AstraZeneca PLC
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First quarter 2022 results

Strong start to the year. Continued investment in the pipeline to drive sustainable long-term growth.

Revenue and EPS summary

	Q1 2022		
		% Change	
	$m	Actual	CER[1]
- Product Sales	10,980	51	56
- Collaboration Revenue	410	n/m [2]	n/m
Total Revenue	11,390	56	60
Reported[3] EPS[4]	$0.25	(79)	(73)
Core[5] EPS [6]	$1.89	16	20

Financial performance (growth numbers at CER)

- Total Revenue increased 60% to $11,390m, reflecting growth across the Company, the contribution of the Alexion medicines and several *Vaxzevria* contracts that are expected to complete delivery by half year 2022
- Total Revenue from Oncology increased 25%[7], including a milestone payment; Product Sales from Oncology increased 18%. Total Revenue from CVRM[8] increased 18%, R&I[9] increased 4% and Rare Disease increased 7%[10]
- Operating Margin in the quarter benefitted from phasing of costs
- Core EPS increased 20% to $1.89
- FY 2022 guidance at CER reiterated

Key milestones achieved since the prior results

- Key data: *Enhertu*[11] in HER2[12]-low breast cancer (DESTINY-Breast04), AZD8233 in hypercholesterolaemia (ETESIAN, Phase IIb) and publication of data for *Lynparza* in prostate cancer (PROpel) and nirsevimab in RSV[13] (MELODY/MEDLEY)
- Key approvals: *Saphnelo* and *Evusheld* in the EU, *Ondexxya* in Japan, and in the US, approvals of *Ultomiris* for gMG[14] and *Lynparza*[15] for early breast cancer (OlympiA)
- Other key milestones: US FDA[16] Breakthrough Therapy Designation for *Enhertu* in HER2-low breast cancer (DESTINY-Breast04), Priority Reviews for *Enhertu* in HER2-mutant metastatic non-small cell lung cancer (DESTINY-Lung01), and *Imfinzi* and tremelimumab in advanced liver cancer (HIMALAYA), and EMA[17] accelerated assessment for nirsevimab in RSV (MELODY/MEDLEY)

Pascal Soriot, Chief Executive Officer, AstraZeneca, said:

"2022 has started strongly for AstraZeneca. *Farxiga* achieved $1bn revenue in the quarter and our Oncology medicines delivered Product Sales growth of 18%, despite COVID-19 continuing to impact cancer diagnosis and treatment. High-level results from the DESTINY-Breast04 trial pointed to *Enhertu*'s potential to redefine treatment of HER2-low metastatic breast cancer, and *Ultomiris* became the first and only long-acting C5 inhibitor approved for generalised myasthenia gravis in the US.

Today we have unveiled plans for a new strategic research and development centre in the heart of Cambridge, Massachusetts' scientific hub. In line with our sustainability commitments, it will be designed to the highest environmental standards. Our investments in pioneering science give us confidence of further advances in the years to come."

Guidance

The Company reiterates FY 2022 guidance at CER.

Total Revenue is expected to increase by a high teens percentage

Core EPS is expected to increase by a mid-to-high twenties percentage

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- The CER growth rates include the full-year contribution of *Vaxzevria* in both FY 2021 and FY 2022
- Total Revenue from COVID-19 medicines is anticipated to decline by a low-to-mid twenties percentage, with an expected decline in sales of *Vaxzevria* being partially offset by growth in *Evusheld* sales. The majority of *Vaxzevria* revenue in 2022 is expected to come from initial contracts. The Gross Margin from the COVID-19 medicines is expected to be lower than the Company average
- Core Operating Expenses are expected to increase by a low-to-mid teens percentage, driven in substantial part by the full year integration of Alexion expenses
- Emerging Markets Total Revenue, including China, is expected to grow mid-single-digits in FY 2022. China Total Revenue is expected to decline by a mid-single-digit percentage in FY 2022, primarily due to continued NRDL and VBP programme impacting various medicines. The Company remains confident in the longer term outlook for Emerging Markets, driven by a large market opportunity, broader patient access and an increased mix of new medicines
- A Core Tax Rate between 18-22%

AstraZeneca continues to recognise and actively manage the heightened risks from COVID-19 and geopolitical and supply chain uncertainties on overall business performance. Variations in performance between quarters can be expected to continue.

