\$m
Reported Operating Profit	2,504	1,590	914
Depreciation, Amortisation and Impairment	1,551	1,403	148
Increase in Working Capital and Short-Term Provisions	(780)	(634)	(146)
Gains on Disposal of Intangible Assets	(411)	(590)	179
Non-Cash and Other Movements	(555)	(177)	(378)
Interest Paid	(338)	(378)	40
Taxation Paid	(792)	(723)	(69)
Net Cash Inflow from Operating Activities	1,179	491	688
Net Cash Inflow/(Outflow) Before Financing Activities	1,336	(298)	1,634
Net Cash (Outflow)/Inflow from Financing Activities	(1,236)	941	(2,177)

The increase in Net Cash Inflow from Operating Activities in the half primarily reflected an underlying improvement in business performance. The increase in Non-Cash and Other Movements of \$378m to \$555m was driven by a reduction in fair-value movements on business combination-related liabilities and included the effect of the re-acquisition of US rights to *Duaklir/Tudorza* from Circassia Pharmaceuticals plc (Circassia) in May 2020 in settlement of a loan receivable balance included in working capital.

The increase in Net Cash Inflow before Financing Activities was a result of the aforementioned improvement in Net Cash Inflow from Operating Activities, as well as a \$931m increase in the Disposal of Non-Current Asset Investments to \$949m; AstraZeneca sold an undisclosed proportion of its equity portfolio in the first half. Recorded within the Purchase of Intangible Assets, AstraZeneca made the second of two \$675m upfront payments to Daiichi Sankyo as part of the 2019 [agreement](#) on *Enhertu*. There was a \$313m reduction in the Purchase of Intangible Assets, versus H1 2019, to \$983m.

The cash payment of contingent consideration, in respect of the former Bristol-Myers Squibb Company (BMS) share of the global diabetes alliance, amounted to \$257m in the half.

The second interim dividend payment, amounting to \$2,398m, was made in the period.

Capital Expenditure

Capital expenditure amounted to \$370m in the half, compared to \$438m in H1 2019. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK; total capital expenditure on the entire project to the end of June 2020 amounted to \$993m (£787m, based on average exchange rates). It is too early to state the potential impact of ongoing COVID-19 restrictions and physical-distancing measures to the Cambridge construction schedule and project expenditure. The Company has made other progress on its transition to Cambridge, including the Anne McLaren Building on the Cambridge Biomedical Campus. As of the end of June 2020, over 3,300 colleagues were based in and around the city.

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

Table 23: Net Debt summary

	At 30 Jun 2020	At 31 Dec 2019	At 30 Jun 2019
	\$m	\$m	\$m
Cash and Cash Equivalents	5,673	5,369	5,428
Other Investments	442	911	875
Cash and Investments	6,115	6,280	6,303
Overdrafts and Short-Term Borrowings	(1,799)	(225)	(629)
Lease Liabilities	(639)	(675)	(720)
Current Instalments of Loans	(2,159)	(1,597)	(1,000)
Non-Current Instalments of Loans	(15,150)	(15,730)	(17,355)
Interest-Bearing Loans and Borrowings (Gross Debt)	(19,747)	(18,227)	(19,704)
Net Derivatives	(18)	43	321
Net Debt	(13,650)	(11,904)	(13,080)

Net Debt increased by \$1,746m in the half, principally due to Net Cash Inflow from Operating Activities of \$1,179m being more than offset by the payment of the second interim dividend of 2019 of \$2,398m (representing two thirds of the 2019 full year).

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

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

Capital allocation

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

Foreign exchange

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

Table 24: Currency sensitivities

The Company provides the following currency-sensitivity information:

Currency	Primary Relevance	Average Exchange Rates versus USD			Annual Impact of 5% Strengthening in Exchange Rate versus USD (\$m) ⁴⁰	
		FY 2019 ⁴¹	H1 2020 ⁴²	% change	Product Sales	Core Operating Profit
CNY	Product Sales	6.92	6.88	-	288	190
EUR	Product Sales	0.89	0.93	(4)	171	68
JPY	Product Sales	108.98	105.74	3	139	98
Other ⁴³					231	123
GBP	Operating Expense	0.78	0.81	(4)	27	(93)
SEK	Operating Expense	9.46	9.45	-	5	(51)

Related-party transactions

There have been no significant related-party transactions in the period.

Principal risks and uncertainties

It is not anticipated that the nature of the principal risks and uncertainties that affect the business (including the Company's scientific and operational response to the COVID-19 pandemic), and which are set out on pages 74 to 77 of the Annual Report and Form 20-F Information 2019, will change in respect of the second six months of the financial year. The impact of COVID-19 on AstraZeneca's operations is highly uncertain and cannot be predicted with confidence. The extent of any adverse impact on AstraZeneca's operations (including the effects of any governmental or regulatory response to the pandemic) will depend on the global duration, extent and severity of the pandemic. To the extent the pandemic adversely affects AstraZeneca operations and/or performance, the Company expects it to have the effect of heightening 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 potential impact of Brexit continues to be treated as an integral part of the Principal Risks rather than as a stand-alone risk, as summarised on page 75 of the Annual Report and 20F information 2019.

In summary, the principal risks and uncertainties listed in the Annual Report and 20-F Information 2019 are:

1. Medicine pipeline and intellectual property risks: failure or delay in delivery of pipeline and new medicines; failure to meet regulatory or ethical requirements for medicine development or approval; failure to obtain, defend and enforce effective intellectual property (IP) protection or IP challenges by third parties.
2. Commercialisation risks: pricing, affordability, access and competitive pressures; failures or delays in quality execution of commercial strategies.
3. Supply-chain and business-execution risks: failure to maintain supply of compliant, quality medicines; failure of information technology and data protection or cybercrime; failure to attract, develop, engage and retain a diverse, talented and capable workforce.
4. Legal, regulatory and compliance risks: safety and efficacy of marketed medicines is questioned; adverse outcome of litigation and / or governmental investigations; failure to meet regulatory and ethical expectations on commercial practices, including bribery and corruption, and scientific exchanges.
5. Economic and financial risks: failure to achieve strategic plans or meet targets or expectations.

⁴⁰ As per the FY 2019 results announcement.

⁴¹ Based on average daily spot rates in FY 2019.

⁴² Based on average daily spot rates from 1 January 2020 to 30 June 2020.

⁴³ Other currencies include AUD, BRL, CAD, KRW and RUB.

Sustainability

AstraZeneca's sustainability approach has three priority areas⁴⁴, 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

In April 2020, AstraZeneca signed a licence, development and distribution [agreement](#) with the University of Oxford for AZD1222. The Company also made several landmark agreements in the period, most notably, with BARDA and parallel agreements with the UK Government, Europe's IVA, and CEPI, GAVI and the SII to supply low-and-middle-income countries.

In May 2020, AstraZeneca achieved the support of more than \$1bn from BARDA for the development, production and delivery of the AZD1222 vaccine, starting in H2 2020. The development programme includes a Phase III clinical trial, with c.30,000 participants.

In June 2020, the Company announced a \$750m [agreement](#) with CEPI and GAVI to support the manufacturing, procurement and distribution of 300 million doses of the vaccine, with delivery starting by the end of the year. Also, AstraZeneca reached a licensing agreement with the SII to supply one billion doses for low and middle-income countries, with a commitment to provide 400 million doses before the end of 2020. The agreement with CEPI and GAVI also represented the first advanced market commitment through the Access to COVID-19 Tools Accelerator, a global collaboration of philanthropic, multi-lateral, private sector and civil society partners.

The Company also announced in June 2020 that it had reached an [agreement](#) with Europe's IVA, spearheaded by Germany, France, Italy and the Netherlands, to supply up to 400 million doses of the vaccine. The IVA aims to accelerate the supply of the vaccine and to make it available to other European countries that wish to participate in the initiative and is committed to providing equitable access to all participating countries across Europe. In July 2020, AstraZeneca announced agreements with R-Pharm in Russia and SK Biopharmaceuticals Co., Ltd in the Republic of Korea to manufacture and export for other global markets.

These agreements marked the latest commitments to support broad and equitable global access to the vaccine, particularly for low and middle-income countries. In aggregate, these parallel agreements have helped to provide a total manufacturing capacity of over two billion doses of the vaccine at no profit to AstraZeneca during the pandemic, in line with the aforementioned licence agreement with the University of Oxford.

During the period, AstraZeneca announced the signing of a Memorandum of Understanding with the Ministry of Health (MoH) of the Republic of Uganda for the expansion of the Company's [Healthy Heart Africa](#) programme. The agreement will make Uganda the fifth country of implementation after Kenya, Ethiopia, Tanzania and Ghana. The partnership aims to strengthen the provision of services for managing and preventing hypertension, including raising awareness of lifestyle risk factors for CV disease, using MoH guidelines to standardise care, and upskilling health workers through training and education.

b) Environmental protection

In the period, the [Solutions Journal published a 10-point action plan](#) co-authored by Professor Jason Snape, Head of Environmental Protection, Global Sustainability, AstraZeneca. The action plan highlighted the strategies required for a more sustainable future post-pandemic and focused on the implementation of a circular

⁴⁴ 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'.

bioeconomy. The article reflected the work of the [Sustainable Markets Council](#), established by His Royal Highness, The Prince of Wales in September 2019, of which AstraZeneca and Pascal Soriot are founding council members.

In June 2020, The Prince of Wales launched [The Great Reset](#) with the World Economic Forum, a new global and multi-stakeholder call to action. The initiative will explore the necessary steps to recalibrate global systems in a post-pandemic world for a future that is more resilient, sustainable and inclusive. AstraZeneca actively supports progress towards a circular bioeconomy and The Great Reset as part of the Sustainable Markets Initiative and the need to operate responsibly and sustainably in the post-COVID-19 recovery.

During the period, Pascal Soriot was one of 176 business leaders¹³ from member companies of the [Science-Based Targets initiative](#) that signed a [statement](#) urging governments around the world to align their COVID-19 economic aid and recovery efforts with the latest climate science, which was [announced by the UNGC](#) in May 2020.

c) [Ethics and transparency](#)

Further highlighting the Company's commitment to inclusion and diversity, AstraZeneca was recognised by [DiversityInc](#) as one of the [2020 Top 50 Companies for Diversity](#) and the Company was also named as a Top Company for LGBT employees. In further recognition, Caireen Hargreaves, Associate Director, Product Sustainability, AstraZeneca, was awarded a position in the [2020 Top 50 Women in Engineering - Sustainability](#) by the UK's Women's Engineering Society.

In July 2020, an [interview](#) was published by Reuters with AstraZeneca's Executive Vice President, Human Resources, Fiona Cicconi. This focused on the additional measures implemented by the Company to support employees impacted by COVID-related gaps in children's education and care provision. Measures included recruiting up to 80 teachers to run online lessons, providing personal tutoring and helping to locate some childcare spaces to ensure employees are able to focus and continue to develop and deliver life-changing medicines.

During the period, Heather Stewart, Vice President, Ethics & Transparency and Deputy Chief Compliance Officer, Global Sustainability spoke at a UNGC Deep Dive Insights kick-off webinar, as part of Workstream II Putting a Human Face to Climate Change of the [Business Ambition for Climate and Health Action Platform](#), where the Company is Patron sponsor, which is developing a Human Rights Impact Guide for companies.

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

Research and development

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

A comprehensive breakdown of AstraZeneca's pipeline of medicines in human trials can be found in the latest clinical-trials appendix, available on astrazeneca.com. Highlights of developments in the Company's late-stage pipeline since the prior results announcement are shown below:

Table 25: Late-stage pipeline

<p>New molecular entities and major lifecycle events for medicines in Phase III trials or under regulatory review</p>	<p>17</p>	<p>Oncology</p> <ul style="list-style-type: none"> - <i>Tagrisso</i> - NSCLC - <i>Imfinzi</i> - multiple cancers - <i>Lynparza</i> - multiple cancers - <i>Enhertu</i> - multiple cancers - capivasertib - breast cancer - <i>Calquence</i> - blood cancers - tremelimumab - multiple cancers - savolitinib - NSCLC⁴⁵ <p>CVRM</p> <ul style="list-style-type: none"> - <i>Farxiga</i> - multiple indications - roxadustat - anaemia in CKD <p>Respiratory & Immunology</p> <ul style="list-style-type: none"> - <i>Fasenra</i> - multiple indications - PT010 - COPD - PT027 - asthma - tezepelumab - severe asthma - nirsevimab - respiratory syncytial virus - anifrolumab - lupus (SLE) - brazikumab - inflammatory bowel disease⁴³
<p>Total projects in clinical pipeline</p>	<p>142</p>	

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Oncology

During the period, AstraZeneca presented new results across its broad portfolio of cancer medicines at the 2020 American Society of Clinical Oncology (ASCO20) Virtual Scientific Program, comprising 98 abstracts, including 19 oral presentations with one plenary and 10 late-breakers.

