

AstraZeneca PLC 29 April 2020 07:00 BST

## First-quarter 2020 results

# Robust results in unprecedented times; leveraging scientific expertise in the fight against COVID-19

AstraZeneca delivered a quarter of strong revenue and profit growth, reflecting the immense efforts of supply-chain, commercial and other colleagues around the world to get vital medicines to patients. As part of the fight, the Company has rapidly responded to the pandemic, firstly in China and then globally.

#### Pascal Soriot, Chief Executive Officer, commented:

"Our focus ensured another quarter of strong growth across every therapy area and region. The new medicines performed extremely well, and our pipeline continued to deliver. Standouts included landmark news for *Tagrisso*, *Farxiga* and *Koselugo*, our latest oncology medicine. The progress made on all fronts provides confidence that we will, once again, meet our full-year commitments.

I could not be prouder of how the AstraZeneca team has responded to the challenges of COVID-19. We moved quickly to maintain continuity of care, contribute to society, and use our scientific expertise to fight the pandemic. We hope our efforts to protect organs from damage, mitigate the cytokine storm and the associated hyperinflammatory state, and target the virus prove to be successful."

#### COVID-19

The Company donated nine million face masks to support healthcare workers around the world, delivered in collaboration with the World Economic Forum's COVID Action Platform. AstraZeneca also contributed to the UK Government's testing effort with a dedicated site in Cambridge operated in collaboration with the University of Cambridge and GlaxoSmithKline plc (GSK), with a goal to deliver 30,000 tests a day in May 2020.

The Company has mobilised research efforts to find new ways to help target the virus, reduce the cytokine storm, arising from an overactive immune response, and potentially protect organs. As part of the effort to target the virus, the Company is identifying novel SARS-CoV-2-neutralising monoclonal antibodies that can be used for treatment, as well as a prophylaxis against viral infection.

AstraZeneca is evaluating the use of *Calquence*, approved in a number of countries for the treatment of chronic lymphocytic leukaemia, in the Phase II CALAVI trial, which is assessing the suppression of the cytokine storm that inflames the lungs and other organs of some COVID-19 patients. The Company is also looking at protecting organs in the Phase III DARE-19 trial, assessing whether *Farxiga*, an oral medicine that has demonstrated benefits in heart failure and kidney disease, can potentially reduce organ failure. The Company has also joined the UK Government's ACCORD-2 proof-of-concept clinical-trial platform, to speed the development of medicines for patients with COVID-19.

# Q1 2020 financial performance

**Table 1: Financial summary** 

		Q1 2020		
	¢m	% cha	ange	
	\$m	Actual	CER <sup>1</sup>	
Total Revenue	6,354	16	17	
Product Sales	6,311	15	17	
Collaboration Revenue	43	69	70	
Reported <sup>2</sup> EPS <sup>3</sup>	\$0.59	27	33	
Core⁴ EPS	\$1.05	17	21	



Of the growth at CER in Total Revenue, AstraZeneca estimates a low-to-mid single-digit percentage benefit of short-term inventory increases in the distribution channel, longer prescriptions and improved treatment-regimen adherence by patients, as indirect effects of the ongoing COVID-19 pandemic. This benefit is anticipated to reverse in the coming months.

The new medicines<sup>5</sup> continued to perform especially well and there was excellent progress from the pipeline, with several regulatory approvals and particularly significant news regarding the potential use of *Tagrisso* in the adjuvant treatment of EGFRm<sup>6</sup> lung cancer, as well as *Farxiga* in chronic kidney disease.

Total Revenue growth of 16% (17% at CER) to \$6,354m; this included Product Sales of \$6,311m (+15%, +17% at CER). Total Revenue increased in the quarter across all three therapy areas<sup>7</sup> and in every region. Highlights included:

- The performance of the new medicines, improving by 47% (49% at CER) to \$2,986m, included new-medicine growth in Emerging Markets of 82% (87% at CER) to \$658m. These medicines represented 47% of Total Revenue (Q1 2019: 37%)
- Total Revenue growth across all therapy areas: Oncology +33% (+34% at CER) to \$2,518m, New CVRM<sup>8</sup> +7% (+8% at CER) to \$1,102m and Respiratory & Immunology +21% (+22% at CER) to \$1,555m
- Total Revenue growth in every region: an increase in Emerging Markets of 13% (16% at CER) to \$2,273m, with China Total Revenue growth of 14% (17% at CER) to \$1,416m. Total Revenue in the US increased by 16% in the quarter to \$2,091m and in Europe by 22% (25% at CER) to \$1,204m; Japan Total Revenue increased by 10% (8% at CER) to \$553m

### **Broad Company response to COVID-19**

AstraZeneca's priority during the COVID-19 global pandemic is to continue to safely supply all of the Company's medicines to millions of patients. A description of the specific impact on and the actions by the Company regarding the pandemic is shown below; for the latest AstraZeneca communications regarding COVID-19, please click <a href="here">here</a>.

#### a) Colleagues

Office-based colleagues are typically working from home; in a growing number of countries that are potentially past the pandemic's peak, however, colleagues have returned to the office, in line with government guidelines. For supply-chain and research and development (R&D) roles that cannot be performed from home, AstraZeneca has put clear processes in place relating to social distancing. In April 2020, the Company implemented voluntary assessments of critical supply-chain and manufacturing colleagues at three sites, using the Company's own laboratories, to rapidly identify and isolate COVID-19 cases.

# b) Supply chain

The Company did not see any material disruptions to its supply chain in the period. AstraZeneca's manufacturing sites in China returned to full capacity within weeks of the declared outbreak, with little intervening impact on supply. The Company's supply chain includes an effective inventory management policy for each medicine, as well as robust business continuity plans (BCPs). These plans seek to ensure that there are appropriate inventory levels of active pharmaceutical ingredients and critical materials to ensure manufacturing and supply continuity. AstraZeneca's approach to BCP utilises various strategic measures, for example, inventory, dual-supply processes, and operational agility.

Some medicines experienced particular growth in global demand in the quarter, partly reflecting short-term inventory increases in the distribution channel, as well as prescription-lengthening and improved treatment-regimen adherence by patients. This growth in the quarter was within the Company's fulfilment capability; AstraZeneca is, however, closely monitoring fulfilment risks, particularly within Respiratory & Immunology.

# c) Sales and marketing

Interactions with healthcare professionals and organisations have been significantly impacted and virtual meetings today, especially in the US, Europe and Japan, remain predominant. As part of the early response to the pandemic, AstraZeneca quickly expanded its levels of digital activities, including:

- remote detailing to healthcare professionals



- collaborating with telemedicine providers and e-pharmacies
- investing in new platforms designed for communication with healthcare professionals

In a growing number of countries that are potentially past the pandemic's peak, face-to-face meetings with healthcare professionals have been increasingly reinitiated.

## d) Clinical trials

AstraZeneca has focused on ensuring the continued safety of patients in all of its ongoing clinical trials, while activating continuity plans in order to minimise trial disruption from the pandemic. Mitigation strategies included home-based treatment and monitoring options, moving patient recruitment to less-affected regions, and planning for accelerated recruitment once the pandemic has receded. Having assessed the COVID-19 impact across the pipeline, the Company does not expect material delays to anticipated dates of late-stage and lifecycle-management news flow in 2020 and 2021.

## Impact on operations, performance and the Condensed Consolidated Interim Financial Statements

The impact of COVID-19 on the Company's operations is highly uncertain and cannot be predicted with confidence and the extent of any adverse impact on AstraZeneca's operations 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 many of the risks described beginning on page 246 in the Risk section of the <u>Annual Report and Form 20-F Information 2019</u>, such as those relating to the delivery of the pipeline or launch of new medicines, the execution of the Company's commercial strategy, the manufacturing and supply of medicines and reliance on third-party goods and services.

In the current environment, the Directors have considered the impact of a range of possible future COVID-19 related scenarios and believe the Group retains sufficient liquidity to continue to operate. As detailed in Note 1 of the Notes to the Interim Financial Statements, the going-concern basis has been adopted in these Condensed Consolidated Interim Financial Statements (Interim Financial Statements). For an impact assessment on the Interim Financial Statements, also see Note 1.

## Guidance

The Company provides guidance for FY 2020 at CER on:

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

Guidance on Total Revenue and Core EPS reflects the changing nature and growing strategic impact of Collaboration Revenue which, over time, will primarily comprise potential income from existing collaborations as follows:

- 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)<sup>9</sup>
- Milestone revenue from the MSD<sup>10</sup> collaboration on *Lynparza*
- Smaller amounts of milestone and royalty revenue from other marketed and pipeline medicines

The guidance below is subject to the assumption that the global impact of the COVID-19 pandemic lasts for several more months and is based on recent trends in the business. The Company will monitor closely the development of the pandemic and anticipates providing an update at the H1 2020 results. Variations in performance between quarters can be expected to continue.

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 above.



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

#### **Indications**

The Company provides indications for FY 2020 at CER:

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

### **Currency impact**

If foreign-exchange rates for April to December 2020 were to remain at the average of rates seen in the quarter, it is anticipated that there would be a low single-digit adverse impact on Total Revenue and Core EPS. In addition, 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 16% in the quarter (17% at CER) to \$6,354m. Product Sales increased by 15% (17% at CER) to \$6,311m, primarily driven by the performance of the new medicines, as well as *Symbicort*'s double-digit growth at CER in every region
- The Reported and Core Gross Profit Margin<sup>11</sup> declined by two percentage points in the quarter to 77% and 78% respectively. The falls reflected the impact of one-off adjustments related to Group inventory, the growth in profit share from the collaboration with MSD in respect of *Lynparza* and an element of foreign-exchange impact
- Reported Total Operating Expense increased by 9% in the quarter (10% at CER) to \$4,194m and represented 66% of Total Revenue (Q1 2019: 70%); part of the rise, also reflected in Core R&D Expense, was driven by the investment related to *Enhertu*. Core Total Operating Expense increased by 7% (8% at CER) to \$3,600m and represented 57% of Total Revenue (Q1 2019: 61%); the increase was also driven by SG&A Expense related to investment in Oncology-medicine launches and AstraZeneca's further expansion in China. In addition, Reported SG&A Expense was adversely impacted by intangible asset impairments, including a \$102m charge relating to *Bydureon*
- The Reported Operating Profit Margin declined in the quarter by one percentage point (stable at CER) to 19%; the Core Operating Profit Margin also declined by one percentage point (stable at CER) to 29%
- Reported EPS of \$0.59 in the quarter, represented an increase of 27% (33% at CER); this was despite an increase in the weighted-average number of shares to 1,312m (Q1 2019: 1,267m). Core EPS increased by 17% (21% at CER) to \$1.05



# **Commercial summary**

# Oncology

Total Revenue increased by 33% in the quarter (34% at CER) to \$2,518m.

**Table 2: Select Oncology medicine performances** 

	Q1 2020			
	¢m.	% change		
	ΦIII	56 58	CER	
Tagrisso: Product Sales	982	56	58	
<i>Imfinzi</i> : Product Sales	462	57	57	
Lynparza: Product Sales	397	67	69	
Calquence: Product Sales	88	n/m <sup>12</sup>	n/m	
Enhertu: Collaboration Revenue	14	n/m	n/m	

Oncology Total Revenue increased in Emerging Markets by 45% (49% at CER) to \$711m.

# **New CVRM**

Total Revenue increased by 7% in the quarter (8% at CER) to \$1,102m.

**Table 3: Select New CVRM medicine performances** 

	Q1 2020			
	\$m	% ch	ange	
	\$m	16 1 17 1	CER	
Farxiga: Total Revenue	407	16	19	
Brilinta: Product Sales	408	17	19	
Bydureon: Product Sales	100	(30)	(29)	
Lokelma: Product Sales	11	n/m	n/m	
Roxadustat: Collaboration Revenue	3	n/m	n/m	

New CVRM Total Revenue increased in Emerging Markets by 39% in the quarter (43% at CER) to \$332m.

## Respiratory & Immunology

Total Revenue increased by 21% in the quarter (22% at CER) to \$1,555m.

Table 4: Select Respiratory & Immunology medicine performances

	Q1 2020		
	\$m	% change	
	φiii	Actual	CER
Symbicort. Product Sales	790	35	36
Pulmicort: Product Sales	380	(1)	-
Fasenra: Product Sales	199	54	55



Respiratory & Immunology Total Revenue increased in Emerging Markets by 4% (6% at CER) to \$540m.

Following the launch of an authorised-generic version of *Symbicort* in the US in collaboration with Prasco, LLC (Prasco), US sales of *Symbicort* grew by 76% in the quarter to \$310m. The performance partly reflected an element of inventory build by Prasco.

#### **Emerging Markets**

As the Company's largest region, at 36% of Total Revenue, Emerging Markets' Total Revenue increased by 13% in the quarter (16% at CER) to \$2,273m, including:

- A China Total Revenue increase of 14% (17% at CER) to \$1,416m
- An ex-China Total Revenue increase of 12% (15% at CER) to \$857m

## **Sustainability summary**

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

- Access to healthcare: during the period, AstraZeneca announced a donation of nine million face masks to support healthcare workers around the world as they respond to the COVID-19 global pandemic; more than eight million masks have already been delivered. In addition, AstraZeneca, GSK and the University of Cambridge announced a collaboration to support the UK Government's five-pillar plan to boost testing
- Environmental protection: to coincide with Earth Day on 22 April 2020, the Company announced a new one-year collaboration focusing on water stewardship with World Wide Fund for Nature Sweden, to identify opportunities to improve the Company's approach and strategy towards water stewardship. AstraZeneca's longer-term ambition is to implement Science-Based Targets for Water, once a global methodology is available, to lead the way on water stewardship for the pharmaceutical industry; including the development of industry-specific tools to assess water risk in the context of Pharmaceuticals in the Environment
- Ethics and transparency: since committing to providing greater transparency around payments to healthcare professionals and healthcare organisations at the 2018 Annual General Meeting, the Company has further progressed this work during the period across Canada, the Philippines and New Zealand, while continuing to monitor the regulatory landscape in Argentina, Chile, India and Morocco

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

## **Notes**

The following notes refer to pages one to six.