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

Currency impact

If foreign-exchange rates for April to December 2022 were to remain at the average of rates seen in Q1 2022, it is anticipated that there would be a low single-digit adverse impact on Total Revenue and a mid single-digit adverse impact on Core EPS versus the financials at CER. The Company's foreign-exchange rate sensitivity analysis is contained in Table 15.

Table 1: Key elements of Total Revenue performance

		% Change		
Revenue type	**$m**	**Actual**	**CER**	
Product Sales	10,980	51	56	• $1,688m from medicines acquired with Alexion
Collaboration Revenue	410	n/m	n/m	• $76m for *Enhertu* (Q1 2021: $39m), and milestone payments of $175m for *Lynparza* and $70m for tralokinumab (Q1 2021: $nil)
Total Revenue	11,390	56	60	
Disease areas	**$m**	**Actual**	**CER**	
Oncology	3,644	21	25	• Product Sales up 14% (18% CER). Strong performance despite a continuing COVID-19 impact on cancer diagnoses and treatment rates
CVRM	2,219	14	18	• *Farxiga* grew 60% (67% at CER) to $1,001m
R&I	1,584	2	4	• *Pulmicort* declined 34% primarily due to inclusion in China's VBP[18] programme, implemented in October 2021
V&I[19]	1,814	[20] >6x	>6x	• $1,145m from *Vaxzevria*[21] and $469m from *Evusheld* • Majority of *Vaxzevria* revenue from initial contracts, several of which completed during the quarter. In-line with guidance, *Vaxzevria* revenue is expected to decline in later quarters
Rare Disease	1,694	3	7	• Durable C5 franchise growth, including continued conversion from *Soliris* to *Ultomiris* in PNH[22] and aHUS[23], and *Soliris* growth in gMG and NMOSD[24]
Other Medicines	435	(18)	(15)	
Total Revenue	11,390	56	60	
Regions exc. *Vaxzevria*	**$m**	**Actual**	**CER**	
Emerging Markets	2,833	11	14	
- China	*1,575*	*(6)*	*(8)*	• Pricing pressure associated with the NRDL[25] and VBP programmes
- Ex-China Emerging Markets	*1,258*	*45*	*57*	• $110m from medicines acquired with Alexion
US	4,055	76	76	• $1,014m from medicines acquired with Alexion
Europe	2,150	63	73	• $366m from medicines acquired with Alexion
Established RoW	1,207	40	51	• $208m from medicines acquired with Alexion
Total Revenue exc. *Vaxzevria*	10,245	45	50	• $1,698m from medicines acquired with Alexion
Regions inc. *Vaxzevria*	**$m**	**Actual**	**CER**	
Emerging Markets	3,364	30	32	• Impacted by quarterly phasing of *Vaxzevria*
- China	*1,622*	*(3)*	*(6)*	• In line with FY 2022 guidance
- Ex-China Emerging Markets	*1,742*	*91*	*>2x*	
US	4,134	79	79	
Europe	2,284	48	57	
Established RoW	1,608	85	98	
Total Revenue	11,390	56	60	