Presentations demonstrated the Company's leadership in the treatment of early lung cancer, reflected by a late-breaking plenary presentation of the unprecedented results from the Phase III ADAURA trial for *Tagrisso* in the adjuvant treatment of patients with Stage IB, II and IIIA EGFRm NSCLC. Detailed results from an updated analysis of the Phase III CASPIAN trial were also presented where *Imfinzi*, in combination with a choice of chemotherapies, demonstrated a sustained, clinically meaningful overall survival (OS) benefit in ES-SCLC. Data from the DESTINY programme highlighted the potential of *Enhertu* across HER2-driven tumours, including lung, breast, gastric and colorectal cancers.

Oncology: lung cancer

a) *Tagrisso*

During the ASCO20 Virtual Scientific Program, detailed results from the Phase III ADAURA trial were presented in a plenary session. *Tagrisso* demonstrated a statistically significant and clinically meaningful improvement in disease-free survival (DFS) in the adjuvant treatment of patients with early-stage (IB, II and IIIA) EGFRm NSCLC after complete tumour resection with curative intent. For the primary endpoint of DFS in patients with Stage II and IIIA disease, adjuvant treatment with *Tagrisso* reduced the risk of disease recurrence or death by 83% (hazard ratio [HR] 0.17; 95% confidence interval (CI) 0.12-0.23; p<0.0001). DFS results in the overall trial population, Stage IB through IIIA, a key secondary endpoint, demonstrated a reduction in the risk of disease recurrence or death of 79% (HR 0.21; 95% CI 0.16-0.28; p<0.0001). Consistent DFS results were seen across

⁴⁵ Phase II/IIb trial with potential for registration.

all subgroups, including patients who were treated with surgery followed by chemotherapy and those who received surgery only, as well as in Asian and non-Asian patients.

Table 26: Key *Tagrisso* trials in lung cancer

Trial	Population	Design	Timeline	Status
Phase III NeoADAURA	Neo-adjuvant EGFRm NSCLC	Placebo or <i>Tagrisso</i>	FPCD ⁴⁶ Q2 2020 First data anticipated 2021+	Recruitment ongoing
Phase III ADAURA	Adjuvant EGFRm NSCLC	Placebo or <i>Tagrisso</i>	FPCD Q4 2015 LPCD ⁴⁷ Q1 2019	Trial unblinded early due to overwhelming efficacy
Phase III LAURA	Locally advanced, unresectable EGFRm NSCLC	Placebo or <i>Tagrisso</i>	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III FLAURA2	1st-line EGFRm NSCLC	<i>Tagrisso</i> or <i>Tagrisso</i> + platinum-based chemotherapy doublet	FPCD Q4 2019 First data anticipated 2021+	Recruitment ongoing

b) *Imfinzi*

Detailed results from an updated analysis of the Phase III CASPIAN *Imfinzi* trial were presented at the ASCO20 Virtual Scientific Program. *Imfinzi*, in combination with a choice of chemotherapies, etoposide plus either carboplatin or cisplatin, demonstrated a sustained, clinically meaningful OS benefit for adults with ES-SCLC. The CASPIAN trial had previously met the primary endpoint of OS in June 2019, which formed the basis of the US FDA approval in March 2020.

After a median follow-up of more than two years, the latest results for *Imfinzi* plus chemotherapy showed sustained efficacy, maintaining a 25% reduction in the risk of death versus chemotherapy alone (HR 0.75; 95% CI 0.62-0.91; nominal p=0.0032). Updated median OS was 12.9 months, versus 10.5 for chemotherapy.

During the period, the Company announced that *Imfinzi* had been recommended for marketing authorisation in the EU for the 1st-line treatment of adults with ES-SCLC in combination with a choice of chemotherapies, etoposide plus either carboplatin or cisplatin. The Committee for Medicinal Products for Human Use⁴⁸ (CHMP) based its positive opinion on results from the Phase III CASPIAN trial for *Imfinzi* plus chemotherapy, which were also published in [The Lancet](#).

Table 27: Key *Imfinzi* trials in lung cancer

⁴⁶ First patient commenced dosing.

⁴⁷ Last patient commenced dosing.

⁴⁸ The European Medicines Agency committee responsible for human medicines.

Trial	Population	Design	Timeline	Status
Phase III MERMAID-1	Stage II-III resected NSCLC	SoC chemotherapy +/- <i>Imfinzi</i>	- First data anticipated 2021+	Initiating
Phase III AEGEAN	Neo-adjuvant (before surgery) NSCLC	SoC chemotherapy +/- <i>Imfinzi</i> , followed by surgery, followed by placebo or <i>Imfinzi</i>	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase III ADJUVANT BR.31 ⁴⁹	Stage Ib-IIIa NSCLC	Placebo or <i>Imfinzi</i>	FPCD Q1 2015 LPCD Q1 2020 First data anticipated 2021+	Recruitment completed
Phase III PACIFIC-2	Stage III unresected locally advanced NSCLC (concurrent CRT)	Placebo or <i>Imfinzi</i>	FPCD Q2 2018 LPCD Q3 2019 First data anticipated H2 2020	Recruitment completed
Phase III ADRIATIC	Limited- stage SCLC	Concurrent CRT, followed by placebo or <i>Imfinzi</i> or <i>Imfinzi</i> + treme	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III PEARL	Stage IV, 1st-line NSCLC	SoC chemotherapy or <i>Imfinzi</i>	FPCD Q1 2017 LPCD Q1 2019 First data anticipated H1 2021	Recruitment completed
Phase III POSEIDON	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + <i>Imfinzi</i> or SoC + <i>Imfinzi</i> + treme	FPCD Q2 2017 LPCD Q4 2018 OS data anticipated H2 2021	PFS ⁵⁰ primary endpoint met

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⁴⁹ Conducted by the Canadian Cancer Trials Group.

⁵⁰ Progression-free survival.

Trial	Population	Design	Timeline	Status
Phase III CASPIAN	ES-SCLC	SoC chemotherapy or SoC + <i>Imfinzi</i> or SoC + <i>Imfinzi</i> + treme	FPCD Q1 2017 LPCD Q2 2018	OS primary endpoint met for <i>Imfinzi</i> monotherapy arm OS primary endpoint not met for <i>Imfinzi</i> + treme

As a result of the positive *Tagrisso* ADAURA Phase III trial in the adjuvant treatment of EGFRm NSCLC, the impact on the *Imfinzi* ADJUVANT BR.31 Phase III trial analysis plan is currently being reviewed; data from this trial is anticipated in 2021+.

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

Trial	Population	Design	Timeline	Status
Phase III POTOMAC	Non-muscle invasive bladder cancer	SoC BCG ⁵¹ or SoC BCG + <i>Imfinzi</i>	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III NIAGARA	Muscle-invasive bladder cancer	Neo-adjuvant cisplatin and gemcitabine SoC chemotherapy or SoC + <i>Imfinzi</i> , followed by adjuvant placebo or <i>Imfinzi</i>	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase III EMERALD-1	Locoregional HCC ⁵²	TACE ⁵³ followed by placebo or TACE + <i>Imfinzi</i> , followed by <i>Imfinzi</i> + bevacizumab or TACE + <i>Imfinzi</i> followed by <i>Imfinzi</i>	FPCD Q1 2019 First data anticipated H2 2021	Recruitment ongoing
Phase III EMERALD-2	Locoregional HCC at high risk of recurrence after surgery or radiofrequency ablation	Adjuvant <i>Imfinzi</i> or <i>Imfinzi</i> + bevacizumab	FPCD Q2 2019 First data anticipated 2021+	Recruitment ongoing
Phase III CALLA	Locally advanced cervical cancer	CRT or CRT + <i>Imfinzi</i> , followed by placebo or <i>Imfinzi</i>	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing

⁵¹ Bacillus Calmette-Guerin.

⁵² Hepatocellular carcinoma.

⁵³ Transarterial chemoembolisation.

Trial	Population	Design	Timeline	Status
Phase III NILE	Stage IV, 1st-line cisplatin chemotherapy- eligible bladder cancer	SoC chemotherapy or SoC + <i>Imfinzi</i> or SoC + <i>Imfinzi</i> + treme	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III KESTREL	Stage IV, 1st-line HNSCC ⁵⁴	SoC or <i>Imfinzi</i> or <i>Imfinzi</i> + treme	FPCD Q4 2015 LPCD Q1 2017 First data anticipated H1 2021	Recruitment completed
Phase III HIMALAYA	Stage IV, 1st-line unresectable HCC	Sorafenib or <i>Imfinzi</i> or <i>Imfinzi</i> + treme	FPCD Q4 2017 LPCD Q4 2019 First data anticipated H2 2020	Recruitment completed Orphan Drug Designation (US) ⁵⁵
Phase III TOPAZ-1	Stage IV, 1st-line biliary-tract cancer	Gemcitabine and cisplatin SoC chemotherapy or SoC + <i>Imfinzi</i>	FPCD Q2 2019 First data anticipated H2 2021	Recruitment ongoing

c) *Lynparza* (multiple cancers)

During the period, AstraZeneca announced that *Lynparza*, in combination with bevacizumab, was approved in the US for the maintenance treatment of platinum-sensitive ovarian cancer patients whose cancer is associated with HRD-positive status. The approval by the US FDA was based on a subgroup analysis of the Phase III PAOLA-1 trial, which showed that *Lynparza*, in combination with bevacizumab maintenance treatment, reduced the risk of disease progression or death by 67% (equal to a hazard ratio of 0.33). The addition of *Lynparza* improved progression-free survival (PFS) to a median of 37.2 months, versus 17.7 months with bevacizumab alone in patients with HRD-positive advanced ovarian cancer.

During the period, AstraZeneca also announced that *Lynparza* had received regulatory approval in the US for patients with HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC). The approval was based on results from the Phase III PROfound trial, which were published in [The New England Journal of Medicine](#). *Lynparza* demonstrated a radiographic PFS (rPFS) benefit in the overall HRR gene-mutated trial population, a key secondary endpoint, and reduced the risk of disease progression or death by 51% (equal to a hazard ratio of 0.49; p-value <0.0001) and improved rPFS to a median of 5.8 months, versus 3.5 months with enzalutamide or abiraterone.

Additional results from the PROfound trial, announced in April 2020, demonstrated a statistically significant and clinically meaningful improvement in the key secondary endpoint of OS with *Lynparza* versus enzalutamide or abiraterone in men with mCRPC and BRCA1/2 or Ataxia-Telangiectasia Mutated gene mutations. Results showed that *Lynparza* reduced the risk of death by 31% (equal to a hazard ratio of 0.69; p-value=0.0175) and improved OS to a median of 19.0 months, versus 14.6 months with enzalutamide or abiraterone.

⁵⁴ Head and neck squamous cell carcinoma.

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 sponsor. Designation qualifies the sponsor of the medicine for various development incentives.

During the period, the Company announced that *Lynparza* had been approved in the EU for patients with germline BRCAm (gBRCAm) metastatic pancreatic cancer, based on results from the Phase III POLO trial. The trial demonstrated that *Lynparza* nearly doubled the time patients with gBRCAm metastatic pancreatic cancer lived without disease progression or death to a median of 7.4 months, versus 3.8 months on placebo.

Table 29: Key *Lynparza* trials

Trial	Population	Design	Timeline	Status
Phase III OlympiA	Adjuvant BRCAm breast cancer	SoC placebo or <i>Lynparza</i>	FPCD Q2 2014 LPCD Q2 2019 First data anticipated H1 2021	Recruitment completed
Phase III PROfound	Metastatic castration-resistant 2nd-line+ HRRm prostate cancer	SoC (abiraterone or enzalutamide) or <i>Lynparza</i>	FPCD Q2 2017 LPCD Q4 2018	Primary endpoint met Priority Review (US)
Phase III PAOLA-1 ⁵⁶	Advanced 1st-line ovarian cancer	Bevacizumab maintenance or bevacizumab + <i>Lynparza</i> maintenance	FPCD Q2 2015 LPCD Q2 2018	Primary endpoint met Priority Review (US)
Phase II/III GY005	Recurrent platinum-resistant/refractory ovarian cancer	SoC chemotherapy or cediranib or cediranib + <i>Lynparza</i>	FPCD Q2 2016 (Phase II) FPCD Q1 2019 (Phase III) First data anticipated 2021+	Recruitment ongoing (Phase III component)
Phase III DuO-O	Advanced 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + <i>Imfinzi</i> +/- <i>Lynparza</i> maintenance	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase III DuO-E	Advanced 1st-line endometrial cancer	Chemotherapy or chemotherapy + <i>Imfinzi</i> + <i>Imfinzi</i> maintenance or chemotherapy + <i>Imfinzi</i> followed by <i>Imfinzi</i> + <i>Lynparza</i> maintenance	FPCD Q2 2020 First data anticipated 2021+	Recruitment ongoing

⁵⁶ Conducted by the ARCAGY/Groupe d'Investigateurs national des Etudes des Cancers Ovariens et du sein.