- 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.
- 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 yet to announce its IFRS endorsement authority and is anticipated to continue to follow the EU endorsement process for the foreseeable future.
- 3. Earnings per share.
- 4. 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.
- 5. Tagrisso, Imfinzi, Lynparza, Calquence, Enhertu, Farxiga, Brilinta, Lokelma, roxadustat, Fasenra, Bevespi and Breztri. The new medicines are pillars in the three therapy areas and are important platforms for future growth. The Total Revenue of Enhertu and roxadustat in the quarter entirely reflected Ongoing Collaboration Revenue.
- 6. Epidermal growth factor receptor mutation.
- 7. Defined here as Oncology, New CVRM and Respiratory & Immunology.
- 8. New Cardiovascular (CV), Renal & Metabolism comprises Brilinta and Renal & Diabetes medicines.



- 9. 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.
- 10. Merck & Co., Inc., Kenilworth, NJ, US, known as MSD outside the US and Canada.
- 11. Gross Profit is defined as Total Revenue minus Cost of Sales. The calculation of Reported and Core Gross Margin excludes the impact of Collaboration Revenue and any associated costs, thereby reflecting the underlying performance of Product Sales.
- 12. Not meaningful.

# **Table 5: Pipeline highlights**

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

Regulatory approvals	<ul> <li>Imfinzi - ES<sup>13</sup>-SCLC<sup>14</sup> (US)</li> <li>Enhertu - breast cancer (3rd line<sup>15</sup>, HER2+<sup>16</sup>) (JP)</li> <li>Koselugo (selumetinib) - NF1<sup>17</sup> (US)</li> <li>Lokelma - hyperkalaemia (JP)</li> </ul>
Regulatory submission acceptances and/or submissions	<ul> <li>Lynparza - prostate cancer (2nd line): regulatory submission (JP)</li> <li>Koselugo - NF1: regulatory submission acceptance (EU)</li> </ul>
Major Phase III data readouts or other significant developments	<ul> <li>Tagrisso - adjuvant NSCLC<sup>18</sup> (EGFRm): unblinded for overwhelming efficacy</li> <li>Imfinzi - ES-SCLC: OS<sup>19</sup> confirmed</li> <li>Imfinzi + treme - ES-SCLC: primary endpoint not met</li> <li>Imfinzi +/- treme - bladder cancer (1st line<sup>20</sup>): primary endpoints not met</li> <li>Lynparza - prostate cancer: secondary OS endpoint met</li> <li>Lynparza - pancreatic cancer: orphan designation (JP)</li> <li>cediranib - ovarian cancer (2nd line<sup>21</sup>): primary endpoint not met</li> <li>Farxiga - CKD<sup>22</sup>: primary endpoint met early</li> </ul>

<sup>&</sup>lt;sup>13</sup> Extensive stage.

<sup>&</sup>lt;sup>14</sup> Small cell lung cancer.

<sup>&</sup>lt;sup>15</sup> The treatment of a cancer in the advanced, metastatic setting after 2nd-line treatment (see below).

<sup>&</sup>lt;sup>16</sup> Human epidermal growth factor receptor 2 positive.

<sup>&</sup>lt;sup>17</sup> Neurofibromatosis type 1.

<sup>&</sup>lt;sup>18</sup> Non-small cell lung cancer.

<sup>19</sup> Overall survival.

<sup>&</sup>lt;sup>20</sup> The initial treatment of a cancer in the advanced, metastatic setting.

<sup>&</sup>lt;sup>21</sup> The treatment of a cancer in the advanced, metastatic setting after the initial treatment.

<sup>&</sup>lt;sup>22</sup> Chronic kidney disease.



# 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.

Timing	News flow
Q2 2020	<ul> <li>Imfinzi - ES-SCLC: regulatory submission (CN)</li> <li>Lynparza - ovarian cancer (1st line) (PAOLA-1): regulatory decision (US)</li> <li>Lynparza - breast cancer (BRCAm<sup>23</sup>): regulatory decision (CN)</li> <li>Lynparza - prostate cancer (2nd line): regulatory decision (US)</li> <li>Enhertu - gastric cancer (3rd line, HER2+): regulatory submission</li> <li>Forxiga - T2D<sup>24</sup> CVOT<sup>25</sup>: regulatory decision (CN)</li> <li>Farxiga - HF<sup>26</sup> CVOT: regulatory decision (US)</li> <li>Symbicort - mild asthma: regulatory submission (EU)</li> <li>Bevespi - COPD<sup>27</sup>: regulatory decision (CN)</li> </ul>
H2 2020	<ul> <li>Tagrisso - adjuvant NSCLC (EGFRm): regulatory submission</li> <li>Imfinzi - unresectable<sup>28</sup>, Stage III NSCLC (PACIFIC-2): data readout</li> <li>Imfinzi - ES-SCLC: regulatory decision (EU, JP)</li> <li>Imfinzi +/- treme - liver cancer (1st line): data readout</li> <li>Lynparza - ovarian cancer (1st line) (PAOLA-1): regulatory decision (EU)</li> <li>Lynparza - pancreatic cancer (3rd line, BRCAm): regulatory submission (US)</li> <li>Lynparza - prostate cancer (1st line): regulatory decision (EU)</li> <li>Lynparza - prostate cancer (2nd line): regulatory decision (EU)</li> <li>Enhertu - breast cancer (3rd line, HER2+): regulatory submission (EU)</li> <li>Calquence - CLL<sup>29</sup>: regulatory decision (EU)</li> <li>Forxiga - HF CVOT: regulatory decision (EU, JP, CN)</li> <li>Farxiga - CKD: regulatory submission</li> <li>Brilinta/Brilique - CAD<sup>30</sup>/T2D CVOT: regulatory decision (US, EU)</li> <li>roxadustat - anaemia in CKD: regulatory decision (US)</li> <li>Symbicort - mild asthma: regulatory decision (CN)</li> <li>Fasenra - nasal polyposis<sup>31</sup>: data readout</li> <li>PT010 - COPD: regulatory decision (US, EU)</li> <li>PT027 - asthma: data readout</li> <li>tezepelumab - severe asthma: data readout</li> <li>anifrolumab - lupus (SLE<sup>32</sup>): regulatory submission</li> </ul>

Breast cancer susceptibility genes 1/2 mutation.
 Type-2 diabetes.
 CV outcomes trial.

<sup>26</sup> Heart failure.
27 Chronic obstructive pulmonary disease.
28 Cannot be removed completely through surgery.

<sup>&</sup>lt;sup>29</sup> Chronic lymphocytic leukaemia.<sup>30</sup> Coronary artery disease.

Painless, benign soft growths inside the nose. Systemic lupus erythematosus.



Timing	News flow
2021	<ul> <li>Imfinzi - unresectable, Stage III NSCLC (PACIFIC-2): regulatory submission</li> <li>Imfinzi - adjuvant NSCLC: data readout, regulatory submission</li> <li>Imfinzi - liver cancer (locoregional): data readout, regulatory submission</li> <li>Imfinzi +/- treme - NSCLC (1st line) (POSEIDON): data readout (OS), regulatory submission</li> <li>Imfinzi +/- treme - liver cancer (1st line): regulatory submission</li> <li>Imfinzi +/- treme - head &amp; neck cancer (1st line): data readout, regulatory submission</li> <li>Lynparza - adjuvant breast cancer: data readout, regulatory submission</li> <li>Lynparza - prostate cancer (2nd line): regulatory decision (JP)</li> <li>Lynparza - prostate cancer (1st line, castration-resistant): data readout, regulatory submission</li> <li>Enhertu - breast cancer (2nd line, HER2+): data readout, regulatory submission</li> <li>Enhertu - breast cancer (3rd line, HER2+) (Phase III): data readout</li> <li>Enhertu - breast cancer (HER2-low³³): data readout</li> <li>Calquence - CLL: regulatory decision (JP)</li> <li>Koselugo - NF1: regulatory decision (EU)</li> <li>roxadustat - anaemia in myelodysplastic syndrome³⁴: data readout</li> <li>Fasenra - nasal polyposis: regulatory submission</li> <li>PT027 - asthma: regulatory submission</li> <li>tezepelumab - severe asthma: regulatory submission</li> </ul>

#### Conference call

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

# Report calendar

The Company intends to publish its first-half and second-quarter financial results on 30 July 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 <a href="mailto:astrazeneca.com">astrazeneca.com</a> and follow the Company on Twitter <a href="mailto:astrazeneca.com">astrazeneca.com</a>.

# **Contacts**

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

<sup>&</sup>lt;sup>33</sup> HER2 immunohistochemistry 1+ or 2+ with fluorescence in situ hybridisation test result negative.

<sup>&</sup>lt;sup>34</sup> A group of disorders in which the bone marrow fails to produce healthy blood cells.



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# Operating and financial review

All narrative on growth and results in this section is based on actual exchange rates, and financial figures are in US\$ millions (\$m), unless stated otherwise. The performance shown in this announcement covers the three-month period to 31 March 2020 (the quarter or Q1 2020) compared to the three-month period to 31 March 2019 (Q1 2019) respectively, unless stated otherwise.

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

- Amortisation and impairment of intangible assets, including impairment reversals but excluding any charges relating to IT assets
- Charges and provisions related to restructuring programmes, which includes charges that relate to the impact of restructuring programmes on capitalised IT assets
- Other specified items, principally comprising 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 <u>Annual Report and Form 20-F Information 2019</u>. 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

	Q1 2020				
	\$m	¢m.		% ch	ange
		% of total	Actual	CER	
Oncology	2,518	40	33	34	
BioPharmaceuticals	2,657	42	15	16	
New CVRM	1,102	17	7	8	
Respiratory & Immunology	1,555	24	21	22	
Other medicines	1,179	19	(8)	(6)	
Total	6,354	100	16	17	

Specialty-care medicines comprise all Oncology medicines, *Brilinta*, *Lokelma*, roxadustat and *Fasenra*. At 49% of Total Revenue (Q1 2019: 43%), specialty-care medicine Total Revenue increased by 32% in the quarter (34% at CER) to \$3,139m.

Table 8: Top-ten medicines by Total Revenue

		Q1 2020			
Medicine	Therapy Area	\$m	% of total	% change	
				Actual	CER
Tagrisso	Oncology	982	15	56	58
Symbicort	Respiratory	790	12	35	36
Imfinzi	Oncology	462	7	57	57
Brilinta	CVRM	408	6	17	19
Farxiga	CVRM	407	6	16	19
Lynparza	Oncology	397	6	67	69
Pulmicort	Respiratory	380	6	(1)	-
Nexium	Other medicines	348	5	(6)	(5)
Crestor	CVRM	302	5	(10)	(8)
Zoladex	Oncology	228	4	16	19
Total		4,704	74	26	28

**Table 9: Collaboration Revenue** 

	Q1 2020			
	0/ 25 4 24 2	% chan		nange
	\$m	% of total	Actual	CER
Enhertu: profit share	14	33	n/m	n/m
Roxadustat: profit share	3	7	n/m	n/m
Other Ongoing Collaboration Revenue	26	60	4	5
Total	43	100	69	70

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



# **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

			Q1 2	020	
Therapy area	Medicine	\$m	% of total		ange CER
	Tagrisso	982	16		58
	Imfinzi	462	7	57	57
	Lynparza	397	6	67	69
	Calquence	88	1	n/m	n/m
	Zoladex	225	4	16	19
Product Sales: Oncology	Faslodex	166	3	(35)	(34)
<u> </u>	Iressa	77	1	` '	(41)
	Arimidex	50	1	, ,	1
	Casodex	42	1		(10)
	Others	13	-		(36)
	Total Oncology	2,502	40	32	34
	Farxiga	405	6	16	19
	Brilinta	408	6	17	19
	Bydureon	100	2	(30)	(29)
	Onglyza	141	2	(8)	(6)
	Byetta	20	-	(32)	(31)
Product Sales:	Other diabetes	13	-	Actual 56 57 67 n/m 16 (35) (42) (1) (12) (37) 32 16 17 (30) (8)	18
BioPharmaceuticals - CVRM	Lokelma	11	-		n/m
	Crestor	301	5		(9)
	Seloken/Toprol-XL	177	3	(21)	(18)
	Atacand	66	1	33	36
	Others	59	1	(18)	(17)
	BioPharmaceuticals: total CVRM	1,701	27	(1)	1
	Symbicort	790	13	35	36
	Pulmicort	380	6	(1)	-
	Fasenra	199	3	54	55
Product Sales:	Daliresp/Daxas	53	1	11	12
BioPharmaceuticals - Respiratory & Immunology	Bevespi	12	-	22	22
respiratory a miniminiology	Breztri	4	-	n/m	n/m
	Others	113	2	(11)	(10)
	BioPharmaceuticals: total Respiratory & Immunology	1,551	25	21	22



		Q1 2020			
Therapy area	Medicine	\$m % of		% change	
		фііі	total	Actual	CER
Product Sales: other medicines	Nexium	338	5	(7)	(6)
	Synagis	85	1	61	61
	Losec/Prilosec	54	1	(30)	(28)
	Seroquel XR/IR	36	1	(4)	(3)
	Others	44	1	(8)	(7)
	Total other medicines	557	9	(4)	(3)
	Total Product Sales	6,311	100	15	17
	Total Collaboration Revenue	43		69	70
	Total Revenue	6,354		16	17

# **Total Revenue summary**

### Oncology

Total Revenue of \$2,518m in the quarter; an increase of 33% (34% at CER). No *Lynparza* Collaboration Revenue was recorded in this quarter. The performance of *Enhertu* was reflected in Collaboration Revenue; no Product Sales of *Enhertu* were recorded in the quarter.