Table 2: Key elements of financial performance

	Q1 2022				
Metric ($m or %)	**Reported**	**Reported change**	**Core**	**Core change**	**Comments[26]**
Total Revenue	11,390	56% Actual 60% CER	11,390	56% Actual 60% CER	• See Table 1
Gross Margin[27]	68%	-6pp Actual -7pp CER	79%	+5pp Actual +4pp CER	+ Contribution of Alexion + Increasing mix of Oncology sales – Increasing mix of COVID-19 therapies – China impact of NRDL and VBP – Increasing impact from profit-sharing arrangements including the *Lynparza* collaboration with MSD – Reported impacted by unwind of Alexion inventory fair value adjustment
R&D Expense	2,133	24% Actual 26% CER	2,186	33% Actual 36% CER	+ Increased investment in pipeline + Addition of Alexion R&D – Beneficial phasing of costs resulted in a Core R&D-to-Total Revenue ratio of 19% (FY 2021: 21%)
SG&A Expense	4,840	65% Actual 68% CER	2,946	23% Actual 25% CER	+ Addition of Alexion + Reported impacted by $775m legal settlement with Chugai Pharmaceutical Co. Ltd and amortisation related to Alexion acquisition – Beneficial phasing of costs resulted in a Core SG&A-to-Total Revenue ratio of 26% (FY 2021: 30%)
Other Operating Income[28]	97	(92%) Actual (92%) CER	98	(92%) Actual (92%) CER	• Limited divestments in quarter, majority of income coming from royalties and prior transactions
Operating Margin	8%	-18pp Actual -18pp CER	35%	Stable Actual and CER	• See Gross Margin and Expenses commentary above
Net Finance Expense	319	13% Actual 7% CER	252	35% Actual 23% CER	+ Alexion debt financing costs – Reported impacted by lower discount unwind on acquisition-related liabilities
Tax Rate	30%	+27pp	21%	+13pp	• In-line with full year expectation of 18-22% + The Tax Rate in the comparable period of Q1 2021 was favourably impacted by the disposal of Viela and settlements with tax authorities
EPS	$0.25	(79%) Actual (73%) CER	$1.89	16% Actual 20% CER	• Further details of differences between Reported and Core are shown in Table 10

Corporate and business development

In April 2022, AstraZeneca and Harbour BioMed (HBM) committed to a global out-license agreement for HBM7022, a pre-clinical bispecific antibody targeting Claudin18.2 and CD3. AstraZeneca will be granted an exclusive global license for research, development, registration, manufacturing, and commercialisation of HBM7022.

HBM shall receive an upfront payment of $25m with the potential for additional payments up to $325m pending achievement of certain development, regulatory and commercial milestones. HBM is also eligible to receive tiered royalties on net sales.

Sustainability summary

AstraZeneca published its eighth annual Sustainability Report and Sustainability Data summary, released in conjunction with the 2021 Annual Report. The report outlines progress on strategic priorities, material focus areas, challenges and aims for the future.

AstraZeneca continues to provide urgent humanitarian support in Ukraine and neighbouring countries. To date, AstraZeneca has committed over $7m to response efforts, including donations of:

- Medicines to the Company's humanitarian relief partner Direct Relief, which is working directly with the Ukrainian Ministry of Health
- Medicines via The Red Cross affiliates in neighbouring countries
- $2m to support relief agencies working in Ukraine, Poland and surrounding areas with a focus on providing healthcare and humanitarian assistance. Funding is being provided to Project HOPE, working with and through the World Health Organization, and International Medical Corps
- More than $1m to UNICEF and The Red Cross

Reporting changes for Q1 2022

AstraZeneca's Total Revenue and Product Sales tables in FY 2022 include a new disease area: BioPharmaceuticals: Vaccines & Immune Therapies (V&I). This incorporates revenues from *Vaxzevria*, *Evusheld*, *FluMist*, *Synagis* and nirsevimab. In the FY 2021 quarterly and annual reports, *Vaxzevria* and *Evusheld* revenues were shown under COVID-19, and *FluMist*, *Synagis* and nirsevimab revenues were shown under Other Medicines. In addition, revenue from *Koselugo* have moved from Oncology to Rare Disease, and revenue from *Andexxa* has moved from Rare Disease to BioPharmaceuticals: CVRM.

The growth rate for each disease area has been calculated as though these changes had been implemented in FY 2021.

Conference call

A conference call and webcast for investors and analysts will begin today (29 April 2022) at 11:45 BST. Details can be accessed via astrazeneca.com.

Reporting calendar

The Company intends to publish its half-year and second-quarter results on Friday 29 July 2022.

Notes

The following notes refer to pages one to five.