Trial	Population	Design	Timeline	Status
Phase III PROpel	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or abiraterone + <i>Lynparza</i>	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase III LYNK-003	Stage IV, 1st-line colorectal cancer	Bevacizumab + 5-FU maintenance or bevacizumab + <i>Lynparza</i> maintenance or <i>Lynparza</i> maintenance	First data anticipated 2021+	Initiating

d) *Enhertu* (breast and other cancers)

During the period, the regulatory submission for *Enhertu* was accepted in the EU for the treatment of adults with unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens. *Enhertu* was granted accelerated assessment by the CHMP. Daiichi Sankyo also announced a supplemental New Drug Application with expedited review by the Japan Ministry of Health, Labour and Welfare, based on SAKIGAKE-designation for *Enhertu* for the treatment of patients with HER2-positive metastatic gastric cancer.

During the period, key *Enhertu* data were presented at the ASCO20 Virtual Scientific Program in gastric cancer. Results from the positive, registrational, randomised controlled Phase II DESTINY-Gastric01 trial showed *Enhertu* demonstrated a statistically significant and clinically meaningful improvement in the objective response rate (ORR) of 42.9% and OS, a key secondary endpoint with a HR of 0.59 (95% CI 0.39-0.88; p=0.0097) versus chemotherapy. During the period, the US FDA awarded Breakthrough Therapy Designation to *Enhertu* for HER2-positive metastatic gastric cancer.

Enhertu also had results in lung and colorectal cancer at the ASCO20 Virtual Scientific Program. In lung cancer, data from the ongoing Phase II DESTINY-Lung01 trial showed *Enhertu* achieved a clinically meaningful tumour response in patients with HER2m unresectable and/or metastatic non-squamous NSCLC, whose disease had progressed following one or more systemic therapies with an ORR, assessed by independent central review of 61.9%. In colorectal cancer at the same meeting, results from the Phase II DESTINY-CRC01 trial demonstrated clinically meaningful activity in patients with HER2-positive unresectable and/or metastatic colorectal cancer who had received at least two prior lines of standard treatment, with 45.3% of patients achieving a tumour response. During the period, the US FDA awarded Breakthrough Therapy Designation to *Enhertu* for HER2m lung cancer.

Table 30: Key *Enhertu* trials

Trial	Population	Design	Timeline	Status
Phase II DESTINY-Breast01	Stage IV, HER2+ ⁵⁷ breast cancer post trastuzumab emtansine	<i>Enhertu</i> (single arm)	FPCD Q4 2017 LPCD Q4 2018	Primary objective met Breakthrough Therapy Designation (US) Approval (JP), Accelerated Approval (US)
Phase III	Stage IV, HER2+ breast cancer post	SoC chemotherapy or <i>Enhertu</i>	FPCD Q4 2018	Recruitment ongoing

⁵⁷ IHC 3+ and IHC 2+/ISH.

Trial	Population	Design	Timeline	Status
DESTINY-Breast02	trastuzumab emtansine		First data anticipated H2 2021	
Phase III DESTINY- Breast03	Stage IV, HER2+ breast cancer	Trastuzumab emtansine or <i>Enhertu</i>	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase III DESTINY- Breast04	Stage IV, HER2- low	SoC chemotherapy or <i>Enhertu</i>	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing
Phase II DESTINY- Gastric01	Stage IV, HER2+ gastric cancer	SoC chemotherapy or <i>Enhertu</i>	FPCD Q4 2017 LPCD Q2 2019	Primary endpoint met US Breakthrough Therapy Designation
Phase II DPT02	HER2-expressing tumours	<i>Enhertu</i>	-	Initiating

e) Calquence

During the period, *Calquence* was recommended for marketing authorisation in the EU for the treatment of adult patients with CLL. The CHMP based its positive opinion on results from two Phase III clinical trials, ELEVATE TN in patients with previously untreated CLL, and ASCEND in patients with relapsed or refractory CLL.

f) Koselugo (NF1)

During the period, the Company announced that *Koselugo* (formerly selumetinib) was granted orphan drug designation in Japan for the treatment of NF1, following results from the Phase II SPRINT trial which demonstrated that *Koselugo* reduced tumour volume in paediatric patients with NF1 plexiform neurofibromas.

g) New collaboration to develop and commercialise new antibody drug conjugate

In July 2020, the Company announced that it had entered into a new global development and commercialisation agreement with Daiichi Sankyo for DS-1062, its proprietary trophoblast cell-surface antigen 2 (TROP2)-directed antibody drug conjugate and potential new medicine for the treatment of multiple tumour types. DS-1062 is currently in development for the treatment of multiple tumours that commonly express the cell-surface glycoprotein TROP2. Among them, TROP2 is overexpressed in the majority of NSCLCs and breast cancers that have long been a strategic focus for AstraZeneca. The collaboration reflects AstraZeneca's strategy to invest in antibody drug conjugates as a class, the innovative nature of the technology and the successful existing collaboration with Daiichi Sankyo.

h) Savolitinib (lung cancer)

During the period, Hutchison China MediTech Limited announced that the NMPA has granted Priority Review status to the new drug application for savolitinib for the treatment of NSCLC with MET Exon 14 skipping mutations. As per the original agreement announced in 2011, AstraZeneca will manufacture and commercialise savolitinib.

i) FKB238: bevacizumab biosimilar - (multiple cancers)

During the period, Centus Biotherapeutics Ltd., a joint venture between AstraZeneca and Fujifilm Kyowa Kirin Biologics Co., Ltd, announced that the CHMP had adopted a positive opinion for the Marketing Authorisation Application of FKB238, the companies' Avastin bevacizumab biosimilar, for indications including metastatic carcinoma of the colon or rectum, metastatic breast cancer, unresectable advanced, metastatic or recurrent

NSCLC, advanced and/or metastatic renal cell cancer, epithelial ovarian, fallopian tube, or primary peritoneal cancer, and persistent, recurrent, or metastatic carcinoma of the cervix.

CVRM

During the period, AstraZeneca presented new data from the Phase III DAPA-HF and DECLARE-TIMI 58 trials at the American Diabetes Association Virtual Conference. The data were among 23 accepted abstracts, including four oral presentations, covering trials across the Company's cardio, renal and metabolic portfolio.

In June 2020, AstraZeneca presented new data across its broad portfolio of renal medicines at the 57th European Renal Association - European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress. The 20 abstracts presented, included four oral presentations for *Lokelma*, roxadustat and *Farxiga*, respectively, across different stages of CKD.

a) *Farxiga* (chronic kidney disease and heart failure)

In March 2020, the Company announced that the DAPA-CKD trial, which evaluated *Farxiga* in CKD, was stopped early due to overwhelming efficacy. In July 2020, AstraZeneca announced that the trial showed a statistically significant and clinically meaningful effect on its primary endpoint of a composite of worsening of renal function or risk of death (defined as a composite endpoint of $\geq 50\%$ sustained decline in estimated glomerular filtration rate (eGFR), onset of end-stage renal disease (ESRD) or CV or renal death) in adult patients with CKD. The trial also met all its secondary endpoints in CKD patients with and without T2D, making *Farxiga* the first medicine to significantly reduce the risk of death from any cause in this patient population. The full DAPA-CKD trial results will be presented at a forthcoming medical meeting.

In May 2020, the Company announced that the US FDA had approved *Farxiga* to reduce the risk of CV death and hospitalisation for HF in adults with HF (New York Heart Association class II-IV) with reduced ejection fraction with and without T2D. The approval was based on positive results from the landmark Phase III DAPA-HF trial, which showed *Farxiga* achieving a statistically significant and clinically meaningful reduction of CV death or hospitalisation for HF, compared to placebo.

In July 2020, the Company announced that the US FDA had granted Fast Track Designation for the development of *Farxiga* to reduce the risk of hospitalisation for heart failure or cardiovascular death in adults following an acute myocardial infarction (MI) or heart attack. The designation is based on the Phase III DAPA-MI trial that will explore the efficacy and safety of *Farxiga* in this patient population and is the first indication-seeking registry-based randomised controlled trial. The trial is expected to begin recruiting in the fourth quarter of 2020.

b) *Brilinta* (heart disease and stroke)

During the period, the US FDA approved *Brilinta* to reduce the risk of a first heart attack or stroke in high-risk patients with CAD, the most common type of heart disease. The approval was based on positive results from the Phase III THEMIS trial. The Company also decided to stop the HESTIA3 trial, which evaluated *Brilinta* for the prevention of vaso-occlusive crises in paediatric patients with sickle-cell disease. The decision was based on a recommendation from an Independent Data Monitoring Committee (IDMC), due to a low likelihood of demonstrating benefits that outweigh the risks.

In July 2020, the Company announced that the US FDA had accepted a supplemental New Drug Application and granted Priority Review designation for *Brilinta* for the reduction of subsequent stroke in patients who experienced an acute ischemic stroke or transient ischemic attack. The PDUFA date is set for the fourth quarter of 2020. The Priority Review designation was based on data from the Phase III THALES trial. During the period, the Company also received regulatory submission acceptance in the EU for the same indication.

The full results from the THALES trial were published in *The New England Journal of Medicine* in July, showing that *Brilinta* 90mg used twice daily and taken with daily aspirin for 30 days, reduced the rate of the primary composite endpoint of stroke and death by 17% (HR 0.83 [95% CI 0.71-0.96], $p=0.02$), compared to aspirin alone in patients who had an acute ischemic stroke or transient ischemic attack.

Table 31: Key large CVRM outcomes trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Farxiga					
Phase III DAPA-HF	c.4,500 patients with HF with reduced ejection fraction, with and without T2D	Arm 1: <i>Farxiga</i> 10mg or 5mg QD ⁵⁸ + SoC Arm 2: placebo + SoC	Time to first occurrence of CV death or hospitalisation due to HF or an urgent HF visit	FPCD Q1 2017 LPCD Q4 2018	Primary endpoint met Fast Track designation (US)
Phase III DELIVER	c.4,700 patients with HF and preserved ejection fraction, with and without T2D	Arm 1: <i>Farxiga</i> 10mg QD Arm 2: placebo	Time to first occurrence of CV death or worsening HF	FPCD Q4 2018 First data anticipated H2 2021	Recruitment ongoing Fast Track designation (US)
Phase III DAPA-CKD	c.4,000 patients with CKD, with and without T2D	Arm 1: <i>Farxiga</i> 10mg or 5mg QD Arm 2: placebo	Time to first occurrence of \geq 50% sustained decline in eGFR or reaching ESRD or CV death or renal death	FPCD Q1 2017 LPCD Q1 2020	Trial stopped early based on recommendation from an IDMC Primary endpoint and secondary endpoints met Fast Track designation (US)
Brilinta					
Phase III THEMIS	c.19,000 patients with T2D and CAD without a history of MI or stroke	Arm 1: <i>Brilinta</i> 60mg BID ⁵⁹ Arm 2: placebo BID on a background of aspirin if not contra-indicated ⁶⁰ or not tolerated	Composite of CV death, non-fatal MI and non-fatal stroke	FPCD Q1 2014 LPCD Q2 2016	Primary endpoint met
Phase III THALES	c.11,000 patients with acute ischaemic stroke or transient ischaemic attack	Arm 1: <i>Brilinta</i> 90mg BID Arm 2: placebo BID on a background of aspirin if not contra-indicated or not tolerated	Prevention of the composite of subsequent stroke and death at 30 days	FPCD Q1 2018 LPCD Q4 2019	Primary endpoint met Fast Track designation (US)

c) Roxadustat (anaemia)

⁵⁸ *Quaque die*, or once a day.

⁵⁹ *Bis in die*, or twice a day.

⁶⁰ A specific situation in which a medicine should not be used as a treatment as it may be harmful to the patient.

Roxadustat is currently undergoing US FDA review, with an anticipated regulatory decision expected at the end of this year. During the period, the US Institute for Clinical and Economic Review (ICER), an independent non-profit research institute that produces reports analysing the evidence on the effectiveness and value of medicines and other medical services, announced that it will assess the comparative clinical effectiveness and value of roxadustat for treatment of anaemia in CKD. The assessment is anticipated to be publicly discussed during a meeting of the California Technology Assessment Forum in February 2021, where the independent evidence review panel will deliberate and vote on evidence presented in ICER's report.

In June 2020, FibroGen and Astellas presented data at the ERA-EDTA Virtual Congress from the Phase III DOLOMITES trial, which evaluated the efficacy and safety of roxadustat compared to darbepoetin alfa for the treatment of anaemia in NDD patients with Stage 3-5 CKD. In the primary endpoint analysis, the trial demonstrated non-inferiority of roxadustat compared to darbepoetin alfa in the proportion of patients achieving correction of haemoglobin (Hb) levels during the first 24 weeks of treatment (89.5% vs 78.0%; a difference of 11.51% [95% CI 5.66%-17.36%]), with a lower bound of 95% CI >0%. The response in correction of haemoglobin levels was defined as achieving Hb \geq 11g/dL and Hb increase from baseline of \geq 1g/dL with baseline Hb >8g/dL, or Hb increase from baseline of \geq 2.0 g/dL in patients with baseline Hb \leq 8.0 g/dL.

FibroGen and AstraZeneca have made a number of regulatory submissions in RoW countries, including Australia, Brazil, Canada, Chile, India, Mexico, Philippines, Singapore, South Korea, Taiwan. FibroGen and Astellas have received a regulatory approval in DD, and a regulatory submission acceptance for NDD in Japan, while in Europe, the FibroGen and Astellas received a regulatory submission acceptance from the EMA in May 2020.