Oncology Total Revenue represented 40% of overall Total Revenue (Q1 2019: 35%).

# Tagrisso

*Tagrisso* has received regulatory approval in 81 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 20 countries, with further reimbursement decisions anticipated throughout 2020, as well as additional regulatory decisions in many countries. This followed *Tagrisso*'s approval and launch in 88 countries, including the US, China, in the EU and Japan for the treatment of patients with EGFR T790M<sup>35</sup>-mutated NSCLC.

Total Revenue, entirely comprising Product Sales, amounted to \$982m in the quarter and represented growth of 56% (58% 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. Sequentially, Total Revenue increased by \$98m from Q4 2019 to Q1 2020, including sequential growth in the US. Total Revenue in the US increased by 43% year-on-year in the quarter to \$371m. Demand growth continued, with *Tagrisso* established as the standard of care (SoC) in the 1st-line setting, following regulatory approval in 2018.

In Emerging Markets, *Tagrisso* Total Revenue increased by 103% in the quarter (109% at CER) to \$280m, 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 25% (23% at CER) to \$153m. In Europe, Total Revenue of \$162m in the quarter represented an increase of 62% (66% at CER), driven by its emerging use in the 1st-line setting, as more reimbursements were granted, as well as continued strong levels of demand in the 2nd-line setting.

## **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 reimbursement agreements increased to 27 in the quarter. During the period, *Imfinzi* was also approved for the treatment of ES-SCLC patients in the US and Singapore.

 $<sup>^{35}</sup>$  Substitution of threonine (T) with methionine (M) at position 790 of exon 20 mutation.



It is also approved for the 2nd-line treatment of patients with locally advanced or metastatic urothelial carcinoma (bladder cancer) in 16 countries, including in the US.

Total Revenue, entirely comprising Product Sales, amounted to \$462m in the quarter and represented growth of 57%, almost exclusively for the treatment of unresectable, Stage III NSCLC. Total Revenue in the US increased by 24% to \$286m. In Japan, growth of 66% (64% at CER) represented sales of \$56m. Sales in Europe of \$75m followed recent regulatory approvals and launches. *Imfinzi* was also launched in the quarter in China for the treatment of unresectable, Stage III NSCLC.

#### Lynparza

Lynparza has received regulatory approval in 73 countries for the treatment of ovarian cancer. Launches for the treatment of metastatic breast cancer took place in the US and Japan in 2018 in the EU in April 2019. Lynparza has now been approved in 64 countries for the treatment of metastatic breast cancer and, in four countries, including the US, for the treatment of pancreatic cancer.

Total Revenue amounted to \$397m in the quarter and represented growth of 67% (69% at CER); no *Lynparza* Collaboration Revenue was recorded in the period. The strong performance was geographically spread, with launches continuing in Emerging Markets and the Established Rest of World region (RoW).

US sales amounted to \$197m and increased by 66%, 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-inhibitor class, as measured by total prescription volumes in both ovarian and breast cancer. Sales in Europe increased by 57% (61% at CER) to \$102m, driven by 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 \$34m, representing growth of 55% (53% at CER). Emerging Markets sales of \$56m, up by 113% (120% at CER), reflected the regulatory approval of *Lynparza* as a 2nd-line maintenance treatment of patients with ovarian cancer by the China National Medical Products Administration (NMPA). *Lynparza* was admitted to the China NRDL for the same indication, with effect from January 2020.

## <u>Calquence</u>

Total Revenue, entirely comprising Product Sales, amounted to \$88m in the quarter and represented growth of 202%, with the overwhelming majority of sales in the US. *Calquence* was approved by the US Food and Drug Administration (FDA) for the treatment of CLL and small lymphocytic lymphoma (SLL) in November 2019. *Calquence* has received 13 regulatory approvals for the treatment of patients with mantle-cell lymphoma, and six in CLL.

#### Enhertu

Product Sales, recorded by Daiichi Sankyo, amounted to \$30m. This reflected sales in the US, where *Enhertu* has been launched and where Daiichi Sankyo is the principal. Total Revenue, entirely comprising resulting Collaboration Revenue recorded by AstraZeneca, amounted to \$14m in the quarter, following the recent launch in the US at the beginning of the year. *Enhertu* was approved by the US FDA for the treatment of 3rd-line HER2+ breast cancer in December 2019.

# Legacy: Iressa

Total Revenue, entirely comprising Product Sales, amounted to \$77m in the quarter and represented a decline of 42% (41% at CER). Sales in Emerging Markets declined by 28% (26% at CER) to \$62m, reflecting *Iressa*'s inclusion on the China volume-based procurement programme.

#### Legacy: Faslodex

Total Revenue, entirely comprising Product Sales, amounted to \$166m in the quarter and represented a decline of 35% (34% at CER).

Emerging Markets sales of *Faslodex* increased by 7% (10% at CER) to \$48m. US sales declined by 83% to \$23m, reflecting the launch of multiple generic *Faslodex* medicines. In Europe, where generic competitor medicines are established, sales increased by 19% (22% at CER) to \$64m, while in Japan, sales increased by 4% (3% at CER) to \$29m.



# Legacy: Zoladex

Total Revenue, predominantly comprising Product Sales, amounted to \$228m in the quarter and represented growth of 16% (19% at CER).

Emerging Markets sales of *Zoladex* increased by 30% (35% at CER) to \$149m. Sales in Europe increased by 1% (3% at CER) to \$35m. In the Established RoW region, sales declined by 10% (9% at CER) to \$39m, driven by the effects of increased competition.

#### **BioPharmaceuticals: CVRM**

Total Revenue, which included roxadustat Ongoing Collaboration Revenue of \$3m and sales of *Crestor* and other legacy medicines, were stable in the quarter (increase of 1% at CER) to \$1,707m and represented 27% of Total Revenue (Q1 2019: 31%).

New CVRM Total Revenue, which excluded sales of *Crestor* and other legacy medicines, increased by 7% in the quarter (8% at CER) to \$1,102m, reflecting strong performances from *Farxiga* and *Brilinta*. New CVRM Total Revenue represented 17% of overall Total Revenue in the quarter (Q1 2019: 19%); this change partly reflected the particular growth of Oncology.

### Farxiga

Total Revenue, predominantly comprising Product Sales, amounted to \$407m in the quarter and represented growth of 16% (19% at CER).

Emerging Markets sales increased by 49% (55% at CER) to \$141m. In China, *Farxiga* was admitted to the NRDL with effect from the start of 2020; as expected, this adversely impacted the price of the medicine. This impact, however, was offset by the volume benefit derived from the launch within the NRDL listing. The performance also reflected growth in the sodium-glucose layer transport protein 2 (SGLT2) inhibitor class at the expense of the dipeptidyl-peptidase 4 (DPP-4) inhibitor class.

US sales declined by 14% to \$113m. Growth in the quarter was adversely affected by the impact on price from increased levels of competition, the mix of sales and managed markets. 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.

Sales in Europe increased by 30% (34% at CER) to \$116m, partly reflecting growth in the SGLT2 inhibitor class and an acceleration of new-to-brand prescriptions following a similar DECLARE label update. In Japan, sales to the collaborator, Ono Pharmaceutical Co., Ltd, which records in-market sales, declined by 24% (25% at CER) to \$13m.

#### Brilinta

Total Revenue, entirely comprising Product Sales, amounted to \$408m in the quarter and represented growth of 17% (19% at CER). Patient uptake continued in the treatment of acute coronary syndrome and high-risk post-myocardial infarction (MI); the performance also reflected aforementioned short-term inventory increases, given the hospital-dispensation setting.

Emerging Markets sales of *Brilinta* increased by 38% (42% at CER) to \$134m. US sales of *Brilinta*, at \$165m, represented an increase of 8%, 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 12% in the quarter (15% at CER) to \$93m, reflecting performances in Spain, Germany and the UK.

#### Onglyza

Total Revenue, entirely comprising Product Sales, amounted to \$141m in the quarter and represented a decline of 8% (6% at CER).

Sales in Emerging Markets increased by 10% (13% at CER) to \$47m, driven by the performance in China. US sales of *Onglyza* declined by 14% in the quarter to \$67m; given the significant future potential of *Farxiga*, the Company continues to prioritise commercial support over *Onglyza*. Europe sales declined by 19% (17% at CER) to \$15m, also highlighting the broader trend of a shift away from the DPP-4 inhibitor class.



#### **Bydureon**

Total Revenue, entirely comprising Product Sales, amounted to \$100m in the quarter and represented a decline of 30% (29% at CER).

US sales of \$84m reflected a decline of 28% in the guarter, 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 34% (32% at CER) to \$12m. Reflecting the recent and potential performance of Bydureon, a \$102m intangible asset impairment charge was recorded in the quarter.

#### Lokelma

Total Revenue, entirely comprising Product Sales, amounted to \$11m in the quarter and reflected sequential growth of 42% over Q4 2019.

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 quarter. The medicine has received regulatory approval 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 \$3m in the guarter. The period saw a focus on achieving hospital listings across the country. Roxadustat was approved by the China NMPA for the treatment of anaemia in CKD in dialysis-dependent and non-dialysis dependent patients in December 2018 and August 2019, respectively. Roxadustat was admitted to the China NRDL with effect from January 2020.

## Legacy: Crestor

Total Revenue, predominantly comprising Product Sales, amounted to \$302m in the quarter and represented a decline of 10% (8% at CER).

Sales in Emerging Markets declined by 15% (13% at CER) to \$192m. The performance was adversely impacted by the effect of volume-based procurement in China. US sales increased by 9% to \$28m. In Europe, sales declined by 12% (10% at CER) to \$34m. In Japan, where AstraZeneca collaborates with Shionogi Co. Ltd, sales increased by 5% (3% at CER) to \$34m.

## BioPharmaceuticals: Respiratory & Immunology

Total Revenue, which included Ongoing Collaboration Revenue of \$3m from Duaklir and Eklira, increased by 21% in the guarter (22% at CER) to \$1,555m and represented 24% of Total Revenue (Q1 2019: 23%).

<u>Symbicort</u>
Total Revenue, entirely comprising Product Sales, amounted to \$790m in the quarter and represented growth of 35% (36% at CER).

An authorised-generic version of *Symbicort* was launched in the US by the Company's collaborator, Prasco. US sales grew by 76% to \$310m; this partly reflected an element of inventory build by Prasco. 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 17% in the quarter (20% at CER) to \$156m, reflecting particularly strong performances in China and the Middle East & Africa.

In Europe, sales increased by 7% in the quarter (10% at CER) to \$195m. In Japan, sales grew by 40% (38% at CER) to \$56m, supported by the continued effect of AstraZeneca regaining full rights, following termination in 2019 of the Astellas co-promotion agreement. In Japan, Symbicort pricing was, however, adversely impacted by the recent market entry of a generic medicine.

# **Pulmicort**

Total Revenue, entirely comprising Product Sales, amounted to \$380m in the quarter and represented a decline of 1% (stable at CER).

Emerging Markets, where sales were stable in the quarter (+1% at CER) at \$313m, represented 82% of global Total Revenue of *Pulmicort*. The performance in China was impacted by local COVID-19 pandemic restrictions.



resulting in a disruption of hospital dispensation and significantly reduced access and attendance to outpatient nebulisation rooms. It also reflected a particularly benign influenza season in China, resulting in a significantly reduced number of asthma exacerbations. Sales in the US declined by 3% to \$23m and sales in Europe increased by 3% (6% at CER) to \$26m.

#### <u>Fasenra</u>

Fasenra has received regulatory approval in 56 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 39 countries. Total Revenue, entirely comprising Product Sales, amounted to \$199m in the guarter and represented growth of 54% (55% at CER).

Sales in the US increased by 29% in the quarter to \$120m. For the aforementioned treatment of patients, *Fasenra* ended the quarter as the leading novel biologic medicine in the US, as measured by new-to-brand prescriptions. In Europe, sales of \$46m in the quarter represented an increase of 154% (161% at CER), reflecting a number of successful launches. Sales in Japan increased by 32% (30% at CER) to \$21m. In its approved indication and among new patients, *Fasenra* obtained the leading market share of all biologic medicines in the 'top-five' European countries and in Japan. In Emerging Markets, sales amounted to \$6m in the quarter (Q1 2019: \$nil).

### Daliresp/Daxas

Total Revenue, entirely comprising Product Sales, amounted to \$53m in the quarter and represented growth of 11% (12% at CER).