1. Constant exchange rates. The differences between Actual Change and CER Change are due to foreign exchange movements between periods in 2022 vs 2021. CER financial measures are not accounted for according to generally accepted accounting principles (GAAP) because they remove the effects of currency movements from Reported results.
2. Not meaningful
3. Reported financial measures are the financial results presented in accordance with UK-adopted International Accounting Standards and International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB) and International Accounting Standards as adopted by the European Union.
4. Earnings per share.
5. Core financial measures. These are non-GAAP financial measures because, unlike Reported performance, they cannot be derived directly from the information in the Group's Financial Statements. See the Operating and financial review for a definition of Core financial measures and a reconciliation of Core to Reported financial measures.
6. The differences between Reported and Core measures are primarily due to items related to the acquisition of Alexion, amortisation of intangibles, impairments, restructuring charges, and, as previously disclosed, a charge to provisions relating to a legal settlement with Chugai Pharmaceutical Co. Ltd that will lead to a payment of $775m in the Q2 2022. A full reconciliation between Reported EPS and Core EPS is provided in Table 10 in the Financial performance section of this document.
7. In FY 2022, Total Revenue from *Koselugo* is included in Rare Disease (FY 2021: Oncology), and Total Revenue from *Andexxa* is included in BioPharmaceuticals: CVRM (FY 2021: Rare Disease). The growth rate for each disease area has been calculated as though these changes had been implemented in FY 2021.
8. Cardiovascular, Renal & Metabolism.
9. Respiratory & Immunology.
10. FY 2022 Q1 growth rates on medicines acquired with Alexion have been calculated on a pro forma basis comparing to the corresponding period in the prior year, pre-acquisition as previously published by Alexion. The growth rates shown for the Rare Disease and CVRM disease areas include these pro forma adjustments.
11. AstraZeneca is collaborating with Daiichi Sankyo to develop and commercialise *Enhertu*.
12. Human epidermal growth factor receptor 2.
13. Respiratory syncytial virus.
14. Generalised myasthenia gravis.
15. AstraZeneca is collaborating with MSD (Merck & Co., Inc. in the US and Canada) to develop and commercialise *Lynparza*.
16. US Food and Drug Administration.
17. European Medicines Agency.
18. Volume based procurement.
19. Vaccines & Immune Therapies.
20. Growth rates greater than 100% are displayed as a multiple, for example '>2x' signifies that the value is more than double that of the comparable period
21. *Vaxzevria* is AstraZeneca's trademark for the Company's supply of the AstraZeneca COVID-19 Vaccine. In the financial tables in this report, '*Vaxzevria* Total Revenue' includes Collaboration Revenue from sub-licensees that produce and supply the AstraZeneca COVID-19 Vaccine under their own trademarks.
22. Paroxysmal nocturnal haemoglobinuria.
23. Atypical haemolytic uraemic syndrome.
24. Neuromyelitis optica spectrum disorder.
25. National Reimbursement Drug List.
26. The plus and minus signs in Table 2 indicate the directional impact of the item being discussed, e.g. a plus sign in R&D Expenses signifies that the comment refers to an item that increased the R&D Expense relative to the prior year.
27. 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.
28. Where AstraZeneca does not retain a significant ongoing interest in medicines or potential new medicines, income from divestments is reported within Reported and Core Other Operating Income and Expense in the Company's financial statements.