Respiratory & Immunology

a) Bevespi (COPD)

In May 2020, *Bevespi* was approved in China as a maintenance treatment to relieve symptoms in patients with COPD, including chronic bronchitis and/or emphysema. The approval by the NMPA was based on positive results from the Phase III PINNACLE 4 trial in which *Bevespi* demonstrated a statistically significant improvement in lung function as measured by trough forced expiratory volume in one second, compared to its monotherapy components and placebo, all administered twice daily via pressurised metered-dose inhaler in patients with moderate to very severe COPD. The trial formed part of the broader PINNACLE clinical trials programme showing efficacy and safety and involving more than 5,000 patients across Asia, Europe and the US.

b) Breztri (COPD)

In July 2020, AstraZeneca announced that the US FDA had approved triple-combination therapy *Breztri* for the maintenance treatment of patients with COPD. The approval was based on positive results from the Phase III KRONOS and ETHOS trials.

During the period, results from the positive Phase III ETHOS trial showed that *Breztri* demonstrated a statistically significant reduction in the rate of moderate or severe exacerbations, compared with two dual-combination therapies, in patients with moderate to very severe COPD. Compared with *Bevespi*, *Breztri* achieved a 24% reduction ($p < 0.001$) in exacerbations; it also achieved a 13% reduction ($p = 0.003$) compared with PT009. The dual-combination therapies used as comparators in the trial represented recommended therapeutic classes for the treatment of COPD. In a key secondary endpoint, *Breztri* showed a 46% reduction in the risk of all-cause mortality compared with *Bevespi* (95% CI 13%-66%).

The results were recently published in [The New England Journal of Medicine](#) and simultaneously presented at the American Thoracic Society Virtual Scientific Symposium. AstraZeneca will continue to review these data with health authorities.

c) PT027 (asthma)

PT027 is a potential first-in-class fixed-dose combination of budesonide, an ICS, and albuterol, a short-acting beta2 agonist. The Phase III programme is evaluating its use in all severities of asthma from four years of age as a rescue treatment. During the period, as a result of the COVID-19 pandemic, enrolment of new patients into the Phase III clinical development programme was paused in collaboration with co-development partner, Avillion LLP. Recruitment has since restarted, and data readouts are now anticipated in 2021.

d) Fasenra (eosinophil-driven diseases)

Table 32: Key *Fasenra* lifecycle management trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III OSTRO	Patients (aged 18-75 years) with severe bilateral nasal polyposis; symptomatic, despite SoC	Placebo or <i>Fasenra</i> 30mg Q8W ⁶¹ SC ⁶²	Nasal-polyposis burden and reported nasal blockage	FPCD Q1 2018 LPCD Q2 2019 Data anticipated H2 2020	Recruitment completed
Phase III RESOLUTE	Patients with moderate to very severe COPD with a history of frequent COPD exacerbations and elevated peripheral blood eosinophils	Placebo or <i>Fasenra</i> 100mg Q8W SC	Annualised rate of moderate or severe COPD exacerbations	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing
Phase III MANDARA	Eosinophilic granulomatosis with polyangiitis ⁶³	<i>Fasenra</i> 30mg or mepolizumab 3x100mg Q4W ⁶⁴	Proportion of patients who achieve remission, defined as a score ⁶⁵ =0 and an OCS dose ≤4 mg/day at weeks 36 and 48	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)
Phase III NATRON	HES ⁶⁶	Placebo or <i>Fasenra</i> 30mg Q4W SC	Time to HES worsening flare or any cytotoxic and/or immunosuppressive therapy increase or hospitalisation	FPCD Q3 2020 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)

⁶¹ Once every 8 weeks

⁶² Subcutaneous injection

⁶³ A rare autoimmune condition that causes inflammation of small and medium-sized blood vessels.

⁶⁴ Once every 4 weeks

⁶⁵ Birmingham Vasculitis Activity Score.

⁶⁶ Hypereosinophilic syndrome, a group of rare blood disorders.

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III MESSINA	Eosinophilic oesophagitis ⁶⁷	Placebo or <i>Fasenra</i> 30mg Q4W SC	Proportion of patients with a histologic response Changes from baseline in dysphagia PRO ⁶⁸	Data anticipated 2021+	Initiating Orphan Drug Designation (US)
Phase III FJORD	BP	Placebo or <i>Fasenra</i> 30mg Q4W SC	Proportion of patients with partial or complete remission of BP whilst off OCS for ≥ 2 months at Week 36	Data anticipated 2021+	Initiating

d) Tezepelumab (severe asthma)

During the period, Amgen Inc (Amgen) and AstraZeneca updated the [2012 collaboration agreement](#) for tezepelumab. Under the amended agreement in the US, Amgen and AstraZeneca will jointly commercialise tezepelumab and Amgen will record sales in the US. AstraZeneca's share of gross profits from tezepelumab in the US will be recognised as Collaboration Revenue. In Canada, Amgen and AstraZeneca will also jointly commercialise tezepelumab. In all territories outside the US and Canada, AstraZeneca will solely commercialise tezepelumab. AstraZeneca will record all sales outside of the US as Product Sales.

Other terms of clinical development and manufacturing remain unchanged. AstraZeneca continues to lead clinical development and Amgen continues to lead manufacturing. All aspects of the programme are under the oversight of joint governing bodies. Both companies will continue to share costs and profits equally after payment by AstraZeneca of a mid-single-digit royalty to Amgen. No payments are due to Amgen with regard to changes to the agreement.

e) Brazikumab (inflammatory bowel disease)

In May 2020, AstraZeneca completed a previously communicated agreement to recover the global rights to brazikumab (formerly MEDI2070), a monoclonal antibody targeting Interleukin-23. AstraZeneca and Allergan have terminated their previous licence agreement and all rights to brazikumab have therefore now returned to the Company.

COVID-19

a) AZD1222 (SARS-CoV-2 vaccine)

During the period, AstraZeneca advanced its ongoing response to address COVID-19 including licence, development and distribution agreements with the University of Oxford for the recombinant adenovirus vaccine, AZD1222.

The Phase I/II COV001 trial, launched in April 2020 in the UK with more than 1,000 participants, is ongoing. Initial data was reviewed in May 2020 by a Data Safety Monitoring Board and the UK Medicines and Healthcare products Regulatory Agency, resulting in the advancement to the COV002 Phase II/III trial in the UK, with over 10,000 participants.

In July 2020, results from the COV001 trial were published in [The Lancet](#), showing that AZD1222 was tolerated and generated robust immune responses against the SARS-CoV-2 virus in evaluated participants. Neutralising activity against SARS-CoV-2 (as assessed by the MNA80 assay) was seen in 91% of participants (32/35) one month after vaccination and in 100% (10/10) of participants who received a second dose. In all evaluated

⁶⁷ White blood cells gather in the lining of the oesophagus.

⁶⁸ Patient-reported outcomes.

participants, a T-cell response was induced, peaking by day 14, and maintained two months after injection. The levels of neutralising antibodies seen in participants receiving either one or two doses were in a similar range to those seen in convalescent COVID-19 patients. Data from these assays correlated positively with antibody levels to the SARS-CoV-2 spike protein, as measured by Enzyme-Linked Immunosorbent Assays data on the other participants.

COV002 has launched and has recruited almost 9,000 participants in the UK; late-stage development has begun in Brazil and South Africa. As part of the announced [agreement](#) with BARDA, the Company anticipates the launch of a Phase III clinical trial with c.30,000 participants in the US in the third quarter of this year.

b) AZD7442 (neutralising-antibody therapy for the prevention and treatment of COVID-19)

The Company's comprehensive pandemic response includes rapid mobilisation of AstraZeneca's global research efforts to discover novel coronavirus-neutralising antibodies to prevent and treat progression of the COVID-19 disease. During the period, AstraZeneca announced it had licensed coronavirus-neutralising antibodies from Vanderbilt University, US, and plans to advance two of these monoclonal antibodies (AZD8895 and AZD1061) into clinical development as a potential combination therapy (AZD7442) for the prevention and treatment of COVID-19. AstraZeneca has secured support from the Defense Advanced Research Projects Agency, part of the US Department of Defense and BARDA for the Phase I trial and the manufacturing of the potential new medicine for testing in Phase I, which is expected to initiate in the second half of the year.

In July 2020, the UK Government announced an agreement in principle with AstraZeneca for the supply of one million doses of AZD7442, with deliveries anticipated to start as early as first half of 2021, should the monoclonal-antibody combination prove to be tolerated and effective in clinical trials.

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

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

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

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

Table 33: Key trials in COVID-19⁶⁹

Trial	Population	Design	Timeline	Status
AZD1222				
Phase I/II COV001 ⁷⁰ (UK)	Protection against COVID-19 in participants aged 18-55	Control or AZD1222 n=1,077	FPCD Q2 2020 LPCD Q2 2020	Initial data read out

⁶⁹ The dates in the table referring to anticipated data for the accelerated development programme for AZD1222 refer to initial data, the timing of which are uncertain and subject to change resulting from factors such as changes in the level of community transmission. The timelines provided represent the best, current estimate of when initial efficacy data may be available.

⁷⁰ Conducted by University of Oxford.

Trial	Population	Design	Timeline	Status
Phase II/III COV002 ⁷⁰ (UK)	Protection against COVID-19 in participants aged 18-55, 55+ and paediatric	Control or AZD1222 n=10,260	FPCD Q2 2020 First data anticipated H2 2020	Recruitment ongoing
Phase III D8110C00001 (US)	Protection against COVID-19 in participants aged 18+	Placebo or AZD1222 n=30,000	First data anticipated H2 2020	Initiating
Phase I/II ChAdOx1 nCoV-19 ZA ⁷¹ (South Africa)	Protection against COVID-19 in participants aged 18-65 HIV+ ⁷² subgroup	Placebo or AZD1222 n=2,200	FPCD Q2 2020 First data anticipated H2 2020	Recruitment ongoing
Phase II/III COV003 ⁷³ (Brazil)	Protection against COVID-19 in participants aged 18-55	Control or AZD1222 n>=5,000	FPCD Q2 2020 First data anticipated H2 2020	Recruitment ongoing
AZD7442				
Phase I	COVID-19	Placebo or AZD7442	-	Initiating
Calquence				
Phase II CALAVI (US and ex-US)	COVID-19	Current SoC or SoC+ <i>Calquence</i>	First data anticipated H2 2020	Recruitment ongoing
Phase II ACCORD ⁷⁴	COVID-19	Current SoC or current SoC + <i>Calquence</i>	First data anticipated H2 2020	Recruitment ongoing
Farxiga				
Phase II DARE-19	COVID-19	Current SoC or current SoC + <i>Farxiga</i>	First data anticipated H2 2020	Recruitment ongoing
Phase II TACTIC-E ⁷⁵	COVID-19	Current SoC or current SoC + <i>Farxiga</i> + ambrisentan	First data anticipated H2 2020	Recruitment ongoing
MEDI3506				
Phase II ACCORD ⁷⁶	COVID-19	Current SoC or current SoC + MEDI3506	First data anticipated H2 2020	Recruitment ongoing

⁷¹ Conducted by University of Witwatersrand, South Africa.

⁷² Human immunodeficiency virus-positive.

⁷³ Conducted by University of Oxford.

⁷⁴ Sponsored by UK Government's Therapeutics Taskforce.

⁷⁵ Conducted by Cambridge University Hospitals NHS Trust.

⁷⁶ Sponsored by the UK Government's Therapeutics Taskforce.

Trial	Population	Design	Timeline	Status
Pulmicort				
Phase IIIa TACTIC-COVID ⁷⁷	COVID-19	Current SoC or SoC + <i>Pulmicort</i>	First data anticipated H2 2020	Recruitment ongoing
Phase IIIa STOIC ⁷⁸	COVID-19	Current SoC or SoC + <i>Pulmicort</i>	First data anticipated H2 2020	Recruitment ongoing
Symbicort				
Phase IIIa INHASCO ⁷⁹	COVID-19	Current SoC or SoC + <i>Symbicort</i>	First data anticipated H2 2020	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.

Interim Financial Statements

Table 34: Condensed consolidated statement of comprehensive income - H1 2020

For the half year ended 30 June	2020 \$m	2019 \$m
Total Revenue	12,629	11,314
<i>Product Sales</i>	12,359	11,183
<i>Collaboration Revenue</i>	270	131
Cost of Sales	(2,404)	(2,192)
Gross Profit	10,225	9,122
Distribution costs	(191)	(159)
Research and development expense	(2,777)	(2,622)
Selling, general and administrative costs	(5,354)	(5,457)
Other operating income and expense	601	706
Operating Profit	2,504	1,590
Finance income	73	96
Finance expense	(661)	(728)
Share of after-tax losses in associates and joint ventures	(20)	(59)
Profit Before Tax	1,896	899
Taxation	(408)	(229)
Profit for the period	1,488	670
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(205)	(247)
Net gains/(losses) on equity investments measured at fair value through other comprehensive income	1,069	(54)
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	6	(2)
Tax on items that will not be reclassified to profit or loss	(79)	17

⁷⁷ Sponsored by Fundació Clinic per a la Recerca Biomèdica.