US sales, representing 85% of the global total, increased by 10% to \$45m, driven by higher demand, partially offset by adverse inventory movements.

### Bevespi

Total Revenue, entirely comprising Product Sales, amounted to \$12m in the quarter and represented growth of 22%.

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 \$4m in the quarter (Q1 2019: \$nil).

Following regulatory approvals for the treatment of COPD, *Breztri* was launched in Japan and China.

#### Other medicines (outside the three main therapy areas)

Total Revenue, primarily comprising Product Sales, amounted to \$557m in the quarter; a decline of 4% (3% at CER). Other Total Revenue represented 9% of overall Total Revenue (Q1 2019: 10%).

#### Nexium

Total Revenue, predominantly comprising Product Sales, amounted to \$348m in the quarter; a decline of 6% (5% at CER). Emerging Markets sales of *Nexium* declined by 2% (an increase of 1% at CER) to \$187m. In Japan, where AstraZeneca collaborates with Daiichi Sankyo, sales were stable at \$79m.



# **Regional Total Revenue**

**Table 11: Regional Total Revenue** 

Q1 2020				
	\$m	% of total	% ch	
	ФШ	% OI lotai	Actual	CER
Emerging Markets	2,273	36	13	16
China	1,416	22	14	17
Ex-China	857	14	12	15
US	2,091	33	16	16
Europe	1,204	19	22	25
Established RoW	786	12	13	13
Japan	553	9	10	8
Canada	156	2	37	36
Other Established RoW	77	1	(1)	5
Total	6,354	100	16	17

Table 12: Emerging Markets therapy-area performance

	Q1 2020			
	¢m	% of total	% ch	ange
	\$m	% OI total	Actual	CER
Oncology	711	31	45	49
BioPharmaceuticals	872	38	15	18
New CVRM	332	15	39	43
Respiratory & Immunology	540	24	4	6
Other medicines	690	30	(9)	(7)
Total	2,273	100	13	16

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

	Q1 2020		
	¢	% change	
	\$m	Actual	CER
Tagrisso	280	n/m	n/m
Forxiga	142	49	55
Brilinta	134	38	42
Lynparza	55	n/m	n/m
Imfinzi	33	n/m	n/m



The new medicines represented 29% of Emerging Markets Total Revenue (Q1 2019: 18%). Total Revenue from specialty-care medicines increased by 45% (50% at CER) to \$854m and comprised 38% of Emerging Markets sales in the quarter (Q1 2019: 29%).

China Total Revenue, which included \$3m of roxadustat Ongoing Collaboration Revenue, comprised 62% of Emerging Markets Total Revenue in the quarter and increased by 14% (17% at CER) to \$1,416m.

New-medicine Total Revenue in China, primarily driven by *Tagrisso* and *Lynparza* in Oncology and *Brilinta* and *Farxiga* in New CVRM, delivered particularly encouraging growth and represented 27% of China Total Revenue (Q1 2019: 13%). This performance was augmented by strong sales of *Zoladex*, *Symbicort* and a resilient performance from *Pulmicort*.

Ex-China Emerging Markets, comprising entirely of Product Sales, increased by 12% in the quarter (15% at CER) to \$857m. The new medicines represented 32% of ex-China Emerging Markets Total Revenue in the quarter (Q1 2019: 26%), increasing by 41% (45% at CER) to \$277m. The performance was underpinned by strong levels of growth across the following:

Table 14: Ex-China Emerging Markets: Total Revenue

		Q1 2020	
	¢	% change	
	\$m	Actual	CER
Russia	84	72	66
Brazil	89	(5)	6
Ex-Brazil Latin America	108	7	18
Ex-China Asia Pacific	311	11	12
Middle East and Africa	265	11	12



# Financial performance

**Table 15: Reported Profit and Loss** 

	Q1 2020	Q1 2019	% change	
	\$m	\$m	Actual	CER
Total Revenue	6,354	5,491	16	17
Product Sales	6,311	5,465	15	17
Collaboration Revenue	43	26	69	70
Cost of Sales	(1,420)	(1,129)	26	26
Gross Profit	4,934	4,362	13	15
Gross Margin	77.5%	79.3%	(2)	(2)
Distribution Expense	(87)	(78)	11	13
% Total Revenue	1.4%	1.4%	-	-
R&D Expense	(1,388)	(1,266)	10	10
% Total Revenue	21.8%	23.1%	1	2
SG&A Expense	(2,719)	(2,514)	8	9
% Total Revenue	42.8%	45.8%	3	3
Other Operating Income & Expense	480	593	(19)	(19)
% Total Revenue	7.6%	10.8%	(3)	(3)
Operating Profit	1,220	1,097	11	16
Operating Profit Margin	19.2%	20.0%	(1)	-
Net Finance Expense	(281)	(312)	(10)	(9)
Joint Ventures and Associates	(4)	(27)	(85)	(85)
Profit Before Tax	935	758	23	29
Taxation	(185)	(195)	(5)	(1)
Tax Rate	20%	26%		
Profit After Tax	750	563	33	40
EPS	0.59	0.47	27	33

Table 16: Reconciliation of Reported Profit Before Tax to EBITDA

	Q1 2020 Q1 2019		% change	
	\$m	\$m	Actual	CER
Reported Profit Before Tax	935	758	23	29
Net Finance Expense	281	312	(10)	(9)
Joint Ventures and Associates	4	27	(85)	(85)
Depreciation, Amortisation and Impairment	841	676	24	26
EBITDA	2,061	1,773	16	20

Table 17: Reconciliation of Reported to Core financial measures

Q1 2020	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Diabetes Alliance	Other	Core	Core chan	
	\$m	\$m	\$m	\$m	\$m	\$m	Actual	CER
Gross Profit	4,934	19	17	-	5	4,975	12	14
Gross Profit Margin	77.5%					78.1%	-2	-2
Distribution Expense	(87)	-	-	-	-	(87)	11	13
R&D Expense	(1,388)	11	42	-	(1)	(1,336)	9	9
SG&A Expense	(2,719)	25	449	67	1	(2,177)	5	7
Total Operating Expense	(4,194)	36	491	67	-	(3,600)	7	8
Other Operating Income & Expense	480	(2)	1	-	-	479	(19)	(19)
Operating Profit	1,220	53	509	67	5	1,854	12	16
Operating Profit Margin	19.2%					29.2%	-1	-
Net Finance Expense	(281)	-	-	57	55	(169)	(11)	(11)
Taxation	(185)	(11)	(107)	(31)	-	(334)	1	5
EPS	\$0.59	\$0.03	\$0.31	\$0.07	\$0.05	\$1.05	17	21



# **Profit and Loss summary**

#### a) Gross Profit

The increases in Reported and Core Gross Profit in the quarter reflected the growth in Product Sales. The declines in the Reported and Core Gross Margin partly reflected the impact of one-off adjustments related to Group inventory, the growth in profit share from the collaboration with MSD in respect of *Lynparza* and an element of foreign-exchange impact.

### b) Total Operating Expense

Reported Total Operating Expense in the quarter represented 66% of Total Revenue (Q1 2019: 70%), Core Total Operating Expense represented 57% of Total Revenue (Q1 2019: 61%).

Reported and Core R&D Expense increased partly as a result of investment in the development of *Enhertu*. Reported and Core SG&A Expense grew primarily due to additional select investment in Oncology-medicine launches and AstraZeneca's further expansion in China. In addition, Reported SG&A Expense was adversely impacted by an increased level of intangible asset impairments, including a \$102m charge relating to *Bydureon*.

## c) Other Operating Income and Expense<sup>36</sup>

Reported and Core Other Operating Income and Expense in the quarter included \$350m of income that reflected an <u>agreement</u> to divest commercial rights to a number of legacy hypertension medicines.

#### 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 quarter were both 20% (Q1 2019: 26% and 23% respectively). Taxation Paid for the quarter was \$477m, representing 51% of Reported Profit Before Tax (Q1 2019: \$334m, 44%).

#### f) EPS

Reported EPS of \$0.59 in the quarter, represented an increase of 27% (33% at CER). This was despite an increase in the weighted-average number of shares to 1,312m (Q1 2019: 1,267m). Core EPS increased by 17% (21% at CER) to \$1.05.

<sup>&</sup>lt;sup>36</sup> Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from divestments is reported within Other Operating Income and Expense in the Company's financial statements.



**Table 18: Cash Flow** 

	Q1 2020	Q1 2019	Change
	\$m	\$m	\$m
Reported Operating Profit	1,220	1,097	123
Depreciation, Amortisation and Impairment	841	676	165
Increase in Working Capital and Short-Term Provisions	(445)	(710)	265
Gains on Disposal of Intangible Assets	(358)	(512)	154
Non-Cash and Other Movements	(462)	(396)	(66)
Interest Paid	(180)	(208)	28
Taxation Paid	(477)	(334)	(143)
Net Cash Inflow/(Outflow) from Operating Activities	139	(387)	526
Net Cash Inflow/(Outflow) before Financing Activities	148	(59)	207
Net Cash Outflow from Financing Activities	(2,362)	(698)	(1,664)

The increase in Net Cash Inflows from Operating Activities in the quarter primarily reflected an underlying improvement in business performance, combined with favourable working-capital movements. The positive cash performance was partly offset by the aforementioned increase in Taxation Paid.

The increase in Net Cash Inflows before Financing Activities primarily reflected the aforementioned improvement in Net Cash Inflows from Operating Activities, as well as a reduction in the Purchase of Intangible Assets, partially offset by a reduction in cash flows from the Disposal of Intangible Assets. The cash payment of contingent consideration, in respect of the former Bristol-Myers Squibb Company (BMS) share of the global diabetes alliance, amounted to \$124m in the quarter.

# **Capital Expenditure**

Capital expenditure amounted to \$186m in the quarter, compared to \$174m in Q1 2019. This included investment in the new AstraZeneca R&D centre on the Biomedical Campus in Cambridge, UK.

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



**Table 19: Net Debt summary** 

	At 31 Mar 2020	At 31 Dec 2019	At 31 Mar 2019
	\$m	\$m	\$m
Cash and Cash Equivalents	3,413	5,369	4,136
Other Investments	804	911	876
Cash and Investments	4,217	6,280	5,012
Overdrafts and Short-Term Borrowings	(691)	(225)	(2,044)
Lease Liabilities	(653)	(675)	(714)
Current Instalments of Loans	(1,598)	(1,597)	(1,500)
Loans Due After One Year	(15,634)	(15,730)	(17,320)
Interest-Bearing Loans and Borrowings (Gross Debt)	(18,576)	(18,227)	(21,578)
Net Derivatives	(54)	43	295
Net Debt	(14,413)	(11,904)	(16,271)

## **Capital allocation**

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

# Foreign exchange

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



**Table 20: Currency sensitivities** 

The Company provides the following currency-sensitivity information:

		Average Exchange Rates versus USD			Strengtl Exchange	pact of 5% nening in Rate versus (\$m) <sup>37</sup>
Currency	Primary Relevance	FY 2019 <sup>38</sup>	Q1 2020 <sup>39</sup>	% change	Product Sales	Core Operating Profit
CNY	Product Sales	6.92	6.99	(1)	288	190
EUR	Product Sales	0.89	0.91	(1)	171	68
JPY	Product Sales	108.98	108.91	-	139	98
Other <sup>40</sup>					231	123
GBP	Operating Expense	0.78	0.78	-	27	(93)
SEK	Operating Expense	9.46	9.67	(2)	5	(51)

As per the FY 2019 results announcement.
 Based on average daily spot rates in FY 2019.
 Based on average daily spot rates from 1 January 2020 to 31 March 2020.
 Other currencies include AUD, BRL, CAD, KRW and RUB.



## Sustainability

AstraZeneca's sustainability approach has three priority areas<sup>39</sup>, aligned with the Company's purpose and business strategy:

- Access to healthcare
- Environmental protection
- Ethics and transparency

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

### a) Access to healthcare

During the period, AstraZeneca announced a donation of nine million face masks to support healthcare workers around the world as they respond to the COVID-19 global pandemic. The Company has also collaborated with the <a href="World Economic Forum's COVID Action Platform">World Economic Forum's COVID Action Platform</a>, created with the support of the World Health Organization, to identify countries in greatest need; more than eight million masks have already been delivered.

During the period, AstraZeneca proactively communicated with its healthcare and community partners, who are working to support healthcare systems, patients and caregivers around the world, to reinforce the Company's support of their efforts during the COVID-19 pandemic. AstraZeneca will continue to meet funding commitments and support community partner decisions to postpone or cancel programmes or reallocate funding towards relief and response efforts. For example, Healthy Heart Africa (HHA) collaborators who support the delivery of the Company's programme in local communities in Kenya, Ethiopia, Tanzania and Ghana, have repurposed local facilities and diverted resources towards providing protective clothing to healthcare workers. AstraZeneca's Young Health Programme partners have stopped all community-based outreach and are delivering disease prevention messaging over virtual networks. In addition, the Company is ensuring that its collaborators are safe and supported and is encouraging them to follow the appropriate governmental guidance.

In March 2020, the manuscript '<u>Burden of prehypertension among adults in Kenya: a retrospective analysis of findings from the HHA programme</u>' was published in the <u>BMC Public Health</u> journal; this was the third HHA manuscript published in the last twelve months. The publication outlined the high prevalence of hypertension (HTN) and pre-HTN in Kenya, with more than 50% of the six million screening records analysed found to have pre-HTN, in addition to 20% with HTN, among an average screening age of 45 years.