Pipeline

Table 3: Pipeline highlights since prior results announcement

Event	Medicine	Indication / Trial	Event
Regulatory approvals and other regulatory actions	*Lynparza*	gBRCA[29] breast cancer (adjuvant) (OlympiA)	Regulatory approval (US)
	Saphnelo	SLE[30]	Regulatory approval (EU)
	Ondexxya	Acute major bleed	Regulatory approval (JP)
	Evusheld	COVID-19 pre-exposure prophylaxis (PROVENT)	Regulatory approval (EU)
	Ultomiris	gMG (CHAMPION-MG)	Regulatory approval (US)
Regulatory submissions or acceptances	*Imfinzi*	Biliary tract cancer (TOPAZ-1)	Regulatory submission (JP)
	Imfinzi + tremelimumab	Advanced liver cancer (1st-line) (HIMALAYA)	Priority review (US), regulatory submission (EU, JP)
	Lynparza	Prostate cancer (1st-line) (PROpel)	Regulatory submission (JP)
	Enhertu	HER2m NSCLC[31] (2nd-line+) (DESTINY-Lung01)	Priority review (US)
	Calquence	CLL[32] (ELEVATE-TN)	Regulatory submission (JP)
	nirsevimab	RSV (MELODY/MEDLEY)	Regulatory submission and EMA accelerated assessment (EU)
	Evusheld	COVID-19 outpatient treatment (TACKLE)	Regulatory submission (US, EU)
	Ultomiris	Subcutaneous, PNH and aHUS	Regulatory submission (EU)
Major Phase III data readouts and other developments	*Imfinzi*	Cervical cancer (CALLA)	Primary endpoint not met
	Imfinzi	Biliary tract cancer (TOPAZ-1)	Orphan Drug Designation (JP)
	Enhertu	HER2+ breast cancer (2nd-line) (DESTINY-Breast03)	Breakthrough Drug Designation (CN)
	Enhertu	HER2-low breast cancer (DESTINY-Breast04)	Primary endpoint met, Breakthrough Drug Designation, RTOR[33] (US)
	Fasenra	Nasal polyps (OSTRO)	Complete response letter (US)
	Brilinta		Paediatric exclusivity (US)

[29] A breast cancer gene mutation.

[30] Systemic lupus erythematosus.

[31] Non-small cell lung cancer.

[32] Chronic lymphocytic leukaemia.

[33] Real-Time Oncology Review.

Table 4: Pipeline anticipated major news flow

Timing	Medicine	Indication / Trial	Event
H1 2022	*Imfinzi*	Biliary tract cancer (TOPAZ-1)	Regulatory submission (US, EU)
	Lynparza	Prostate cancer (1st-line) (PROpel)	Regulatory submission (US)
	Enhertu	HER2+ breast cancer (2nd-line) (DESTINY-Breast03)	Regulatory decision (US), regulatory submission (CN)
	Enhertu	HER2-low breast cancer (3rd-line) (DESTINY-Breast04)	Regulatory submission
	Forxiga	CKD[34] (DAPA-CKD)	Regulatory decision (CN)
	Farxiga	HFpEF[35] (DELIVER)	Data readout
	eplontersen	hATTR-PN[36] (NEURO-TTRansform)	Data readout[37]
	Brilinta	Stroke (THALES)	Regulatory decision (CN)
	Tezspire	Severe asthma (NAVIGATOR)	Regulatory decision (EU, JP)
	PT027	Asthma	Regulatory submission (US)
	Evusheld	COVID-19 outpatient treatment (EU)	Regulatory decision (EU)
	Vaxzevria	COVID-19	Regulatory submission (US)
	Ultomiris	NMOSD	Data readout
H2 2022	*Tagrisso*	EGFRm NSCLC (adjuvant) (ADAURA)	Regulatory decision (JP)
	Imfinzi	Biliary tract cancer (TOPAZ-1)	Regulatory decision
	Imfinzi	Liver cancer (locoregional) (EMERALD-1)	Data readout, regulatory submission
	Imfinzi	NSCLC (1st-line) (PEARL)	Data readout
	Imfinzi	NSCLC (unresectable, Stg. III) (PACIFIC-2)	Data readout
	Imfinzi	Limited-stage SCLC (ADRIATIC)	Data readout
	Imfinzi +/- tremelimumab	NSCLC (1st-line) (POSEIDON)	Regulatory decision
	Imfinzi +/- tremelimumab	Liver cancer (1L) (HIMALAYA)	Regulatory decision
	Lynparza	gBRCA breast cancer (adjuvant) (OlympiA)	Regulatory decision (EU, JP)
	Lynparza	Ovarian cancer (1st-line) (PAOLA-1)	Regulatory decision (CN)
	Lynparza	Prostate cancer (1st-line) (PROpel)	Regulatory decision
	Enhertu	HER2+ breast cancer (3rd-line) (DESTINY-Breast02)	Data readout, regulatory submission
	Enhertu	HER2+ breast cancer (2nd-line) (DESTINY-Breast03)	Regulatory decision (EU, JP)
	Enhertu	HER2+ gastric cancer (2nd-line) (DESTINY-Gastric01)	Regulatory decision (EU)
	Enhertu	HER2m NSCLC (2nd-line+) (DESTINY-Lung01)	Regulatory decision
	capivasertib	HR+/HER2-neg breast cancer (1st-line) (CAPItello-291)	Data readout
	Farxiga	HFpEF (DELIVER)	Regulatory submission
	eplontersen	hATTR-PN	Regulatory submission (US)
	Fasenra	EOE[38] (MESSINA)	Data readout