⁷⁸ Conducted by University of Oxford.

⁷⁹ Conducted by Direction de la Recherche Clinique et de l'Innovation L'Assistance Publique - Hôpitaux de Paris (DRCI AP-HP).

For the half year ended 30 June	2020 \$m	2019 \$m
	791	(286)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(494)	(86)
Foreign exchange arising on designating borrowings in net investment hedges	(17)	(186)
Fair value movements on cash flow hedges	(131)	(43)
Fair value movements on cash flow hedges transferred to profit or loss	(1)	14
Fair value movements on derivatives designated in net investment hedges	60	(9)
Costs of hedging	4	3
Tax on items that may be reclassified subsequently to profit or loss	29	20
	(550)	(287)
Other comprehensive income/(loss) for the period, net of tax	241	(573)
Total comprehensive income for the period	1,729	97
Profit attributable to:		
Owners of the Parent	1,536	723
Non-controlling interests	(48)	(53)
	1,488	670
Total comprehensive income attributable to:		
Owners of the Parent	1,777	150
Non-controlling interests	(48)	(53)
	1,729	97
Basic earnings per \$0.25 Ordinary Share	\$1.17	\$0.56
Diluted earnings per \$0.25 Ordinary Share	\$1.17	\$0.56
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,289
Diluted weighted average number of Ordinary Shares in issue (millions)	1,313	1,290

Table 35: Condensed consolidated statement of comprehensive income - Q2 2020

For the quarter ended 30 June	Unreviewed ⁸⁰ 2020 \$m	Unreviewed 2019 \$m
Total Revenue	6,275	5,823
Product Sales	6,048	5,718
Collaboration Revenue	227	105
Cost of Sales	(984)	(1,063)
Gross Profit	5,291	4,760
Distribution costs	(104)	(81)
Research and development expense	(1,389)	(1,356)
Selling, general and administrative costs	(2,635)	(2,943)
Other operating income and expense	121	113
Operating Profit	1,284	493
Finance income	22	41
Finance expense	(329)	(361)
Share of after-tax losses in associates and joint ventures	(16)	(32)
Profit Before Tax	961	141
Taxation	(223)	(34)
Profit for the period	738	107
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	(645)	(257)
Net gains/(losses) on equity investments measured at fair value through other comprehensive income	898	(174)

⁸⁰ The Q2 2020 and Q2 2019 information in respect of the three months ended 30 June 2020 and 30 June 2019 respectively included in the Interim Financial Statements has not been reviewed by PricewaterhouseCoopers LLP.

For the quarter ended 30 June	Unreviewed ⁸⁰ 2020 \$m	Unreviewed 2019 \$m
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	(15)	(1)
Tax on items that will not be reclassified to profit or loss	(13)	60
	225	(372)
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	114	(139)
Foreign exchange arising on designating borrowings in net investment hedges	363	(6)
Fair value movements on cash flow hedges	56	11
Fair value movements on cash flow hedges transferred to profit or loss	(46)	(33)
Fair value movements on derivatives designated in net investment hedges	-	(12)
Costs of hedging	9	9
Tax on items that may be reclassified subsequently to profit or loss	(44)	(3)
	452	(173)
Other comprehensive income/(loss) for the period, net of tax	677	(545)
Total comprehensive income/(loss) for the period	1,415	(438)
Profit attributable to:		
Owners of the Parent	756	130
Non-controlling interests	(18)	(23)
	738	107
Total comprehensive income attributable to:		
Owners of the Parent	1,432	(415)
Non-controlling interests	(17)	(23)
	1,415	(438)
Basic earnings per \$0.25 Ordinary Share	\$0.58	\$0.09
Diluted earnings per \$0.25 Ordinary Share	\$0.58	\$0.10
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,311
Diluted weighted average number of Ordinary Shares in issue (millions)	1,313	1,312

Table 36: Condensed consolidated statement of financial position

	At 30 Jun 2020 \$m	At 31 Dec 2019 \$m	At 30 Jun 2019 \$m
Assets			
Non-current assets			
Property, plant and equipment	7,475	7,688	7,442
Right-of-use assets	634	647	702
Goodwill	11,645	11,668	11,668
Intangible assets	19,728	20,833	22,257
Investments in associates and joint ventures	41	58	73
Other investments	1,577	1,401	1,362
Derivative financial instruments	122	61	124
Other receivables	644	740	454
Deferred tax assets	3,133	2,718	2,588
	44,999	45,814	46,670
Current assets			
Inventories	3,562	3,193	3,197
Trade and other receivables	5,024	5,761	5,319
Other investments	442	849	819
Derivative financial instruments	16	36	210
Income tax receivable	213	285	246
Cash and cash equivalents	5,673	5,369	5,428
Assets held for sale	-	70	-

	At 30 Jun 2020 \$m	At 31 Dec 2019 \$m	At 30 Jun 2019 \$m
	14,930	15,563	15,219
Total assets	59,929	61,377	61,889
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(3,958)	(1,822)	(1,629)
Lease liabilities	(174)	(188)	(206)
Trade and other payables	(12,028)	(13,987)	(12,637)
Derivative financial instruments	(35)	(36)	(11)
Provisions	(612)	(723)	(410)
Income tax payable	(1,376)	(1,361)	(1,141)
	(18,183)	(18,117)	(16,034)
Non-current liabilities			
Interest-bearing loans and borrowings	(15,150)	(15,730)	(17,355)
Lease liabilities	(465)	(487)	(514)
Derivative financial instruments	(121)	(18)	(2)
Deferred tax liabilities	(2,526)	(2,490)	(2,932)
Retirement benefit obligations	(2,847)	(2,807)	(2,632)
Provisions	(835)	(841)	(376)
Other payables	(6,144)	(6,291)	(6,973)
	(28,088)	(28,664)	(30,784)
Total liabilities	(46,271)	(46,781)	(46,818)
Net assets	13,658	14,596	15,071
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	328	328	328
Share premium account	7,950	7,941	7,911
Other reserves	2,046	2,046	2,044
Retained earnings	1,913	2,812	3,265
	12,237	13,127	13,548
Non-controlling interests	1,421	1,469	1,523
Total equity	13,658	14,596	15,071

Table 37: 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 2019	317	4,427	2,041	5,683	12,468	1,576	14,044
Adoption of new accounting standards	-	-	-	54	54	-	54
Profit for the period	-	-	-	723	723	(53)	670
Other comprehensive loss	-	-	-	(573)	(573)	-	(573)
Transfer to other reserves	-	-	3	(3)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,403)	(2,403)	-	(2,403)

Issue of Ordinary Shares	11	3,484	-	-	3,495	-	3,495
Share-based payments charge for the period	-	-	-	102	102	-	102
Settlement of share plan awards	-	-	-	(318)	(318)	-	(318)
Net movement	11	3,484	3	(2,418)	1,080	(53)	1,027
At 30 Jun 2019	328	7,911	2,044	3,265	13,548	1,523	15,071
At 1 Jan 2020	328	7,941	2,046	2,812	13,127	1,469	14,596
Profit for the period	-	-	-	1,536	1,536	(48)	1,488
Other comprehensive income	-	-	-	241	241	-	241
Transfer to other reserves	-	-	-	-	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,489)	(2,489)	-	(2,489)
Issue of Ordinary Shares	-	9	-	-	9	-	9
Share-based payments charge for the period	-	-	-	118	118	-	118
Settlement of share plan awards	-	-	-	(305)	(305)	-	(305)
Net movement	-	9	-	(899)	(890)	(48)	(938)
At 30 Jun 2020	328	7,950	2,046	1,913	12,237	1,421	13,658

Table 38: Condensed consolidated statement of cash flows

For the half year ended 30 June	2020 \$m	2019 \$m
Cash flows from operating activities		
Profit Before Tax	1,896	899
Finance income and expense	588	632
Share of after-tax losses of associates and joint ventures	20	59
Depreciation, amortisation and impairment	1,551	1,403
Increase in working capital and short-term provisions	(780)	(634)
Gains on disposal of intangible assets	(411)	(590)
Fair value movements on contingent consideration arising from business combinations	(44)	-
Non-cash and other movements	(511)	(177)
Cash generated from operations	2,309	1,592
Interest paid	(338)	(378)
Tax paid	(792)	(723)
Net cash inflow from operating activities	1,179	491
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(353)	(368)
Purchase of property, plant and equipment	(370)	(438)
Disposal of property, plant and equipment	67	27
Purchase of intangible assets	(983)	(1,296)
Disposal of intangible assets	474	1,071
Movement in profit-participation liability	-	150

For the half year ended 30 June	2020 \$m	2019 \$m
Purchase of non-current asset investments	(119)	(7)
Disposal of non-current asset investments	949	18
Movement in short-term investments, fixed deposits and other investing instruments	463	21
Payments to associates and joint ventures	(8)	(39)
Interest received	37	72
Net cash inflow/(outflow) from investing activities	157	(789)
Net cash inflow/(outflow) before financing activities	1,336	(298)
Cash flows from financing activities		
Proceeds from issue of share capital	9	3,495
Issue of loans	-	500
Repayment of loans	-	(500)
Dividends paid	(2,398)	(2,432)
Hedge contracts relating to dividend payments	(93)	26
Repayment of obligations under leases	(107)	(84)
Movement in short-term borrowings	1,353	(64)
Net cash (outflow)/inflow from financing activities	(1,236)	941
Net increase in cash and cash equivalents in the period	100	643
Cash and cash equivalents at the beginning of the period	5,223	4,671
Exchange rate effects	(18)	16
Cash and cash equivalents at the end of the period	5,305	5,330
Cash and cash equivalents consist of:		
Cash and cash equivalents	5,673	5,428
Overdrafts	(368)	(98)
	5,305	5,330

Responsibility statement of the directors in respect of the half-yearly financial report

We confirm that to the best of our knowledge:

- the condensed consolidated Interim Financial Statements have been prepared in accordance with IAS 34 'Interim Financial Reporting' as issued by the International Accounting Standards Board and adopted by the European Union;
- the half-yearly management report includes a fair review of the information required by:
 - a) DTR 4.2.7R of the Disclosure and Transparency Rules, being an indication of important events that have occurred during the first six months of the financial year and their impact on the condensed consolidated Interim Financial Statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and
 - b) DTR 4.2.8R of the Disclosure and Transparency Rules, being related party transactions that have taken place in the first six months of the current financial year and that have materially affected the financial position or performance of the enterprise during that period; and any changes in the related party transactions described in the last annual report that could do so.

The Board

The Board of Directors that served during all or part of the six-month period to 30 June 2020 and their respective responsibilities can be found on the [Leadership team section of astrazeneca.com](https://www.astrazeneca.com/Leadership-team).

Approved by the Board and signed on its behalf by

Pascal Soriot

Chief Executive Officer

30 July 2020

Independent review report to AstraZeneca PLC

Report on the condensed consolidated interim financial statements

Our conclusion

We have reviewed AstraZeneca PLC's condensed consolidated interim financial statements (the 'Interim Financial Statements') in the half-yearly financial report of AstraZeneca PLC for the 6-month period ended 30 June 2020. Based on our review, nothing has come to our attention that causes us to believe that the Interim Financial Statements are not prepared, in all material respects, in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as issued by the International Accounting Standards Board (IASB) and as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

What we have reviewed

The Interim Financial Statements comprise:

- the Condensed consolidated statement of financial position as at 30 June 2020;
- the Condensed consolidated statement of comprehensive income – H1 2020 for the period then ended;
- the Condensed consolidated statement of cash flows for the period then ended;
- the Condensed consolidated statement of changes in equity for the period then ended; and
- the explanatory notes to the Interim Financial Statements.

The Interim Financial Statements included in the half-yearly financial report have been prepared in accordance with International Accounting Standard 34, 'Interim Financial Reporting', as issued by the IASB and as adopted by the European Union and the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

As disclosed in note 1 to the Interim Financial Statements, the financial reporting framework that has been applied in the preparation of the full annual financial statements of the Group is applicable law and International Financial Reporting Standards as issued by the IASB and as adopted by the European Union.

Responsibilities for the interim financial statements and the review

Our responsibilities and those of the directors

The half-yearly financial report, including the Interim Financial Statements, is the responsibility of, and has been approved by, the directors. The directors are responsible for preparing the half-yearly financial report in accordance with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority.

Our responsibility is to express a conclusion on the Interim Financial Statements in the half-yearly financial report based on our review. This report, including the conclusion, has been prepared for and only for the company for the purpose of complying with the Disclosure Guidance and Transparency Rules sourcebook of the United Kingdom's Financial Conduct Authority and for no other purpose. We do not, in giving this conclusion, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

What a review of interim financial statements involves

We conducted our review in accordance with International Standard on Review Engagements (UK and Ireland) 2410, 'Review of Interim Financial Information Performed by the Independent Auditor of the Entity' issued by the Auditing Practices Board for use in the United Kingdom. A review of interim financial information consists of

making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures.

A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing (UK) and, consequently, does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

We have read the other information contained in the half-yearly financial report and considered whether it contains any apparent misstatements or material inconsistencies with the information in the Interim Financial Statements.