#### b) Environmental protection

To coincide with Earth Day on 22 April 2020, AstraZeneca announced a <a href="new one-year collaboration focusing on water stewardship">new one-year collaboration focusing on water stewardship</a> with World Wide Fund for Nature Sweden, to identify opportunities to improve the Company's approach and strategy towards water stewardship. Responsible management of water, particularly where sites are situated in water-stressed areas, is critical to the development and manufacture of the Company's medicines. AstraZeneca's longer-term ambition is to implement Science-Based Targets for Water, once a global methodology is available, to lead the way on water stewardship for the pharmaceutical industry; including the development of industry-specific tools to assess water risk in the context of <a href="Pharmaceuticals in the Environment">Pharmaceuticals in the Environment</a>.

This approach will ensure that AstraZeneca is more meaningfully contributing to the sustainable management of water resources within river basins. The Company's water target is to maintain absolute water use at the 2015 level through 2025. Since 2015, the Company has developed a standard methodology to assess water risk and stress at its global sites, which has enabled the Company to broaden its understanding of water-related risks and opportunities for priority investment. AstraZeneca has prioritised implementing water-efficiency projects, identified through water audits at 11 sites, including Yelahanka, Bangalore, India; Shanghai, China; and Canóvanas, Puerto Rico; and implemented rainwater harvesting at five sites: Wuxi, China; Cambridge, UK; Macclesfield, UK; Canóvanas, Puerto Rico and Frederick, US.

<sup>&</sup>lt;sup>39</sup> These priorities were determined through a materiality assessment conducted in 2018 with a broad range of external and internal stakeholders, respectively. Combined, they ensure the maximum possible benefit to patients, the Company, broader society and the planet. AstraZeneca's sustainability priorities align with the United Nations Sustainable Development Goals (SDG), and, in particular, SDG three for 'Good Health'.



During the period, the AstraZeneca Green Labs initiative received two 'My Green Lab' certifications, reflecting the Company's commitment to laboratory sustainability. AstraZeneca's R&D site in Boston, US achieved Gold Level Certification for implementing over 60% of recommended sustainable lab practices; and the Company's R&D site in South San Francisco, US achieved Green Level Certification, awarded for implementing over 80% of recommended-sustainability practices. This is the highest level of certification provided by My Green Lab, placing the Company's South San Francisco site as one of only 10 laboratories certified at this level, out of more than 400 worldwide. The programme is the first of its scope in the industry, bringing together scientists, facilities management, engineering and safety health and environment to improve the environmental sustainability of research laboratories. AstraZeneca's major sites in the UK and Sweden are in scope and aim to become My Green Lab certified in the coming months.

## c) Ethics and transparency

Since committing to providing greater transparency around payments to healthcare professionals and healthcare organisations at the 2018 Annual General Meeting, AstraZeneca successfully progressed in 2019 the disclosure programme into an additional five markets covering Brazil, Colombia, Korea, Mexico and Saudi Arabia. In 2020, the Company is intending to further progress this work across Canada, the Philippines (where enhanced legislation has been recently passed, superseding the existing Administrative Order) and New Zealand, while continuing to monitor the regulatory landscape in Argentina, Chile, India and Morocco.

### d) Other developments

In March 2020, the Company released its sixth annual <u>Sustainability Report</u> via its website and social media. The report was released in conjunction with the <u>Annual Report and Form 20-F Information 2019</u>. The report outlined progress and challenges and aims for the future. Many of the new sustainability initiatives and programmes launched in 2019 were a result of engagement and activism from AstraZeneca colleagues around the world, demonstrating how sustainability is being embedded across the organisation.

For more details on AstraZeneca's sustainability ambition, approach and targets, please refer to the latest <u>Sustainability Report 2019</u> and <u>Sustainability Data Summary 2019</u>. 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. AstraZeneca does not expect significant delays to anticipated late-stage and lifecycle-management 2020 and 2021 news-flow dates.

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

Table 21: Update from the late-stage pipeline

New molecular entities and major lifecycle events for medicines in Phase III trials or under regulatory review	17	Oncology  - Tagrisso - NSCLC - Imfinzi - multiple cancers - Lynparza - multiple cancers - Enhertu - breast and other cancers - capivasertib - breast cancer - Calquence - blood cancers - tremelimumab - multiple cancers - savolitinib - NSCLC <sup>40</sup> CVRM - Farxiga - multiple indications - roxadustat - anaemia in CKD  Respiratory & Immunology - Fasenra - multiple indications - Breztri - asthma - PT027 - asthma - pT027 - asthma - nirsevimab - respiratory syncytial virus - anifrolumab - lupus (SLE) - brazikumab <sup>41</sup> - inflammatory bowel disease
Total projects in clinical pipeline	167	

# Oncology

# Oncology: lung cancer

## a) Tagrisso

In April 2020, the Company announced that the ADAURA Phase III trial for *Tagrisso* in the adjuvant treatment of patients with Stage IB, II and IIIA EGFRm NSCLC with complete tumour resection was to be unblinded early following a recommendation from an Independent Data Monitoring Committee (IDMC), based on its determination of overwhelming efficacy. The primary endpoint of the trial is disease-free survival. *Tagrisso* was assessed against placebo for a treatment duration of up to three years. The trial will continue to assess the

<sup>&</sup>lt;sup>40</sup> Phase II trial data, with potential for registration.

<sup>&</sup>lt;sup>41</sup> Subject to regulatory approvals associated with AbbVie Inc.'s (AbbVie) proposed acquisition of Allergan plc (Allergan).



secondary endpoint of OS. In its communication to AstraZeneca, the IDMC did not raise any new safety concerns. The data will be presented at a forthcoming medical meeting.

Table 22: Key Tagrisso trials in lung cancer

Trial	Population	Design	Timeline	Status
Phase III ADAURA	Adjuvant EGFRm NSCLC	Placebo or Tagrisso	FPCD <sup>42</sup> Q4 2015 LPCD <sup>43</sup> Q1 2019	Trial unblinded early due to overwhelming efficacy
Phase III LAURA	Locally advanced, unresectable EGFRm NSCLC	Placebo or Tagrisso	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III FLAURA2	1st-line EGFRm NSCLC	Tagrisso or Tagrisso + platinum-based chemotherapy doublet	FPCD Q4 2019 First data anticipated 2021+	Recruitment ongoing

# b) Imfinzi

In March 2020, the Company announced that *Imfinzi* had been approved in the US as a 1st-line treatment for adult patients with ES-SCLC in combination with SoC chemotherapies, etoposide plus either carboplatin or cisplatin (platinum-etoposide) utilising the fixed dose of *Imfinzi* 1,500mg every three weeks, for four cycles with chemotherapy, then every four weeks until progression. This followed the regulatory approval in Singapore earlier in the period.

Prior to this, AstraZeneca announced high-level results from the final analysis of the Phase III CASPIAN trial, which showed that *Imfinzi*, in combination with a choice of SoC chemotherapies, confirmed a sustained, clinically meaningful OS benefit for patients with ES-SCLC treated in the 1st-line setting. The second experimental arm, testing tremelimumab, an anti-CTLA4 monoclonal antibody, added to *Imfinzi* and SoC, did not meet its primary endpoint of demonstrating a statistically significant improvement in OS. In June 2019, it was announced that the CASPIAN trial met one primary endpoint for *Imfinzi* plus SoC by demonstrating a statistically significant and clinically meaningful improvement in OS versus SoC alone at a planned interim analysis.

During the period, AstraZeneca announced that the Phase III DANUBE trial for *Imfinzi* and *Imfinzi* plus tremelimumab in unresectable, Stage IV (metastatic) bladder cancer did not meet the primary endpoints of improving OS versus SoC chemotherapy for *Imfinzi* monotherapy in patients whose tumour cells and/or tumour-infiltrating immune cells express high levels (≥25%) of PD-L1⁴⁴, or for *Imfinzi* plus tremelimumab in patients regardless of their PD-L1 expression. The safety and tolerability profiles for *Imfinzi* and the combination with tremelimumab were consistent with previous trials. The data will be presented at a forthcoming medical meeting.

<sup>&</sup>lt;sup>42</sup> First patient commenced dosing.

<sup>&</sup>lt;sup>43</sup> Last patient commenced dosing.

<sup>&</sup>lt;sup>44</sup> Programmed death-ligand 1, a protein that assists in the body's immune responses.

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Table 23: Key Imfinzi trials in lung cancer

Trial	Population	Design	Timeline	Status
Phase III AEGEAN	Neo-adjuvant (before surgery) NSCLC	SoC chemotherapy +/- Imfinzi, followed by surgery, followed by placebo or Imfinzi	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase III ADJUVANT BR.31 <sup>45</sup>	Stage lb-Illa 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 Imfinzi or Imfinzi + treme	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III POSEIDON	Stage IV, 1st-line NSCLC	SoC chemotherapy or SoC + <i>Imfinzi</i> or SoC + <i>Imfinzi</i> + treme	FPCD Q2 2017 LPCD Q4 2018 OS data anticipated 2021	PFS <sup>46</sup> primary endpoint met
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 Imfinzi monotherapy arm OS primary endpoint not met for Imfinzi + treme

During the period, the AEGEAN trial in neo-adjuvant NSCLC was expanded to include 800 patients and the primary endpoints optimised to include event-free survival, as well as major pathological response. The first data are now anticipated beyond 2021.

 $<sup>^{\</sup>rm 45}$  Conducted by the Canadian Cancer Trials Group.

<sup>&</sup>lt;sup>46</sup> Progression-free survival.



As previously announced, the POSEIDON trial of *Imfinzi* and chemotherapy trial with and without tremelimumab in 1st-line NSCLC will continue to assess the additional primary endpoint of OS, following the positive PFS readout in 2019, with data anticipated in 2021. The Company anticipates presenting the trial outcomes at a forthcoming medical meeting when the overall trial outcomes are obtained.

Table 24: Key Imfinzi trials in tumour types other than lung cancer

Trial	Population	Population Design		Status
Phase III POTOMAC	Non-muscle invasive bladder cancer	SoC BCG <sup>47</sup> 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 + Imfinzi, followed by adjuvant placebo or Imfinzi	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing
Phase III EMERALD-1	Locoregional HCC <sup>48</sup>	TACE <sup>49</sup> 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 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 + Imfinzi, followed by placebo or Imfinzi	FPCD Q1 2019 First data anticipated 2021+	Recruitment ongoing
Phase III DANUBE	Stage IV, 1st-line cisplatin chemotherapy-eligible/ineligible bladder cancer	SoC chemotherapy or <i>Imfinzi</i> or <i>Imfinzi</i> + treme	FPCD Q4 2015 LPCD Q1 2017	Primary endpoints not met
Phase III NILE	Stage IV, 1st-line cisplatin chemotherapy- eligible bladder cancer	SoC chemotherapy or SoC + Imfinzi or SoC + Imfinzi + treme	FPCD Q4 2018 First data anticipated 2021+	Recruitment Ongoing

<sup>&</sup>lt;sup>47</sup> Bacillus Calmette-Guerin.

<sup>&</sup>lt;sup>48</sup> Hepatocellular carcinoma (liver cancer).

<sup>&</sup>lt;sup>49</sup> Transarterial chemoembolisation.



Trial	Population	Design	Timeline	Status
Phase III KESTREL	Stage IV, 1st-line HNSCC <sup>50</sup>	SoC or <i>Imfinzi</i> or <i>Imfinzi</i> + treme	FPCD Q4 2015  LPCD Q1 2017  First data anticipated 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) <sup>51</sup>
Phase III TOPAZ-1	Stage IV, 1st-line biliary-tract cancer	Gemcitabine and cisplatin SoC chemotherapy or SoC + Imfinzi	FPCD Q2 2019 First data anticipated 2021+	Recruitment ongoing

The Phase III KESTREL trial's final analysis plan for *Imfinzi* with and without tremelimumab in 1st-line HNSCC is being optimised following learnings from the EAGLE trial in the 2nd-line HNSCC setting and learned regulatory insights; as such the data readout is now expected in 2021.

# c) Lynparza (multiple cancers)

During the period, *Lynparza* was added to the US National Comprehensive Cancer Network's guidelines, in combination with bevacizumab in ovarian cancer patients who had previously been treated with bevacizumab.

In March 2020, the Company announced that *Lynparza* had been granted orphan designation in Japan for the maintenance treatment of germline BRCAm curatively unresectable pancreatic cancer. The Japan Ministry of Health, Labour and Welfare (MHLW) grants the designation to medicines intended for the treatment of diseases that affect fewer than 50,000 patients in Japan and for which there is a high unmet medical need. During the period, the Company made a regulatory submission in Japan for *Lynparza* in prostate cancer, based on data from the Phase III PROfound trial.

In April 2020, AstraZeneca announced further positive results from the Phase III PROfound trial of *Lynparza* in men with metastatic castration-resistant prostate cancer who have a homologous recombination repair gene mutation (HRRm) and have progressed on prior treatment with new hormonal-agent treatments, such as enzalutamide and abiraterone.

<sup>&</sup>lt;sup>50</sup> Head and neck squamous cell carcinoma.

<sup>&</sup>lt;sup>51</sup> 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.