[34] Chronic kidney disease.

[35] Heart failure with preserved ejection fraction.

[36] Hereditary amyloid transthyretin polyneuropathy.

[37] Interim analysis, as disclosed by Ionis Pharmaceuticals, Inc.

[38] Eosinophilic oesophagitis.

	nirsevimab	RSV (MELODY/MEDLEY)	Regulatory submission (US) and regulatory decision
	Evusheld	COVID-19 (TACKLE/PROVENT)	Regulatory submission (JP, CN)
	Evusheld	COVID-19 outpatient treatment (TACKLE)	Regulatory decision
	Utomiris	gMG (CHAMPION-MG)	Regulatory decision (EU, JP)
	Ultomiris	Subcutaneous, PNH and aHUS	Regulatory decision
	Ultomiris	NMOSD	Regulatory submission
	Koselugo	NF1-PN (SPRINT)	Regulatory submission (CN), regulatory decision (JP)
2023	*Tagrisso*	EGFRm[39] NSCLC (1st-line) (FLAURA2)	Data readout, regulatory submission
	Tagrisso	EGFRm NSCLC (unresectable Stg. III) (LAURA)	Data readout, regulatory submission
	Imfinzi	Bladder cancer (muscle invasive) (NIAGARA)	Data readout, regulatory submission
	Imfinzi	Bladder cancer (1st-line) (NILE)	Data readout, regulatory submission
	Imfinzi	NSCLC (neoadjuvant) (AEGEAN)	Data readout, regulatory submission
	Imfinzi	Liver cancer (adjuvant) (EMERALD-2)	Data readout, regulatory submission
	Imfinzi	NSCLC (unresectable, Stg. III) (PACIFIC-2)	Regulatory submission
	Imfinzi	NSCLC (1st-line) (PEARL)	Regulatory submission
	Imfinzi	Limited-stage SCLC (ADRIATIC)	Regulatory submission
	Lynparza	gBRCA breast cancer (adjuvant) (OlympiA)	Regulatory submission (CN)
	Lynparza + *Imfinzi*	Endometrial cancer (1st-line) (DUO-E)	Data readout
	Lynparza + *Imfinzi*	Ovarian cancer (1st-line) (DUO-O)	Data readout
	Enhertu	HER2-low breast cancer (2nd-line) (DESTINY-Breast06)	Data readout
	Calquence	CLL (ELEVATE-TN)	Regulatory decision (JP)
	Calquence	CLL (ACE-CL-311)	Data readout
	Calquence	MCL[40] (1st-line) (ECHO)	Data readout
	capivasertib	TNBC[41] (locally adv./met.) (CAPItello-290)	Data readout, regulatory submission
	capivasertib	HR+/HER2-neg breast cancer (1st-line) (CAPItello-291)	Regulatory submission
	camizestrant	HR+/HER2-neg breast cancer (SERENA-6)	Data readout
	Dato-DXd	NSCLC (3rd-line) (TROPION-Lung01)	Data readout, regulatory submission
	Farxiga	Myocardial infarction (DAPA-MI)	Data readout
	roxadustat	Anaemia of myelodysplastic syndrome	Data readout
	Fasenra	Bullous pemphigoid (FJORD)	Data readout
	Fasenra	CRwNP[42] (ORCHID)	Data readout
	Fasenra	EGPA[43] (MANDARA)	Data readout
	Fasenra	EOE (MESSINA)	Regulatory submission
	Fasenra	HES (NATRON)	Data readout

[39] Epidermal growth factor receptor mutation.