PricewaterhouseCoopers LLP
Chartered Accountants
London
30 July 2020

Notes to the Interim Financial Statements

1) Basis of preparation and accounting policies

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

The unaudited Interim Financial Statements for the six months ended 30 June 2020 were approved by the Board of Directors for release on 30 July 2020.

The annual financial statements of the Group are prepared in accordance with IFRSs as issued by the IASB and adopted by the EU. Except as noted below, the Interim Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2019.

IFRS 3

An amendment to IFRS 3 'Business Combinations' relating to the definition of a business was endorsed by the EU in April 2020 with an effective date of 1 January 2020. The change in definition of a business within IFRS 3 introduces an optional concentration test to perform a simplified assessment of whether an acquired set of activities and assets is or is not a business on a transaction by transaction basis. This change is expected to provide more reliable and comparable information about certain transactions as it provides more consistency in accounting in the pharmaceutical industry for substantially similar transactions for which, under the previous definition, may have been accounted in different ways, despite limited differences in substance. The Group has adopted this amendment from the effective date.

IFRS 9, IAS 39 and IFRS 7

Amendments to IFRS 9 'Financial Instruments', IAS 39 'Financial Instruments: Recognition and Measurement' and IFRS 7 'Financial Instruments: Disclosures' relating to interbank offered rate (IBOR) reform were endorsed by the EU in January 2020. The Group adopted the amendments in the year ended 31 December 2019. The replacement of benchmark interest rates such as the London Inter-bank Offered Rate (LIBOR) and other IBORs is a priority for global regulators. The amendments provide relief from applying specific hedge-accounting requirements to hedge relationships directly affected by IBOR reform and have the effect that IBOR reform should generally not cause hedge accounting to terminate. There is no financial impact from the early adoption of these amendments.

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

COVID-19

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

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

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

Given the significant volatility experienced in the financial markets, the assumptions used to estimate the Group's material defined-benefit pension obligations are updated quarterly and resulted in an overall \$40m increase in the Group's defined-benefit pension deficit in the six months ended 30 June 2020. The increase in the deficit primarily reflected increased liability valuations as a result of lower discount rates (due to falling long term AA corporate bond yields linked to the launch of a quantitative easing bond-buying programme in the UK and other regions in June 2020), with an increase in asset values providing a partial offset. In the UK, £79m of deficit-recovery contributions were also paid during the period. The sensitivity of the Group's main defined-benefit liability valuations to changes in assumptions is set out on page 207 of the [Annual Report and Form 20-F Information 2019](#).

No further material accounting impacts relating to the areas assessed above were recognised during the six-month period ending 30 June 2020.

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

Going concern

The Group has considerable financial resources available. As at 30 June 2020, the Group had \$10.2bn in financial resources (cash and cash-equivalent balances of \$5.7bn, \$0.4bn of liquid fixed income securities and undrawn committed bank facilities of \$4.1bn, of which \$3.4bn is available until April 2022, \$0.5bn is available until November 2020 (extendable to November 2021) and \$0.2bn is available until December 2020, with only \$4.1bn of borrowings due within one year). The Group's revenues are largely derived from sales of medicines that are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although government price interventions in response to budgetary constraints are expected to continue to affect adversely revenues in many of the mature markets. The Group, however, anticipates new revenue streams from both recently launched medicines and those in development, and the Group has a wide diversity of customers and suppliers across different geographic areas. Consequently, the Directors believe that, overall, the Group is well placed to manage its business risks successfully. In the current environment, the Directors have also considered the impact of possible future COVID-19 related scenarios and believe the Group retains sufficient liquidity to continue to operate.

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

Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's [Annual Report and Form 20-F Information 2019](#).

Financial information

The comparative figures for the financial year ended 31 December 2019 are not the Group's statutory accounts for that financial year. Those accounts have been reported on by the Group's auditors and have been delivered to the registrar of companies; their report was (i) unqualified, (ii) did not include a reference to any matters to which the auditors drew attention by way of emphasis without qualifying their report, and (iii) did not contain a statement under section 498(2) or (3) of the Companies Act 2006.

2) Intangible assets

In accordance with IAS 36 'Impairment of Assets', reviews for triggers at an individual asset or cash-generating-unit level were conducted. This resulted in a total impairment charge of \$119m being recorded against intangible assets during the six months ended 30 June 2020.

During the first quarter of 2020, a charge of \$102m was recorded in relation to *Bydureon* (revised carrying amount of \$612m). The impairment was driven by an overall reduction in forecast Total Revenue over the remaining asset life, reflecting expectations of returns from promotional activities, including a level of anticipated impact resulting from the restrictions in place due to the COVID-19 pandemic. If Total Revenue projections for *Bydureon* were to decline by a further 10% over the forecast period, it would result in a reduction in the recoverable amount of c.\$100m.

During the second quarter, charges recorded included \$65m and \$31m in relation to *Duaklir* and *Eklira/Tudorza*, respectively, (revised carrying amount of \$274m and \$130m, respectively), and a \$95m impairment reversal in relation to *FluMist* (revised carrying amount of \$258m).

The impairment charges for *Duaklir* and *Eklira/Tudorza* were a consequence of revised market volume and share assumptions following adverse performances during H1 2020, compared to previous forecasts during the H1 2020. If Total Revenue projections for these assets were to decline by a further 20% over the forecast period, it would result in additional reductions to the recoverable amounts of c.\$60m for *Duaklir* and c.\$30m for *Eklira/Tudorza*.

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

3) Net Debt

The table below provides an analysis of Net Debt and a reconciliation of Net Cash Flow to the movement in Net Debt. The Group monitors Net Debt as part of its capital-management policy as described in Note 27 of the [Annual Report and Form 20-F Information 2019](#). Net Debt is a non-GAAP financial measure.

Table 39: Net Debt

	At 1 Jan 2020	Cash flow	Non- cash & other	Exchange movements	At 30 Jun 2020
	\$m	\$m	\$m	\$m	\$m
Non-current instalments of loans	(15,730)	-	550	30	(15,150)
Non-current instalments of leases	(487)	-	11	11	(465)
Total long-term debt	(16,217)	-	561	41	(15,615)
Current instalments of loans	(1,597)	-	(556)	(6)	(2,159)

Current instalments of leases	(188)	117	(107)	4	(174)
Commercial paper	-	(1,262)	-	-	(1,262)
Bank collateral	(71)	(34)	-	-	(105)
Other short-term borrowings excluding overdrafts	(8)	(57)	-	1	(64)
Overdraft	(146)	(230)	-	8	(368)
Total current debt	(2,010)	(1,466)	(663)	7	(4,132)
Gross borrowings	(18,227)	(1,466)	(102)	48	(19,747)
Net derivative financial instruments	43	93	(154)	-	(18)
Net borrowings	(18,184)	(1,373)	(256)	48	(19,765)
Cash and cash equivalents	5,369	330	-	(26)	5,673
Other investments - current	849	(463)	62	(6)	442
Other investments - non-current	62	-	(62)	-	-
Cash and investments	6,280	(133)	-	(32)	6,115
Net Debt	(11,904)	(1,506)	(256)	16	(13,650)

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

Other investments - non-current are included within the balance of \$1,577m (31 December 2019: \$1,401m) in the Condensed consolidated statement of financial position. The equivalent GAAP measure to net debt is 'liabilities arising from financing activities' which excludes the amounts for cash and overdrafts, other investments and non-financing derivatives shown above and includes the Acerta Pharma put-option liability of \$2,219m (31 December 2019: \$2,146m) shown in non-current other payables.

Net Debt increased by \$1,746m in the six months to 30 June 2020, principally due to Net Cash Inflow from Operating Activities of \$1,179m being more than offset by the payment of the second interim dividend of 2019 of \$2,398m (representing two thirds of the 2019 full year).

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

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

4) Financial instruments

As detailed in the Group's most recent annual financial statements, the principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, leases and interest-bearing loans and borrowings. During the period, equity investments previously categorised as Level 3 in the fair-value hierarchy (carrying value of \$103m at 31 December 2019) are now categorised as Level 1 (carrying value of \$188m at 30 June 2020) on availability of quoted prices in an active market. There have been no other changes of significance to the categorisation or fair-value hierarchy classification of financial instruments from those detailed in the Notes to the Group Financial Statements in the [Annual Report and Form 20-F Information 2019](#).

The Group holds certain equity investments that are categorised as Level 3 in the fair-value hierarchy and for which fair-value gains of \$65m have been recognised in the six months ended 30 June 2020. All other fair-value gains and/or losses that are presented in Net gains/(losses) on Equity Investments measured at fair value through other comprehensive income in the condensed consolidated statement of comprehensive income for the six months ended 30 June 2020 are Level 1 fair value measurements.

Financial instruments measured at fair value include \$2,019m of other investments, \$4,743m held in money-market funds, \$339m of loans designated at fair value through profit or loss, \$339m of loans designated in a fair-value hedge relationship and (\$18m) of derivatives as at 30 June 2020. The total fair value of interest-bearing loans and borrowings at 30 June 2020, which have a carrying value of \$19,747m in the Condensed consolidated statement of financial position, was \$22,992m. Contingent-consideration liabilities arising on business combinations have been classified under Level 3 in the fair-value hierarchy and movements in fair value are shown below:

Table 40: Financial instruments

	2020			2019
	Diabetes alliance \$m	Other \$m	Total \$m	Total \$m
At 1 January	3,300	839	4,139	5,106
Settlements	(257)	(96)	(353)	(368)
Revaluations	(22)	(22)	(44)	-
Discount unwind	115	26	141	179
At 30 June	3,136	747	3,883	4,917

Contingent consideration arising from business combinations is fair-valued using decision-tree analysis, with key inputs including the probability of success, consideration of potential delays and the expected levels of future revenues.

The contingent consideration balance relating to BMS's share of the global diabetes alliance of \$3,136m (31 December 2019: \$3,300m) would increase/decline by \$314m with an increase/decline in sales of 10%, as compared with the current estimates.

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

5) Legal proceedings and contingent liabilities

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2019 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the Disclosures, for the majority of claims in which AstraZeneca is involved, it is not possible to make a reasonable estimate of the expected financial effect, if any, that will result from ultimate resolution of the proceedings. In these cases, AstraZeneca discloses information with respect only to the nature and facts of the cases, but no provision is made.

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

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

Matters disclosed in respect of the second quarter of 2020 and to 30 July 2020

Patent litigation

Tagrisso

US patent proceedings

As previously disclosed, in February 2020, in response to Paragraph IV notices from multiple abbreviated new drug application (ANDA) filers, AstraZeneca filed patent infringement lawsuits in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleged that a generic version of *Tagrisso*, if approved and marketed, would infringe a US Orange Book-listed *Tagrisso* patent. The trial is scheduled for May 2022.

Faslodex

Patent proceedings outside the US

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

In Russia, in July 2020, following a challenge to the validity of the *Faslodex* formulation patent by ZAO BIOCAD (Biocad), the Russian Patent Office maintained the patent as valid and dismissed the opposition filed by Biocad.

Symbicort

US patent proceedings

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

Product liability litigation

Nexium and Losec/Prilosec

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

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 scheduled a trial for March 2022.

Commercial litigation

Amplimmune

As previously disclosed, in June 2017, AstraZeneca was served with a lawsuit filed by the stockholders' agents for Amplimmune, Inc. (Amplimmune) in Delaware State Court that alleged, among other things, breaches of contractual obligations relating to a 2013 merger agreement between AstraZeneca and Amplimmune. Trial of the matter was held in February 2020 and post-trial oral argument is scheduled for August 2020.

Array

In December 2017, AstraZeneca was served with a complaint filed in New York State court by Array BioPharma, Inc. (Array) alleging breaches of contractual obligations relating to a 2003 collaboration agreement between AstraZeneca and Array. In June 2020, an appeal court denied AstraZeneca's motion for an early dismissal of the case, allowing the case to continue towards trial. No trial date has been set.

Anti-Terrorism Act Civil Lawsuit

As previously disclosed, in October 2017, AstraZeneca and certain other pharmaceutical and/or medical device companies were named as defendants in a complaint, filed in the US District Court for the District of Columbia (the District Court) by US nationals (or their estates, survivors, or heirs) who were killed or wounded in Iraq between 2005 and 2011, that alleged that the defendants violated the US Anti-Terrorism Act and various state laws by selling pharmaceuticals and medical supplies to the Iraqi Ministry of Health. In July 2020, the District Court granted AstraZeneca's and its co-defendants' jointly filed motion and dismissed the lawsuit in its entirety.

Ocimum lawsuit

In December 2017, AstraZeneca was served with a complaint filed by Ocimum Biosciences, Ltd. (Ocimum) in the Superior Court for the State of Delaware that alleges, among other things, breaches of contractual obligations and misappropriation of trade secrets, relating to a now terminated 2001 licensing agreement between AstraZeneca and Gene Logic, Inc. (Gene Logic), the rights to which Ocimum purports to have acquired from Gene Logic. In December 2019, the court granted AstraZeneca's motion for summary judgment and dismissed the case. Ocimum has appealed.