Table 25: Key Lynparza trials

Trial	Population	Design	Timeline	Status
			FPCD Q2 2014	
Phase III OlympiA	Adjuvant BRCAm breast cancer	SoC placebo or Lynparza	LPCD Q2 2019	Recruitment completed
			First data anticipated 2021	
Phase III PROfound	Metastatic castration-resistant 2nd-line+ HRRm	SoC (abiraterone or enzalutamide)	FPCD Q2 2017	Primary endpoint met
	prostate cancer	or <i>Lynparza</i>	LPCD Q4 2018	Priority Review (US)
Phase III	Advanced 1st-line	Bevacizumab maintenance or bevacizumab +	FPCD Q2 2015	Primary endpoint met
PAOLA-1 <sup>52</sup>	ovarian cancer	Lynparza maintenance	LPCD Q2 2018	Priority Review (US)
Phase III	Recurrent platinum-sensitive ovarian cancer	SoC chemotherapy or <i>Lynparza</i> or	FPCD Q1 2016	Primary endpoint not met
GY004 <sup>53</sup>		cediranib + <i>Lynparza</i>	LPCD Q4 2017	
			FPCD Q2 2016 (Phase II)	
Phase II/III GY005 <sup>53</sup>	Recurrent platinum- resistant/refractory ovarian cancer	SoC chemotherapy or cediranib or cediranib + <i>Lynparza</i>	FPCD Q1 2019 (Phase III)	Recruitment ongoing (Phase III component)
			First data anticipated 2021+	
Dhoos III	nase III Advanced 1st-line ovarian cancer	Chemotherapy + bevacizumab or chemotherapy + bevacizumab + Imfinzi +/- Lynparza maintenance	FPCD Q1 2019	Dogwitmont
DuO-O			First data anticipated 2021+	Recruitment ongoing
Phase III	Stage IV, advanced, castration-resistant prostate cancer	Abiraterone or	FPCD Q4 2018	Recruitment
PROpel		abiraterone + <i>Lynparza</i>	First data anticipated 2021	ongoing

 $<sup>^{52}</sup>$  Conducted by the ARCAGY/Groupe d'Investigateurs national des Etudes des Cancers Ovariens et du sein.  $^{53}$  Conducted by the National Cancer Institute (US).



# Enhertu (breast and other cancers)

During the period, Daiichi Sankyo announced that *Enhertu* had been approved by Japan's MHLW for the treatment of patients with HER2+ unresectable or metastatic breast cancer, following chemotherapy. Approval of *Enhertu* was based on the results of the pivotal Phase II DESTINY-Breast01 trial of *Enhertu* monotherapy in HER2+ metastatic breast cancer patients.

Table 26: Key Enhertu trials

Trial	Population Design		Timeline	Status
Phase II DESTINY- Breast01	Stage IV, HER2+ (IHC <sup>54</sup> 3+ and IHC 2+/ISH <sup>55</sup> +) breast cancer post trastuzumab emtansine	Enhertu (single arm)	FPCD Q4 2017 LPCD Q4 2018	Primary objective met  Breakthrough Therapy Designation (US)  Approval (JP), accelerated approval (US)
Phase III DESTINY- Breast02	Stage IV, HER2+ (IHC 3+ and IHC 2+/ISH+) breast cancer post trastuzumab emtansine	SoC chemotherapy or <i>Enhertu</i>	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase III DESTINY- Breast03	Stage IV, HER2+ (IHC 3+ and IHC 2+/ISH+) breast cancer	Trastuzumab emtansine or <i>Enhertu</i>	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase III DESTINY- Breast04	Stage IV, HER2- low (IHC 1+/2+) breast cancer	SoC chemotherapy or <i>Enhertu</i>	FPCD Q4 2018 First data anticipated 2021	Recruitment ongoing
Phase II DESTINY- Gastric01	Stage IV, HER2+ (IHC 3+ and IHC 2+/ISH+) gastric cancer	SoC chemotherapy or <i>Enhertu</i>	FPCD Q4 2017 LPCD Q2 2019	Primary endpoint met

## Koselugo (NF1)

During the period, the Company announced that the US FDA has approved the MEK 1/2 inhibitor, *Koselugo* (formerly selumetinib) for the treatment of paediatric patients aged two years and older who suffer from NF1 and symptomatic, inoperable plexiform neurofibromas (PNs). The approval was based on positive results from the National Cancer Institute (NCI) Cancer Therapy Evaluation Program-sponsored Phase II SPRINT Stratum 1 trial, coordinated by the NCI's Center for Cancer Research, Pediatric Oncology Branch. This was the first regulatory approval anywhere in the world of a medicine for the treatment of NF1 PNs.

During the period, Koselugo received a regulatory submission acceptance in the EU for the treatment of NF1.

<sup>&</sup>lt;sup>54</sup> Immunohistochemistry.

<sup>&</sup>lt;sup>55</sup> In situ hybridisation.



## Cediranib

In March 2020, the Company announced high-level results from the Phase III GY004 trial, led by NRG Oncology and sponsored by the US NCI, that examined the efficacy and safety of the potential new medicine cediranib when added to *Lynparza* versus platinum-based chemotherapy in patients with platinum-sensitive relapsed ovarian cancer. The trial did not meet the primary endpoint, in the intention-to-treat population, of a statistically significant improvement in PFS. Cediranib is an oral vascular endothelial growth factor receptor inhibitor, which blocks the growth of blood vessels supporting tumour growth.

#### **CVRM**

# a) Farxiga (heart failure)

In March 2020, the Company announced that the DAPA-CKD Phase III trial for *Farxiga* in patients with CKD would be stopped early, following a recommendation from an IDMC, based on its determination of overwhelming efficacy. The decision followed a routine assessment of efficacy and safety. The Company anticipates presentation of the data at a forthcoming medical meeting.

During the period, the Company decided not to pursue the application for *Farxiga* in type-1 diabetes in the US. This followed a complete response letter received in 2019. *Forxiga* is currently approved for the treatment of type-1 diabetes in the EU and Japan.

Table 27: Key large CVRM outcomes trials

Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Farxiga					
Phase III DAPA-HF	c.4,500 patients with HF and reduced ejection fraction, with and without T2D	Arm 1: Farxiga 10mg or 5 mg QD <sup>56</sup> + 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: Farxiga 10mg QD Arm 2: placebo	Time to first occurrence of CV death or worsening HF	FPCD Q4 2018 First data anticipated 2021+	Recruitment ongoing Fast Track designation (US)
Phase III DAPA-CKD	c.4,000 patients with CKD, with and without T2D	Arm 1: Farxiga 10mg or 5mg QD Arm 2: placebo	Time to first occurrence of ≥ 50% sustained decline in eGFR <sup>57</sup> or reaching ESRD <sup>58</sup> or CV death or renal death	FPCD Q1 2017 LPCD Q1 2020	Trial stopped early based on recommendation from an IDMC  Fast Track designation (US)

<sup>&</sup>lt;sup>56</sup> Quaque die, or once a day.

<sup>&</sup>lt;sup>57</sup> Estimated glomerular filtration rate.

<sup>&</sup>lt;sup>58</sup> End-stage renal disease.



Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Brilinta					
Phase III THEMIS	c.19,000 patients with T2D and CAD without a history of MI or stroke	Arm 1: Brilinta 60mg BID <sup>59</sup> Arm 2: placebo BID on a background of aspirin if not contra- indicated <sup>60</sup> or not tolerated	Composite of CV death, non- fatal MI and non-fatal stroke	FPCD Q1 2014 LPCD Q2 2016	Primary endpoint met
Phase III THALES	c.11,000 patients with acute ischaemic stroke or transient ischaemic attack	Arm 1: Brilinta 90mg BID  Arm 2: placebo BID on a background of 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

## b) Lokelma (hyperkalaemia)

In April 2020, the US FDA approved a label update for Lokelma to include a dosing regimen specifically to treat hyperkalaemia (elevated levels of potassium in the blood) in patients with end-stage renal disease on chronic haemodialysis. The approval by the agency was based on positive results from the Phase IIIb DIALIZE trial.

Similarly, during the period, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion on a dosing and administration label update for Lokelma to include patients with hyperkalaemia on stable haemodialysis. The recommendation was also based on data from the Phase IIIb DIALIZE trial, which showed that 41% of patients receiving Lokelma maintained pre-dialysis potassium levels on at least three out of four dialysis treatments after the long interdialytic interval and did not require urgent rescue therapy. This compared with 1.0% of patients receiving placebo, making it a statistically significant and clinically meaningful improvement. The safety profile of Lokelma observed in DIALIZE was consistent with previous trials.

In March 2020, *Lokelma* was approved in Japan for the treatment of patients with hyperkalaemia. The approval by the MHLW was based on positive results from stand-alone trials in Japan and the global clinical-trial programme. *Lokelma* is approved for the treatment of hyperkalaemia in the US, EU, Canada, Hong Kong, China, Russia and most recently, Japan.

# c) Roxadustat (anaemia)

During the period, AstraZeneca accomplished a number of regulatory submissions for roxadustat in rest-of-world countries, including Brazil, Chile, India, Mexico, Philippines, South Korea and Taiwan. In addition, a regulatory submission was made to the ACSS consortium for Australia, Canada and Singapore. FibroGen and Astellas are responsible for European regulatory submissions, including Switzerland.

<sup>&</sup>lt;sup>59</sup> Bis in die, or twice a day.

<sup>&</sup>lt;sup>60</sup> A specific situation in which a medicine should not be used as a treatment as it may be harmful to the patient.



# Respiratory & Immunology

AstraZeneca has taken the opportunity to rename its Respiratory therapy area Respiratory & Immunology. With common pathways and underlying disease drivers across respiratory and immunology, AstraZeneca is following the science from chronic lung diseases to immunology-driven disease areas.

## Fasenra (eosinophil-driven diseases)

During the period, the Company announced three new trials for *Fasenra* in skin diseases, adding to the five trials already underway for the medicine in eosinophil-driven diseases (EDDs) beyond severe asthma. In EDD, immune-system dysfunction causes eosinophil recruitment and activation of eosinophils (a type of white blood cell), leading to chronic local and/or systemic inflammation. The three new trials for *Fasenra* in skin diseases include two Phase II trials to assess the potential of the medicine as a treatment for atopic dermatitis and chronic spontaneous urticaria, as well as a Phase III trial in bullous pemphigoid (BP).

Table 28: 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 Fasenra 30mg Q8W SC	Nasal-polyposis burden and reported nasal blockage  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 Fasenra 100mg Q8W SC	Annualised rate of moderate or severe COPD exacerbations	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing
Phase III MANDARA	Eosinophilic granulomatosis with polyangiitis	Fasenra 30mg or mepolizumab 3x100mg Q4W	Proportion of patients who achieve remission, defined as a score <sup>61</sup> =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 <sup>62</sup>	Placebo or Fasenra 30mg Q4W SC	Time to HES worsening flare or any cytotoxic and/or immuno- suppressive therapy increase or hospitalisation	FPCD Q4 2019 Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)

<sup>&</sup>lt;sup>61</sup> Birmingham Vasculitis Activity Score.

<sup>&</sup>lt;sup>62</sup> Hypereosinophilic syndrome.

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Trial	Population	Design	Primary endpoint(s)	Timeline	Status
Phase III MESSINA	Eosinophilic oesophagitis	Placebo or Fasenra 30mg Q4W SC	Proportion of patients with a histologic response  Changes from baseline in dysphagia PRO <sup>63</sup>	Data anticipated 2021+	Recruitment ongoing Orphan Drug Designation (US)
Phase III FJORD	ВР	Placebo or Fasenra 30mg Q4W SC	Proportion of patients with partial or complete remission of BP whilst off OCS for ≥2 months at Week 36	Data anticipated 2021+	Initiating

For more details on the development pipeline, including anticipated timelines for regulatory submission/acceptances, please refer to the latest <u>Clinical Trials Appendix</u> available on <u>astrazeneca.com</u>.

<sup>&</sup>lt;sup>63</sup> Patient-reported outcomes.