[40] Mantle cell lymphoma.

[41] Triple negative breast cancer.

[42] Chronic rhinosinusitis with nasal polyps.

[43] Eosinophilic granulomatosis with polyangiitis.

Fasenra	Severe asthma (MIRACLE)	Data readout
nirsevimab	RSV (MELODY/MEDLEY)	Regulatory submission (JP, CN)
Soliris	Guillain-Barre syndrome	Data readout
ALXN1840	Wilson disease	Regulatory submission
danicopan	PNH with extravascular haemolysis	Data readout, regulatory submission

Contents

List of tables

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 2022 ('the quarter' or 'Q1 2022') compared to the three-month period to 31 March 2021 (Q1 2021), 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, 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 as well as Post Alexion Acquisition Group Review items
- Alexion acquisition-related items, primarily fair-value adjustments on acquired inventories and fair-value impact of replacement employee share awards
- Other specified items, principally 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 54 of the Annual Report and Form 20-F Information 2021.

Reference should be made to the Reconciliation of Reported to Core financial measures table included in the financial performance section in this announcement.

Gross Margin, previously termed Gross Profit Margin, is the percentage by which Product Sales exceeds the Cost of sales, calculated by dividing the difference between the two by the sales figure. 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.

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

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

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

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

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

Total Revenue

Table 5: Disease area and medicine performance

	Q1 2022			
			% Change	
Product Sales	**$m**	**% Total**	**Actual**	**CER**
Oncology	**3,388**	**30**	**14**	**18**
- *Tagrisso*	1,304	11	14	17
- *Imfinzi*	599	5	8	11
- *Lynparza*	617	5	14	17
- *Calquence*	414	4	98	100
- *Enhertu*	11	-	>9x	>9x
- *Orpathys*	13	-	n/m	n/m
- *Zoladex*	240	2	9	12
- *Faslodex*	93	1	(24)	(20)
- *Iressa*	32	-	(47)	(47)
- *Arimidex*	32	-	(27)	(25)
- *Casodex*	21	-	(48)	(47)
- Others	12	-	1	6
BioPharmaceuticals: CVRM	**2,207**	**19**	**14**	**17**
- *Farxiga*	1,000	9	60	67
- *Brilinta*	325	3	(13)	(10)
- *Lokelma*	63	1	92	97
- Roxadustat	41	-	6	4
- *Andexxa*[10]	33	-	13	14
- *Crestor*	267	2	(2)	-
- *Seloken/Toprol-XL*	244	2	(2)	(1)
- *Bydureon*	68	1	(34)	(33)
- *Onglyza*	68	1	(33)	(31)
- Others	98	1	(15)	(13)
BioPharmaceuticals: R&I	**1,509**	**13**	**(2)**	**-**
- *Symbicort*	674	6	(2)	-
- *Fasenra*	308	3	18	22
- *Breztri*	87	1	>3x	>3x
- *Saphnelo*	11	-	n/m	n/m
- *Pulmicort*	217	2	(34)	(34)
- *Daliresp*	51	-	(16)	(16)
- *Bevespi*	15	-	15	14
- Others	146	1	(9)	(9)
BioPharmaceuticals: V&I	**1,757**	**15**	**>5x**	**>6x**
- *Vaxzevria*	1,089	10	>3x	>4x
- *Evusheld*	469	4	n/m	n/m
- *Synagis*	200	2	>8x	>8x
- *FluMist*	(1)	-	n/m	n/m
Rare Disease[10]	**1,694**	**15**	**3**	**7**
- *Soliris*[10]	990	9	(5)	-
- *Ultomiris*[10]	419	4	20	25
- *Strensiq*[10]	208	2	5	7
- *Koselugo*	39	-	82	85
- *Kanuma*[10]	38	-	9	15
Other Medicines	**425**	**4**	**(19)**	**(15)**
- *Nexium*	332	3	(18)	(13)
- Others	93	1	(22)	(22)
Product Sales	**10,980**	**96**	**51**	**56**
Collaboration Revenue	**410**	**4**	n/m	n/m
Total Revenue	**11,390**	**100**	**56**	**60**