Government investigations/proceedings

Synagis

Litigation in New York

As previously disclosed, in the US, in June 2011, MedImmune received a demand from the US Attorney's Office for the Southern District of New York requesting certain documents related to the sales and marketing activities of *Synagis*. In July 2011, MedImmune received a similar court order to produce documents from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit pursuant to what the government attorneys advised was a joint investigation. MedImmune has cooperated with these inquiries.

In March 2017, MedImmune was served with a lawsuit filed in US District Court for the Southern District of New York by the Attorney General for the State of New York alleging that MedImmune inappropriately provided assistance to a single specialty care pharmacy. In September 2018, the US District Court in New York denied MedImmune's motion to dismiss the lawsuit brought by the Attorney General for the State of New York. This matter has been resolved and is now concluded.

In June 2017, MedImmune was served with a lawsuit in US District Court for the Southern District of New York by a relator under the qui tam (whistleblower) provisions of the federal and certain state False Claims Acts. The lawsuit was originally filed under seal in April 2009 and alleges that MedImmune made false claims about *Synagis*. In November 2017, MedImmune was served with an amended complaint in which relator set forth additional false claims allegations relating to *Synagis*. In September 2018, the US District Court in New York dismissed the relator's lawsuit. In January 2019, relator appealed the decision of the US District Court in New York. In March 2020, the United States Court of Appeals for the Second Circuit affirmed the US District Court's decision dismissing the relator's lawsuit. This matter is now concluded.

Toprol-XL

Louisiana Attorney General Litigation

As previously disclosed, in April 2019, a Louisiana state court (State Court) 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), which alleged that, in connection with enforcement of its patents for *Toprol-XL*, AstraZeneca engaged in unlawful monopolisation and unfair trade practices, causing the State government to pay increased prices for *Toprol-XL*, and the State appealed that ruling. In July 2020, the Louisiana First Court of Appeals reversed the State Court's ruling and remanded the case to the State Court.

Matters disclosed in respect of the first quarter of 2020 and to 29 April 2020

Patent litigation

Tagrisso

US patent proceedings

As disclosed in February 2020, in response to Paragraph IV notices from multiple ANDA filers, AstraZeneca filed patent-infringement lawsuits in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleged that a generic version of *Tagrisso*, if approved and marketed, would infringe a US Orange Book-listed *Tagrisso* patent. No trial date has been set.

Symbicort

US patent proceedings

As previously disclosed, AstraZeneca has ANDA litigation against Mylan Pharmaceuticals Inc. (Mylan) and 3M Company (3M) in the US District Court for the Northern District of West Virginia. In the action, AstraZeneca alleges that the defendants' generic versions of *Symbicort*, if approved and marketed, would infringe various AstraZeneca patents. Mylan and 3M allege that their proposed generic medicines do not infringe the asserted patents and/or that the asserted patents are invalid and/or unenforceable. The trial of the Mylan and 3M matter is scheduled for October 2020.

Movantik

US patent proceedings

In March 2020, Aether Therapeutics, Inc. filed a patent infringement lawsuit in the US District Court for the District of Delaware against AstraZeneca, Nektar Therapeutics and Daiichi Sankyo relating to *Movantik*.

Commercial litigation

Amplimmune

As disclosed in the US in June 2017, AstraZeneca was served with a lawsuit filed by the stockholders' agents for Amplimmune, Inc. (Amplimmune) in Delaware State Court that alleged, among other things, breaches of contractual obligations relating to a 2013 merger agreement between AstraZeneca and Amplimmune. Trial of the matter was held in February 2020 and post-trial oral argument is scheduled for June 2020.

Government investigations/proceedings

Crestor

Qui tam litigation

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

Synagis

Litigation in New York

As disclosed in the US in June 2011, MedImmune received a demand from the US Attorney's Office for the Southern District of New York requesting certain documents related to the sales and marketing activities of Synagis. In July 2011, MedImmune received a similar court order to produce documents from the Office of the Attorney General for the State of New York Medicaid and Fraud Control Unit pursuant to what the government attorneys advised was a joint investigation. MedImmune has co-operated with these inquiries. In March 2017, MedImmune was served with a lawsuit filed in US District Court for the Southern District of New York by the Attorney General for the State of New York, alleging that MedImmune inappropriately provided assistance to a single specialty-care pharmacy. In September 2018, the US District Court in New York denied MedImmune's motion to dismiss the lawsuit brought by the Attorney General for the State of New York.

In June 2017, MedImmune was served with a lawsuit in US District Court for the Southern District of New York by a relator under the qui tam (whistle-blower) provisions of the federal and certain state False Claims Acts. The lawsuit was originally filed under seal in April 2009 and alleged that MedImmune made false claims about Synagis. In November 2017, MedImmune was served with an amended complaint in which relator set forth additional false claims' allegations relating to *Synagis*. In September 2018, the US District Court in New York dismissed the relator's lawsuit. In January 2019, relator appealed the decision of the US District Court in New York. In March 2020, the United States Court of Appeals for the Second Circuit affirmed the US District Court's decision dismissing the relator's lawsuit.

Vermont US Attorney investigation

In April 2020, AstraZeneca received a Civil Investigative Demand from the US Attorney's Office in Vermont and the Department of Justice, Civil Division, seeking documents and information relating to AstraZeneca's relationships with electronic health-record vendors. AstraZeneca intends to co-operate with this enquiry.

Taxation

As previously disclosed in the [Annual Report and Form 20-F Information 2019](#), AstraZeneca faces a number of audits and reviews in jurisdictions around the world and, in some cases, is in dispute with the tax authorities. The issues under discussion are often complex and can require many years to resolve. Accruals for tax contingencies require management to make key judgements with respect to the ultimate outcome of current and potential future tax audits, and actual results could vary from these estimates. The total net accrual to cover the worldwide tax exposure for transfer pricing and other international tax contingencies of \$139m (December 2019: \$140m) reflected the progress in those tax audits and reviews during the half and for those audits where AstraZeneca and tax authorities are in dispute, AstraZeneca estimates the potential for reasonably possible additional liabilities above and beyond the amount provided to be up to \$226m, including associated interest (December 2019: \$76m). However, the Company believes that it is unlikely that these additional liabilities will arise. It is possible that some of these contingencies may reduce in the future to the extent that any tax authority challenge is concluded, or matters lapse following expiry of the relevant statutes of limitation resulting in a reduction in the tax charge in future periods.

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

6) Subsequent Events

In July 2020, the Company announced that it had entered into a new global development and commercialisation agreement with Daiichi Sankyo for DS-1062, its proprietary TROP2-directed antibody drug conjugate and potential new medicine for the treatment of multiple tumour types. AstraZeneca will pay Daiichi Sankyo an upfront payment of \$1bn in staged payments, additional conditional amounts of up to \$1bn for the successful achievement of regulatory approvals and up to \$4bn for sales-related milestones. The transaction will be accounted for as an intangible-asset acquisition, recognised initially at the present value of non-contingent consideration, with any potential future milestone payments capitalised into the intangible asset as they are recognised.

The companies will jointly develop and commercialise DS-1062 jointly worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. AstraZeneca and Daiichi Sankyo will share equally development and commercialisation expenses as well as profits relating to DS-1062 worldwide, except for Japan where Daiichi Sankyo will be responsible for such costs and will pay AstraZeneca mid single-digit royalties. Daiichi Sankyo will record sales in the US, certain countries in Europe and certain other countries where Daiichi Sankyo has affiliates. Profits shared with AstraZeneca from those countries will be recorded as Collaboration Revenue by AstraZeneca. AstraZeneca will record Product Sales in other countries worldwide, for which profits shared with Daiichi Sankyo will be recorded within Cost of Sales. Daiichi Sankyo will manufacture and supply DS-1062.

7) Table 41: Product Sales year-on-year analysis - H1 2020⁸¹

	World			Emerging Markets			US		Europe			Established RoW		
	\$m	% change Actual	CER	\$m	% change Actual	CER	\$m	% change Actual	\$m	% change Actual	CER	\$m	% change Actual	CER
Oncology														
<i>Tagrisso</i>	2,016	43	45	595	81	89	725	30	325	53	58	371	18	18
<i>Imfinzi</i>	954	51	52	63	n/m	n/m	574	21	167	n/m	n/m	150	70	71
<i>Lynparza</i>	816	57	60	120	n/m	n/m	406	55	198	51	56	92	35	34
<i>Calquence</i>	195	n/m	n/m	2	n/m	n/m	193	n/m	-	-	-	-	-	-
<i>Koselugo</i>	7	n/m	n/m	-	-	-	7	n/m	-	-	-	-	-	-
<i>Zoladex*</i>	442	13	18	288	22	29	5	40	68	5	8	81	(7)	(6)
<i>Faslodex*</i>	312	(40)	(38)	100	4	10	34	(87)	116	6	9	62	(4)	(4)
<i>Iressa*</i>	147	(42)	(40)	120	(27)	(24)	7	(3)	9	(81)	(81)	11	(67)	(66)
<i>Arimidex*</i>	107	(3)	-	90	26	30	-	-	1	(90)	(90)	16	(32)	(32)
<i>Casodex*</i>	89	(15)	(13)	69	8	11	-	-	1	(84)	(84)	19	(43)	(42)
Others	26	(50)	(47)	14	(23)	(14)	-	-	3	(15)	(16)	9	(64)	(69)
Total Oncology	5,111	26	28	1,461	39	46	1,951	20	888	37	41	811	10	9
BioPharmaceuticals: CVRM														
<i>Farxiga</i>	848	17	21	306	49	59	237	(12)	223	25	29	82	14	15
<i>Brilinta</i>	845	15	17	291	34	40	351	9	173	2	5	30	7	10
<i>Onglyza</i>	256	(5)	(3)	100	15	21	105	(12)	29	(21)	(18)	22	(15)	(13)
<i>Bydureon</i>	216	(24)	(23)	2	(74)	(72)	185	(21)	24	(29)	(26)	5	(37)	(34)
<i>Byetta</i>	35	(36)	(35)	5	13	21	19	(47)	7	(29)	(26)	4	(21)	(20)
Other diabetes	23	3	6	3	n/m	n/m	13	(21)	6	44	50	1	(60)	(25)
<i>Lokelma</i>	28	n/m	n/m	1	n/m	n/m	22	n/m	2	n/m	n/m	3	n/m	n/m
<i>Crestor*</i>	582	(10)	(8)	369	(9)	(6)	45	(17)	64	(15)	(13)	104	(5)	(5)
<i>Seloken/ Toprol-XL*</i>	395	-	6	376	8	14	6	(78)	8	(39)	(39)	5	-	5
<i>Atacand*</i>	126	19	25	94	23	31	5	(15)	15	(2)	(2)	12	37	43
Others	106	(20)	(18)	65	(30)	(28)	-	-	35	15	18	6	(36)	(39)
BioPharmaceuticals: total CVRM	3,460	3	6	1,612	11	17	988	(9)	586	3	6	274	-	2
BioPharmaceuticals: Respiratory & Immunology														
<i>Symbicort</i>	1,442	23	26	290	10	16	558	46	356	1	4	238	39	42
<i>Pulmicort</i>	477	(33)	(32)	371	(36)	(34)	36	(36)	40	(8)	(4)	30	(26)	(25)
<i>Fasenra</i>	426	44	45	7	n/m	n/m	272	31	88	96	n/m	59	41	41
<i>Daliresp/ Daxas</i>	106	1	2	2	(13)	(7)	90	1	13	7	11	1	(3)	(36)
<i>Bevespi</i>	22	10	10	-	-	-	21	5	1	n/m	n/m	-	-	-
<i>Breztri</i>	11	n/m	n/m	9	n/m	n/m	-	-	-	-	-	2	n/m	n/m
Others	184	(20)	(18)	80	(29)	(27)	7	n/m	89	(16)	(14)	8	(14)	4
BioPharmaceuticals: total Respiratory & Immunology	2,668	5	7	759	(21)	(18)	984	30	587	5	8	338	29	31
Other medicines														
<i>Nexium</i>	714	(5)	(3)	371	-	5	80	(32)	36	14	18	227	(4)	(4)
<i>Synagis</i>	176	18	18	5	n/m	n/m	21	(40)	150	32	32	-	-	-
<i>Losec/ Prilosec</i>	99	(32)	(30)	81	(15)	(12)	3	(44)	10	(68)	(68)	5	(62)	(62)
<i>Seroquel XR/IR</i>	63	(9)	(8)	27	11	15	14	n/m	15	(69)	(69)	7	(36)	(37)
Others	68	(32)	(31)	3	(64)	(73)	33	(44)	28	5	5	4	(34)	(22)
Total other medicines	1,120	(8)	(6)	487	(2)	1	151	(26)	239	(4)	(4)	243	(9)	(9)
Total Product Sales	12,359	11	13	4,319	9	14	4,074	11	2,300	13	17	1,666	8	9

⁸¹ The table provides an analysis of year-on-year Product Sales, with Actual and CER growth rates reflecting year-on-year growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals. *Denotes a legacy medicine.