Table 29: Condensed consolidated statement of comprehensive income - Q1 2020

For the assertion and to LOA Mount	2020	2019
For the quarter ended 31 March	\$m	\$m
Total Revenue	6,354	5,491
Product Sales	6,311	5,465
Collaboration Revenue	43	26
Cost of Sales	(1,420)	(1,129)
Gross Profit	4,934	4,362
Distribution costs	(87)	(78)
Research and development expense	(1,388)	(1,266)
Selling, general and administrative costs	(2,719)	(2,514)
Other operating income and expense	480	593
Operating Profit	1,220	1,097
Finance income	51	55
Finance expense	(332)	(367)
Share of after-tax losses in associates and joint ventures	(4)	(27)
Profit Before Tax	935	758
Taxation	(185)	(195)
Profit for the period	750	563
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	440	10
Net gains on equity investments measured at fair value through other comprehensive income	171	120
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	21	(1)
Tax on items that will not be reclassified to profit or loss	(66)	(43)
	566	86
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(608)	53
Foreign exchange arising on designating borrowings in net investment hedges	(380)	(180)
Fair value movements on cash flow hedges	(187)	(54)
Fair value movements on cash flow hedges transferred to profit or loss	45	47
Fair value movements on derivatives designated in net investment hedges	60	3
Costs of hedging	(5)	(6)
Tax on items that may be reclassified subsequently to profit or loss	73	23
	(1,002)	(114)
Other comprehensive loss for the period, net of tax	(436)	(28)
Total comprehensive income for the period	314	535
Profit attributable to:		
Owners of the Parent	780	593
Non-controlling interests	(30)	(30)
Total comprehensive income ettributable to	750	563
Total comprehensive income attributable to:  Owners of the Parent	245	EGE
	345	565
Non-controlling interests	(31) 314	(30) 535
Basic earnings per \$0.25 Ordinary Share	\$0.59	\$0.47
Diluted earnings per \$0.25 Ordinary Share	\$0.59	\$0.47
Weighted average number of Ordinary Shares in issue (millions)	1,312	1,267
Diluted weighted average number of Ordinary Shares in issue (millions)	1,312	1,267
Diluted weighted average number of Ordinary Shales in Issue (millions)	1,313	1,200



Table 30: Condensed consolidated statement of financial position

	At 31 Mar 2020	At 31 Dec 2019	At 31 Mar 2019
Accete	\$m	\$m	\$m
Assets			
Non-current assets	7 2 4 7	7.000	7 446
Property, plant and equipment	7,347	7,688	7,446
Right-of-use assets	644	647	707
Goodwill	11,569	11,668	11,674
Intangible assets	19,718	20,833	22,852
Investments in associates and joint ventures	44	58	76
Other investments	1,476	1,401	1,530
Derivative financial instruments	104	61	94
Other receivables	527	740	496
Deferred tax assets	2,960	2,718	2,531
Ourse set a south	44,389	45,814	47,406
Current assets	0.400	0.400	0.050
Inventories	3,123	3,193	3,050
Trade and other receivables	5,080	5,761	5,289
Other investments	752	849	822
Derivative financial instruments	61	36	234
Income tax receivable	262	285	118
Cash and cash equivalents	3,413	5,369	4,136
Assets held for sale	131	70	-
	12,822	15,563	13,649
Total assets	57,211	61,377	61,055
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(2,289)	(1,822)	(3,544)
Lease liabilities	(181)	(188)	(175)
Trade and other payables	(12,633)	(13,987)	(13,102)
Derivative financial instruments	(31)	(36)	(28)
Provisions	(649)	(723)	(397)
Income tax payable	(1,260)	(1,361)	(1,010)
	(17,043)	(18,117)	(18,256)
Non-current liabilities			
Interest-bearing loans and borrowings	(15,634)	(15,730)	(17,320)
Lease liabilities	(472)	(487)	(539)
Derivative financial instruments	(188)	(18)	(5)
Deferred tax liabilities	(2,501)	(2,490)	(3,267)
Retirement benefit obligations	(2,129)	(2,807)	(2,385)
Provisions	(807)	(841)	(379)
Other payables	(6,221)	(6,291)	(6,875)
	(27,952)	(28,664)	(30,770)
Total liabilities	(44,995)	(46,781)	(49,026)
Net assets	12,216	14,596	12,029
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	328	328	317
Share premium account	7,946	7,941	4,438
Other reserves	2,056	2,046	2,046
Retained earnings	448	2,812	3,682
	10,778	13,127	10,483
Non-controlling interests	1,438	1,469	1,546
Total equity	12,216	14,596	12,029



Table 31: 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	-	-	-	593	593	(30)	563
Other comprehensive loss	-	-	-	(28)	(28)	-	(28)
Transfer to other reserves	-	-	5	(5)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,403)	(2,403)	-	(2,403)
Issue of Ordinary Shares	-	11	-	-	11	-	11
Share-based payments charge for the period	-	-	-	53	53	-	53
Settlement of share plan awards	-	-	-	(265)	(265)	-	(265)
Net movement	-	11	5	(2,001)	(1,985)	(30)	(2,015)
At 31 Mar 2019	317	4,438	2,046	3,682	10,483	1,546	12,029
At 1 Jan 2020	328	7,941	2,046	2,812	13,127	1,469	14,596
Profit for the period	-	-	-	780	780	(30)	750
Other comprehensive loss	-	-	-	(435)	(435)	(1)	(436)
Transfer to other reserves Transactions with owners:	-	-	10	(10)	-	-	-
Dividends	-	-	-	(2,489)	(2,489)	-	(2,489)
Issue of Ordinary Shares	-	5	-	-	5	-	5
Share-based payments charge for the period	-	-	-	53	53	-	53
Settlement of share plan awards	-	-	-	(263)	(263)	-	(263)
Net movement	-	5	10	(2,364)	(2,349)	(31)	(2,380)
At 31 Mar 2020	328	7,946	2,056	448	10,778	1,438	12,216



Table 32: Condensed consolidated statement of cash flows

For the quarter ended 31 March	2020	2019
·	\$m	\$m
Cash flows from operating activities		
Profit Before Tax	935	758
Finance income and expense	281	312
Share of after-tax losses of associates and joint ventures	4	27
Depreciation, amortisation and impairment	841	676
Increase in working capital and short-term provisions	(445)	(710)
Gains on disposal of intangible assets	(358)	(512)
Fair value movements on contingent consideration arising from business combinations	(33)	8
Non-cash and other movements	(429)	(404)
Cash generated from operations	796	155
Interest paid	(180)	(208)
Tax paid	(477)	(334)
Net cash inflow/(outflow) from operating activities	139	(387)
Cash flows from investing activities		
Payment of contingent consideration from business combinations	(167)	(219)
Purchase of property, plant and equipment	(186)	(174)
Disposal of property, plant and equipment	-	28
Purchase of intangible assets	(190)	(586)
Disposal of intangible assets	365	1,071
Movement in profit-participation liability	-	150
Purchase of non-current asset investments	(115)	(3)
Disposal of non-current asset investments	184	17
Movement in short-term investments, fixed deposits and other investing instruments	98	20
Payments to associates and joint ventures	(8)	(12)
Interest received	28	36
Net cash inflow from investing activities	9	328
Net cash inflow/(outflow) before financing activities	148	(59)
Cash flows from financing activities		
Proceeds from issue of share capital	6	11
Issue of loans	-	500
Dividends paid	(2,398)	(2,432)
Hedge contracts relating to dividend payments	(93)	26
Repayment of obligations under leases	(53)	(42)
Movement in short-term borrowings	176	1,239
Net cash outflow from financing activities	(2,362)	(698)
Net decrease in cash and cash equivalents in the period	(2,214)	(757)
Cash and cash equivalents at the beginning of the period	5,223	4,671
Exchange rate effects	(32)	12
Cash and cash equivalents at the end of the period Cash and cash equivalents consist of:	2,977	3,926
Cash and cash equivalents	3,413	4,136
Overdrafts	(436)	(210)
	2,977	3,926



#### **Notes to the Interim Financial Statements**

## 1) Basis of preparation and accounting policies

These unaudited Interim Financial Statements for the three months ended 31 March 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 has yet to announce its post-Brexit IFRS-adoption authority and, for the current time, will follow the EU approval process.

The unaudited Interim Financial Statements for the three months ended 31 March 2020 were approved by the Board of Directors for release on 29 April 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 (IBOR) 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 will be assessed this year.

## COVID-19

AstraZeneca has assessed the impact of the uncertainty presented by the COVID-19 pandemic on the Interim Financial Statements comprising the financial results to 31 March 2020 and the financial position as at 31 March 2020, specifically considering the impact on key judgements and significant estimates as detailed on page 173 of the <a href="Annual Report and 20-F Information 2019">Annual Report and 20-F Information 2019</a> 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



Given the significant volatility experienced in the financial markets, the assumptions used to estimate the Group's material defined-benefit pension obligations were updated and resulted in a \$678m reduction in the Group's overall defined-benefit pension deficit. This reduction primarily reflected declines in liability valuations from lower-inflation expectations and higher discount rates (due to rising long term AA corporate bond yields) and more than offset declines in asset values, which held up relatively well in difficult market conditions. In the UK, £79m of deficit-recovery contributions were also paid. 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 three-month period ending 31 March 2020.

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

## Going concern

The Group has considerable financial resources available. As at 31 March 2020, the Group had \$8.3bn in financial resources (cash and cash-equivalent balances of \$3.4bn, \$0.8bn of liquid fixed income securities and undrawn committed bank facilities of \$4.1bn, of which \$3.4bn is available until April 2022, \$0.5bn is available until November 2020 (extendable to November 2021) and \$0.2bn is available until December 2020, with only \$2.5bn of borrowings due within one year). The Group's revenues are largely derived from sales of medicines which are covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although government price interventions in response to budgetary constraints are expected to continue to adversely affect revenues in many of the mature markets. The Group, however, anticipates new revenue streams from both recently launched medicines 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 a range 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 <u>Annual Report and Form 20-F Information 2019</u>.

## 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 will be 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-generatingunit level have been conducted. This has resulted in a total impairment charge of \$117m being recorded during the three months ended 31 March 2020, of which \$102m is in relation to *Bydureon* (revised carrying amount of \$627m). 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 5% over the forecast period, it would result in a further impairment charge of c.\$50m.



## 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 33: Net Debt

	At 1 Jan 2020	Cash flow	Non- cash & other	Exchange movements	At 31 Mar 2020
	\$m	\$m	\$m	\$m	\$m
Non-current instalments of loans	(15,730)	-	7	89	(15,634)
Non-current instalments of leases	(487)	-	-	15	(472)
Total long-term debt	(16,217)	-	7	104	(16,106)
Current instalments of loans	(1,597)	-	(1)	-	(1,598)
Current instalments of leases	(188)	58	(56)	5	(181)
Commercial paper	-	(85)	-	-	(85)
Bank collateral	(71)	(93)	-	-	(164)
Other short-term borrowings excluding overdrafts	(8)	2	-	-	(6)
Overdraft	(146)	(297)	-	7	(436)
Total current debt	(2,010)	(415)	(57)	12	(2,470)
Gross borrowings	(18,227)	(415)	(50)	116	(18,576)
Net derivative financial instruments	43	93	(190)	-	(54)
Net borrowings	(18,184)	(322)	(240)	116	(18,630)
Cash and cash equivalents	5,369	(1,917)	-	(39)	3,413
Other investments - current	849	(98)	6	(5)	752
Other investments - non-current	62	-	(10)	-	52
Cash and investments	6,280	(2,015)	(4)	(44)	4,217
Net Debt	(11,904)	(2,337)	(244)	72	(14,413)

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

Other investments - non-current are included within the balance of \$1,476m (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 \$2,182m (31 December 2019: \$2,146m) shown in non-current other payables.



## 4) Financial instruments

As detailed in the Group's most recent annual financial statements, the principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, leases and interest-bearing loans and borrowings. There have been no changes of significance to the categorisation or fair-value hierarchy classification of our financial instruments from those detailed in the Notes to the Group Financial Statements in the <u>Annual Report and Form 20-F Information 2019</u>.

The Group holds certain equity investments that are categorised as Level 3 in the fair-value hierarchy and for which fair-value gains of \$6m have been recognised in the quarter ended 31 March 2020. These are presented in Net gains on equity investments measured at fair value through other comprehensive income in the Condensed consolidated statement of comprehensive income.

Financial instruments measured at fair value include \$2,228m of other investments, \$2,035m held in money market funds, \$327m of loans designated at fair value through profit or loss, \$332m of loans designated in a fair value hedge relationship and (\$54m) of derivatives as at 31 March 2020. The total fair value of interest-bearing loans and borrowings at 31 March 2020, which have a carrying value of \$18,576m in the Condensed consolidated statement of financial position, was \$20,929m. 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 34: Financial instruments** 

		2019		
	Diabetes alliance	Other	Total	Total
	\$m	\$m	\$m	\$m
At 1 January	3,300	839	4,139	5,106
Settlements	(124)	(43)	(167)	(219)
Revaluations	(22)	(11)	(33)	8
Discount unwind	57	16	73	90
At 31 March	3,211	801	4,012	4,985

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 \$3,211m (31 December 2019: \$3,300m) would increase/decline by \$321m with an increase/decline in sales of 10%, as compared with the current estimates.

Included within the BMS contingent consideration liability includes estimates of royalties payable in relation to *Bydureon*. The revised Total Revenue projections for *Bydureon* have also resulted in a \$22m reduction in the contingent consideration balance as at 31 March 2020. A further 5% reduction in *Bydureon* Total Revenue would result in an additional \$11m 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 <u>Annual Report and Form 20-F Information 2019</u> (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.



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

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

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



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

## **Patent litigation**

## a) Tagrisso

US patent proceedings

As 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. No trial date has been set.

#### b) 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.

### c) 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

## a) 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.



## b) 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.

## 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.

## 6) Subsequent events

In April 2020, AstraZeneca completed an agreement to sublicense its global rights to *Movantik*, excluding Europe, Canada and Israel, to RedHill Biopharma (RedHill) for \$67.5m. A related intangible was classified as a current asset held for sale at 31 March 2020.

In April 2020, AstraZeneca and Circassia agreed to terminate the development and commercialisation agreement relating to *Tudorza* and *Duaklir* in the US. The agreement is expected to close in Q2 2020. Upon completion, the rights to the assets will revert to AstraZeneca in consideration for the release of amounts outstanding under a loan agreement that arose from transactions relating to the agreement. The loan was previously classified as a non-current asset and has been reclassified as a current asset at 31 March 2020.

In April 2020, the Company signed and closed an agreement with Taiyo Pharma Co. Ltd to divest the rights to *Inderal, Tenormin*, Seloken and Omepral in Japan for ¥5,900m.