8) Table 42: Product Sales year-on-year analysis - Q2 2020 (Unreviewed)⁸²

	World			Emerging Markets			US		Europe			Established RoW		
	\$m	% change Actual	CER	\$m	% change Actual	CER	\$m	% change Actual	\$m	% change Actual	CER	\$m	% change Actual	CER
Oncology														
<i>Tagrisso</i>	1,034	32	35	315	65	74	354	18	163	46	51	202	12	12
<i>Imfinzi</i>	492	46	48	30	n/m	n/m	287	19	93	n/m	n/m	82	55	56
<i>Lynparza</i>	419	48	52	64	95	n/m	209	47	96	45	50	50	20	21
<i>Calquence</i>	107	n/m	n/m	1	n/m	n/m	107	n/m	-	-	-	(1)	n/m	n/m
<i>Koselugo</i>	7	n/m	n/m	-	-	-	7	n/m	-	-	-	-	-	-
<i>Zoladex*</i>	217	10	17	139	15	24	3	55	33	8	14	42	(4)	(2)
<i>Faslodex*</i>	146	(45)	(43)	52	2	10	11	(91)	52	(7)	(3)	31	(13)	(13)
<i>Iressa*</i>	70	(41)	(38)	58	(26)	(23)	4	(5)	3	(85)	(85)	5	(65)	(62)
<i>Arimidex*</i>	58	(4)	-	48	35	41	-	-	1	(93)	(93)	9	(42)	(43)
<i>Casodex*</i>	47	(17)	(15)	37	8	11	-	-	-	n/m	n/m	10	(47)	(46)
Others	12	(59)	(55)	6	(35)	(18)	(1)	n/m	1	(32)	(35)	6	(67)	(74)
Total Oncology	2,609	20	24	750	34	43	981	15	442	32	37	436	3	4
BioPharmaceuticals: CVRM														
<i>Farxiga</i>	443	17	23	165	49	62	124	(11)	107	20	25	47	24	26
<i>Brilinta</i>	437	12	16	156	30	39	187	11	80	(9)	(5)	14	6	10
<i>Bydureon</i>	116	(18)	(17)	1	(87)	(86)	101	(14)	12	(22)	(19)	2	(23)	(18)
<i>Onglyza</i>	115	(1)	3	52	19	27	38	(9)	14	(22)	(19)	11	(20)	(17)
<i>Byetta</i>	15	(42)	(41)	2	(37)	(30)	7	(53)	4	(16)	(13)	2	(26)	(26)
Other diabetes	10	(9)	(5)	1	n/m	n/m	6	(31)	3	37	44	-	n/m	n/m
<i>Lokelma</i>	17	n/m	n/m	1	n/m	n/m	12	n/m	1	n/m	n/m	3	n/m	n/m
<i>Crestor*</i>	281	(10)	(6)	177	(3)	2	17	(40)	30	(18)	(16)	57	(11)	(10)
<i>Seloken/Toprol-XL*</i>	218	29	38	210	35	45	2	(53)	4	(48)	(48)	2	2	9
<i>Atacand*</i>	59	6	14	45	21	33	2	(39)	6	(43)	(43)	6	43	52
Others	48	(23)	(20)	29	(31)	(28)	-	-	16	25	29	3	(65)	(69)
BioPharmaceuticals: total CVRM	1,759	6	10	839	20	28	496	(6)	277	(3)	1	147	(1)	1
BioPharmaceuticals: Respiratory & Immunology														
<i>Symbicort</i>	653	12	15	135	3	12	248	20	161	(6)	(3)	109	42	47
<i>Pulmicort</i>	97	(71)	(69)	58	(78)	(76)	13	(60)	15	(21)	(18)	11	(43)	(42)
<i>Fasenra</i>	227	36	37	1	(30)	(5)	152	33	42	57	63	32	32	33
<i>Daliresp/Daxas</i>	53	(7)	(7)	1	(17)	(9)	45	(7)	6	(3)	1	1	(37)	(70)
<i>Bevespi</i>	10	(1)	(3)	-	-	-	9	(6)	1	n/m	n/m	-	-	-
<i>Breztri</i>	7	n/m	n/m	5	n/m	n/m	-	-	-	-	-	2	n/m	n/m
Others	70	(30)	(28)	21	(52)	(52)	5	n/m	42	(18)	(15)	2	(60)	(36)
BioPharmaceuticals: total Respiratory & Immunology	1,117	(11)	(8)	221	(50)	(46)	472	15	267	(3)	1	157	23	26
Other medicines														
<i>Nexium</i>	377	(4)	(1)	184	3	9	40	(24)	15	(7)	(4)	138	(5)	(5)
<i>Synagis</i>	90	(5)	(5)	-	-	-	14	41	76	(11)	(11)	-	-	-
<i>Losec/Prilosec</i>	45	(34)	(31)	37	(16)	(12)	1	(90)	5	(60)	(60)	2	(75)	(74)
<i>Seroquel XR/IR</i>	27	(16)	(14)	15	49	57	1	n/m	7	(71)	(71)	4	(23)	(25)
Others	24	(53)	(52)	2	(88)	(93)	8	(74)	13	3	1	1	n/m	n/m
Total other medicines	563	(12)	(10)	238	(5)	-	64	(29)	116	(23)	(23)	145	(3)	(3)
Total Product Sales	6,048	6	9	2,048	5	12	2,013	7	1,102	5	9	885	4	5

⁸² 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. The Q2 2020 information in respect of the three months ended 30 June 2020 included in the Interim Financial Statements has not been reviewed by PricewaterhouseCoopers LLP. *Denotes a legacy medicine.

9) Table 43: Product Sales quarterly sequential analysis - Q2 2020 (Unreviewed)⁸³

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

⁸³ 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. Sequential quarterly Product Sales information included in the Interim Financial Statements has not been reviewed by PricewaterhouseCoopers LLP. *Denotes a legacy medicine.

10) Table 44: Product Sales quarterly sequential analysis - FY 2019 (Unreviewed)⁸⁴

	Q1 2019			Q2 2019			Q3 2019			Q4 2019		
	\$m	% change		\$m	% change		\$m	% change		\$m	% change	
		Actual	CER		Actual	CER		Actual	CER		Actual	CER
Oncology												
Tagrisso	630	6	6	784	24	25	891	14	13	884	(1)	-
Imfinzi	295	13	13	338	15	15	412	22	22	424	3	4
Lynparza	237	13	13	283	19	20	327	16	15	351	7	8
Calquence	29	21	23	35	21	19	44	27	27	56	25	25
Faslodex*	254	(6)	(6)	267	5	6	205	(23)	(23)	166	(20)	(19)
Zoladex*	194	7	6	197	2	1	226	15	16	196	(14)	(12)
Iressa*	134	20	18	118	(12)	(11)	91	(23)	(22)	80	(13)	(12)
Arimidex*	51	11	10	60	18	17	63	5	5	51	(20)	(18)
Casodex*	48	4	3	57	19	18	52	(8)	(6)	43	(18)	(17)
Others	20	(13)	(14)	28	40	29	20	(27)	(22)	26	30	26
Total Oncology	1,892	7	6	2,167	15	15	2,334	8	8	2,274	(3)	(2)
BioPharmaceuticals: CVRM												
Farxiga	349	(12)	(12)	377	8	9	398	5	5	419	5	6
Brilinta	348	(7)	(8)	389	12	12	416	7	8	428	3	3
Onglyza	153	3	3	116	(24)	(24)	127	9	11	131	3	4
Bydureon	142	3	3	141	(1)	-	127	(10)	(10)	139	9	10
Byetta	30	(6)	(5)	25	(17)	(16)	28	10	13	27	(2)	(4)
Other diabetes	11	(8)	(17)	11	-	8	14	26	22	16	17	17
Lokelma	-	n/m	n/m	2	n/m	n/m	4	n/m	n/m	8	87	74
Crestor*	335	(5)	(6)	310	(7)	(7)	337	9	9	296	(12)	(11)
Seloken/Toprol-XL*	225	41	38	168	(25)	(25)	177	6	8	190	7	8
Atacand*	50	(14)	(15)	56	12	14	55	(1)	(1)	60	8	9
Others	71	(3)	(5)	63	(11)	(8)	65	4	2	72	13	16
BioPharmaceuticals: total CVRM	1,714	(2)	(3)	1,658	(3)	(3)	1,749	5	6	1,785	2	3
BioPharmaceuticals: Respiratory & Immunology												
Symbicort	585	(8)	(8)	585	-	1	613	5	4	712	16	17
Pulmicort	383	(2)	(2)	333	(13)	(13)	337	1	3	413	22	23
Fasenra	129	3	4	167	29	30	202	21	21	206	2	2
Dalirespl/Daxas	48	(11)	(12)	56	17	18	53	(6)	(7)	58	10	10
Bevespi	10	-	(5)	10	-	2	10	4	8	12	8	5
Breztri	-	-	-	-	-	-	1	-	-	1	(74)	(73)
Others	128	(14)	(12)	101	(21)	(23)	102	1	(1)	135	33	38
BioPharmaceuticals: total Respiratory & Immunology	1,283	(6)	(6)	1,252	(2)	(2)	1,319	5	6	1,537	17	17
Other medicines												
Nexium	363	(7)	(8)	393	8	8	374	(5)	(4)	353	(6)	(6)
Synagis	53	(79)	(79)	96	81	81	146	52	53	63	(57)	(57)
LOSEC/Prilosec	76	27	26	68	(11)	(10)	73	8	9	46	(38)	(38)
Seroquel XR/IR	37	(34)	(33)	32	(14)	(10)	82	n/m	n/m	40	(50)	(49)
Others	47	(65)	(64)	52	11	11	56	8	-	151	n/m	n/m
Total other medicines	576	(35)	(36)	641	11	12	731	14	14	653	(11)	(10)
Total Product Sales	5,465	(5)	(6)	5,718	5	5	6,132	7	8	6,250	2	3

⁸⁴ The table below provides an analysis of sequential quarterly Product Sales, with actual and CER growth rates reflecting quarter-on-quarter growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals. The sequential quarterly Product Sales information included in the Interim Financial Statements has not been reviewed by PricewaterhouseCoopers LLP. *Denotes a legacy medicine.

Table 45: Historic Collaboration Revenue (Unreviewed)⁸⁵

		H1 2020	H1 2019	FY 2019	FY 2018
		\$m	\$m	\$m	\$m
Initial Collaboration Revenue	Crestor (Spain)	-	-	-	61
	<i>Lynparza</i> : regulatory milestones	135	60	60	140
Ongoing Collaboration Revenue	<i>Lynparza</i> : sales milestones	-	-	450	250
	<i>Lynparza</i> /selumetinib: option payments	-	-	100	400
	<i>Crestor</i> (Spain)	-	-	39	-
	<i>Enhertu</i> : profit share	36	-	-	-
	Roxadustat: profit share	11	-	-	-
	Royalty income	34	32	62	49
	Other Collaboration Revenue	54	39	108	141
	Total	270	131	819	1,041

Table 46: Other Operating Income and Expense (Unreviewed)⁸⁶

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

	H1 2020	H1 2019	FY 2019	FY 2018
	\$m	\$m	\$m	\$m
Hypertension medicines (ex-US, India and Japan)	350	-	-	-
<i>Inderal</i> , <i>Tenormin</i> , <i>Seloken</i> and <i>Omepral</i> (Japan)	51	-	-	-
<i>Synagis</i> (US)	-	515	515	-
<i>Losec</i> (ex-China, Japan, US and Mexico)	-	-	243	-

⁸⁵ Historic Collaboration Revenue information included in the table above has not been reviewed by PricewaterhouseCoopers LLP.

⁸⁶ The Other Operating Income and Expense information included in the table above has not been reviewed by PricewaterhouseCoopers LLP.

<i>Seroquel</i> and <i>Seroquel XR</i> (US, Canada, Europe and Russia)	-	-	213	-
<i>Arimidex</i> and <i>Casodex</i> (various countries)	-	-	181	-
<i>Nexium</i> (Europe) and <i>Vimovo</i> (ex-US)	-	-	-	728
<i>Seroquel</i>	-	-	-	527
Legal settlement	-	-	-	346
<i>Atacand</i>	-	-	-	210
<i>Anaesthetics</i>	-	-	-	172
<i>Alvesco</i> , <i>Omnaris</i> and <i>Zetonna</i>	-	-	-	139
Other	200	191	389	405
Total	601	706	1,541	2,527

Shareholder information

Announcement of year to date and third quarter results	5 November 2020
Announcement of full year and fourth quarter results	11 February 2021

Future dividends will normally be paid as follows:

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

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

The record date for the first interim dividend for 2020, payable on 14 September 2020, will be 14 August 2020. The ex-dividend date will be 13 August 2020.

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Cautionary statements regarding forward-looking statements

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

This document contains certain forward-looking statements with respect to the operations, performance and financial condition of the Group, including, among other things, statements about expected revenues, margins, earnings per share or other financial or other measures. Although the Group believes its expectations are based on reasonable assumptions, any forward-looking statements, by their very nature, involve risks and uncertainties and may be influenced by factors that could cause actual outcomes and results to be materially

different from those predicted. The forward-looking statements reflect knowledge and information available at the date of preparation of this document and the Group undertakes no obligation to update these forward-looking statements. The Group identifies the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond the Group's control, include, among other things:

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

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