# 7) Product Sales year-on-year analysis<sup>64</sup>

Table 35: Product Sales year-on-year analysis - Q1 2020

		World		Er	merging Marke	ts		US	Europe			Established RoW		
		% cha	inge		% cha	inge		% change % change				% change		
	\$m	Actual	CER	\$m	Actual	CER	\$m	Actual	\$m	Actual	CER	\$m	Actual	CER
Oncology														
Tagrisso	982	56	58	280	n/m	n/m	371	43	162	62	66	169	27	26
Imfinzi	462	57	57	33	n/m	n/m	286	24	75	n/m	n/m	68	94	93
Lynparza	397	67	69	56	n/m	n/m	197	66	102	57	61	42	57	56
Calquence	88	n/m	n/m	1	n/m	n/m	86	n/m	-	-	-	1	n/m	n/m
Zoladex*	225	16	19	149	30	35	2	24	35	1	3	39	(10)	(9)
Faslodex*	166	(35)	(34)	48	7	10	23	(83)	64	19	22	31	7	5
Iressa*	77	(42)	(41)	62	(28)	(26)	4	(2)	5	(79)	(78)	6	(69)	(69)
Arimidex*	50	(1)	1	41	16	20	-	-	1	(85)	(85)	8	(14)	(15)
Casodex*	42	(12)	(10)	33	8	11	-	-	1	(84)	(84)	8	(37)	(37)
Others	13	(37)	(36)	8	(11)	(9)	1	-	1	19	23	3	(60)	(61)
Total Oncology	2,502	32	34	711	45	49	970	26	446	42	46	375	18	17
BioPharmaceuticals: CVRM														
Farxiga	405	16	19	141	49	55	113	(14)	116	30	34	35	2	3
Brilinta	408	17	19	134	38	42	165	8	93	12	15	16	8	10
Bydureon	100	(30)	(29)	1	(41)	(39)	84	(28)	12	(34)	(32)	3	(46)	(44)
Onglyza	141	(8)	(6)	47	10	13	67	(14)	15	(19)	(17)	12	(10)	(10)
Byetta	20	(32)	(31)	3	n/m	n/m	11	(42)	4	(37)	(35)	2	(17)	(13)
Other diabetes	13	16	18	2	n/m	n/m	7	(9)	3	50	56	1	-	-
Lokelma	11	n/m	n/m	-	-	-	10	n/m	1	n/m	n/m	-	-	
Roxadustat	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Crestor*	301	(10)	(9)	192	(15)	(13)	28	9	34	(12)	(10)	47	4	4
Seloken/Toprol-XL*	177	(21)	(18)	166	(14)	(11)	4	(82)	4	(29)	(29)	3	(2)	2
Atacand*	66	33	36	49	25	29	3	33	8	n/m	n/m	6	32	36
Others	59	(18)	(17)	37	(28)	(27)	-	-	19	7	9	3	22	22
BioPharmaceuticals: total CVRM	1,701	(1)	1	772	3	6	492	(12)	309	9	12	128	2	3
BioPharmaceuticals: Respiratory & Immunology	1,701	(',	•				702	(12)	555			120		
Symbicort	790	35	36	156	17	20	310	76	195	7	10	129	37	37
Pulmicort	380	(1)	-	313		1	23	(3)	26	3	6	18	(8)	(8)
Fasenra	199	54	55	6	-		120	29	46	n/m	n/m	27	53	53
Daliresp/Daxas	53	11	12	1	(8)	(4)	45	10	7	17	21	-	-	-
Bevespi	12	22	22	-	-	- (4)	12	15	-	- 17	-	-	-	-
Breztri	4	n/m	n/m	4			- 12	-	-	-	-	-	-	-
Others	113				n/m	n/m	2	38	46			6		
		(11) <b>21</b>	(10) <b>22</b>	59	(14) <b>4</b>	(12) <b>6</b>		36 48	320	(15)	(13) <b>15</b>	180	n/m	n/m
BioPharmaceuticals: total Respiratory & Immunology	1,551	21	22	539	4	6	512	48	320	12	15	180	34	34
Other medicines	000	( <del>-</del> )	(0)	407	(0)		40	(00)	00	20		00	(0)	(0)
Nexium	338	(7)	(6)	187	(2)	1 (	40	(39)	22	36	41	89	(3)	(3)
Synagis	85	61	61	5	n/m	n/m	7	(72)	73	n/m	n/m	-	-	- (40)
Losed/Prilosec	54	(30)	(28)	44	(14)	(12)	2	96	5	(74)	(74)	3	(47)	(48)
Seroquel XR/IR	36	(4)	(3)	12	(17)	(15)	13	n/m	8	(67)	(67)	3	(47)	(48)
Others	44	(8)	(7)	1	n/m	n/m	25	(9)	15	6	9	3	(82)	(82)
Total other medicines	557	(4)	(3)	249	-	2	87	(23)	123	23	25	98	(15)	(16)
Total Product Sales	6,311	15	17	2,271	13	16	2,061	15	1,198	22	25	781	13	12

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<sup>&</sup>lt;sup>64</sup> 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) Product Sales quarterly sequential analysis<sup>65</sup>

Table 36: Product Sales quarterly sequential analysis - Q1 2020

	Q1 2020			
	_	% ch	ange	
	\$m	Actual	CER	
Oncology				
Tagrisso	982	11	11	
Imfinzi	462	9	9	
Lynparza	397	13	13	
Calquence	88	58	58	
Zoladex*	225	15	15	
Faslodex*	166	-	-	
Iressa*	77	(3)	(4)	
Arimidex*	50	(1)	(2)	
Casodex*	42	(2)	(3)	
Others	13	(52)	(52)	
Total Oncology	2,502	10	10	
BioPharmaceuticals: CVRM				
Farxiga	405	(3)	(3)	
Brilinta	408	(5)	(5)	
Bydureon	100	(28)	(28)	
Onglyza	141	8	8	
Byetta	20	(24)	(24)	
Other diabetes	13	(22)	(22)	
Lokelma	11	42	42	
Roxadustat	-	-	-	
Crestor*	301	2	1	
Seloken/Toprol-XL*	177	(6)	(6)	
Atacand*	66	11	12	
Others	59	(21)	(22)	
BioPharmaceuticals: total CVRM	1,701	(5)	(5)	
BioPharmaceuticals: Respiratory & Immunology				
Symbicort	790	11	11	
Pulmicort	380	(8)	(9)	
Fasenra	199	(3)	(3)	
Daliresp/Daxas	53	(8)	(8)	
Bevespi	12	9	9	
Breztri	4	n/m	n/m	
Others	113	(16)	(17)	
BioPharmaceuticals: total Respiratory & Immunology	1,551	1	1	
Other medicines				
Nexium	338	(4)	(4)	
Synagis	85	35	35	
Losec/Prilosec	54	18	17	
Seroquel XR/IR	36	(12)	(12)	
Others	44	(71)	(70)	
Total other medicines	557	(15)	(15)	
Total Product Sales	6,311	1	1	

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<sup>&</sup>lt;sup>65</sup> The table below provides an analysis of sequential quarterly Product Sales, with actual and CER growth rates reflecting quarter-on-quarter growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals. \*Denotes a legacy medicine.



# 9) Product Sales quarterly sequential analysis - FY 2019<sup>66</sup>

Table 37: Product Sales quarterly sequential analysis - FY 2019

	Q1 2019			Q2 2019				Q3 2019		Q4 2019		
	\$m	% ch	ange	\$m	% ch	ange	\$m	% ch	ange	\$m	% ch	ange
	ֆm	Actual	CER	ֆm	Actual	CER	ֆm	Actual	CER	φm	Actual	CEF
Oncology												
Tagrisso	630	6	6	784	24	25	891	14	13	884	(1)	-
Imfinzi	295	13	13	338	15	15	412	22	22	424	3	4
Lynparza	237	13	13	283	19	20	327	16	15	351	7	8
Calquence	29	21	23	35	21	19	44	27	27	56	25	25
Faslodex*	254	(6)	(6)	267	5	6	205	(23)	(23)	166	(20)	(19
Zoladex*	194	7	6	197	2	1	226	15	16	196	(14)	(12
Iressa*	134	20	18	118	(12)	(11)	91	(23)	(22)	80	(13)	(12
Arimidex*	51	11	10	60	18	17	63	5	5	51	(20)	(18)
Casodex*	48	4	3	57	19	18	52	(8)	(6)	43	(18)	(17
Others	20	(13)	(14)	28	40	29	20	(27)	(22)	26	30	26
Total Oncology	1,892	7	`6´	2,167	15	15	2,334	`8	`8	2,274	(3)	(2)
BioPharmaceuticals: CVRM											` ,	,
Farxiga	349	(12)	(12)	377	8	9	398	5	5	419	5	6
Brilinta	348	(7)	(8)	389	12	12	416	7	8	428	3	3
Bydureon	142	3	3	141	(1)	-	127	(10)	(10)	139	9	10
Onglyza	153	3	3	116	(24)	(24)	127	`9 <sup>′</sup>	`11 <sup>′</sup>	131	3	4
Byetta	30	(6)	(5)	25	(17)	(16)	28	10	13	27	(2)	(4)
Other diabetes	11	(8)	(17)	11	-	8	14	26	22	16	17	17
Lokelma	-	n/m	n/m	2	n/m	n/m	4	n/m	n/m	8	87	74
Roxadustat	-	-	-	-	-	-	-	-	-	-	-	-
Crestor*	335	(5)	(6)	310	(7)	(7)	337	9	9	296	(12)	(11)
Seloken/Toprol-XL*	225	41	38	168	(25)	(25)	177	6	8	190	7	`8
Atacand*	50	(14)	(15)	56	12	14	55	(1)	(1)	60	8	9
Others	71	(3)	(5)	63	(11)	(8)	65	4	2	72	13	16
BioPharmaceuticals: total CVRM	1,714	(2)	(3)	1,658	(3)	(3)	1,749	5	6	1,785	2	3
BioPharmaceuticals: Respiratory & Immunology		, ,	` ,		. ,	` '						
Symbicort	585	(8)	(8)	585	-	1	613	5	4	712	16	17
Pulmicort	383	(2)	(2)	333	(13)	(13)	337	1	3	413	22	23
Fasenra	129	3	4	167	29	30	202	21	21	206	2	2
Daliresp/Daxas	48	(11)	(12)	56	17	18	53	(6)	(7)	58	10	10
Bevespi	10	-	(5)	10	-	2	10	4	8	12	8	5
Breztri	-	-	-	-	-	-	1	-	-	1	(74)	(73)
Others	128	(14)	(12)	101	(21)	(23)	102	1	(1)	135	33	38
BioPharmaceuticals: total Respiratory & Immunology	1,283	(6)	(6)	1,252	(2)	(2)	1,319	5	6	1,537	17	17
Other medicines	, i		` '	,	. ,	` '	,			,		
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

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<sup>&</sup>lt;sup>66</sup> The table below provides an analysis of sequential quarterly Product Sales, with actual and CER growth rates reflecting quarter-on-quarter growth. Due to rounding, the sum of a number of dollar values and percentages may not agree to totals. \*Denotes a legacy medicine.



**Table 38: Historic Collaboration Revenue** 

		Q1 2020	Q1 2019	FY 2019	FY 2018	
		\$m	\$m	\$m	\$m	
Initial Collaboration Revenue	Crestor (Spain)	-	-	-	61	
Ongoing Collaboration Revenue	Lynparza: regulatory milestones	-	-	60	140	
	Lynparza: sales milestones	-	-	450	250	
	Lynparza/selumetinib: option payments	-	-	100	400	
	Crestor (Spain)	-	-	39		
	Enhertu: profit share	14	-	-	-	
	Roxadustat: profit share	3	-	-	-	
	Royalty income	17	16	62	49	
	Other Collaboration Revenue	9	10	108	141	
	Total	43	26	819	1,041	



# **Table 39: Other Operating Income and Expense**

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

Divestment/other	Q1 2020	Q1 2019	FY 2019	FY 2018
Divestmendomer	\$m	\$m	\$m	\$m
Hypertension medicines (ex-US, India and Japan)	350	-	-	-
Synagis (US)	-	515	515	-
Losec (ex-China, Japan, US and Mexico)	-	-	243	-
Seroquel and Seroquel XR (US, Canada, Europe and Russia)	-	-	213	-
Arimidex and Casodex (various countries)	-	-	181	-
Nexium (Europe) and Vimovo (ex-US)	-	-	-	728
Seroquel	-	-	-	527
Legal settlement <sup>67</sup>	-	-	-	346
Atacand	-	-	-	210
Anaesthetics	-	-	-	172
Alvesco, Omnaris and Zetonna	-	-	-	139
Other	130	78	389	405
Total	480	593	1,541	2,527

<sup>67</sup> Not recorded within Core Other Operating Income and Expense.



#### **Shareholder information**

Announcement of first half and second quarter results

30 July 2020

Announcement of year to date and third quarter results

5 November 2020

Future dividends will normally be paid as follows:

First interim: announced with half-year and second-guarter 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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Information on or accessible through AstraZeneca's websites, including <u>astrazeneca.com</u>, does not form part of and is not incorporated into this announcement.

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# Cautionary statements regarding forward-looking statements

In order, among other things, to utilise the 'safe harbour' provisions of the US Private Securities Litigation Reform Act 1995, 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 AstraZeneca undertakes no obligation to update these forward-looking statements. We identify the forward-looking statements by using the words 'anticipates', 'believes', 'expects', 'intends' and similar expressions in such statements. Important factors that could cause actual results to differ materially from those contained in forward-looking statements, certain of which are beyond our control, include, among other things:

- the 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 our products
- 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
- 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.