Table 6: Collaboration Revenue

	Q1 2022			
			% Change	
	$m	% Total	Actual	CER
Lynparza: milestone revenue	175	43	n/m	n/m
Enhertu: share of gross profits	75	18	96	96
Royalty income	73	18	n/m	n/m
Tralokinumab: sales milestones	70	17	n/m	n/m
Other Collaboration Revenue	17	4	n/m	n/m
Total	**410**	**100**	n/m	n/m

Table 7: Total Revenue by region

	Q1 2022			
		% of	% Change	
	$m	Total	Actual	CER
Emerging Markets	3,364	30	30	32
- China	*1,622*	*14*	*(3)*	*(6)*
- Ex-China	*1,742*	*15*	*91*	*>2x*
US	4,134	36	79	79
Europe	2,284	20	48	57
Established RoW	1,608	14	85	98
Total	**11,390**	**100**	**56**	**60**

Oncology

Total Revenue increased by 21% (25% at CER) in Q1 2022 to $3,644m and represented 32% of overall Total Revenue (Q1 2021: 41%). This included *Lynparza* Collaboration Revenue of $175m and *Enhertu* Collaboration Revenue of $76m. Product Sales increased by 14% (18% at CER) in Q1 2022 to $3,388m, reflecting new launches and increased patient access for *Tagrisso*, *Imfinzi*, *Lynparza*, *Calquence* and *Enhertu* partially offset by declines in legacy medicines and an adverse gross-to-net[44] movement from the seasonal increase in Part-D related deductions typically seen in the first quarter.

Tagrisso

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	1,304	406	439	252	207
Actual change	14%	32%	6%	12%	2%
CER change	17%	33%	6%	21%	11%

Region	
Worldwide	• Increased adjuvant and 1st-line use offset by a continued adverse COVID-19 impact on diagnosis, testing and treatment
Emerging Markets	• Increased 1st-line use in China and continued growth in other Emerging Markets • *Tagrisso* was admitted to the China NRDL in March 2021 for the 1st-line setting and renewed in the 2nd-line setting, resulting in an adverse effect on the comparator period from lower sales to distributors prior to the change and stock compensation payments • Rising demand from increased patient access in China has now offset the impact of the March 2021 NRDL price reduction
US	• Greater 1st-line and adjuvant use, with longer duration of treatment, partially offset by lower 2nd-line use and a continued adverse COVID-19 impact • At the end of Q1 rates of diagnosis, testing and treatment in lung cancer are showing some signs of recovery, but remained around 5-15% below baseline
Established RoW	• Increased use in 1st-line and adjuvant settings

[44] Sales of medicines through managed care and other channels are subject to rebates, discounts, return fees, etc. An estimate of the likely levels of these items is subtracted from the gross (or total) sales of a medicine in order to establish the net product sales. A *gross-to-net adjustment* corrects any divergence between the actual and prior estimated level of rebate, discount or fee, once those items are known.

Imfinzi

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	599	58	315	125	101
Actual change	8%	2%	8%	15%	4%
CER change	11%	3%	8%	23%	12%

Region	
Worldwide	• Increased use of *Imfinzi* to treat patients with ES-SCLC[45] was offset by impact from lower rates of diagnosis and treatment due to the current COVID-19 wave
Emerging Markets	• Growth in ex-China continued, offset in China by reduction in inventory held by distributors and hospitals
US	• Growth driven new patient starts across Stage III NSCLC and ES-SCLC, despite the impact of COVID-19 on lung cancer diagnoses in recent months, offset by unfavourable seasonal inventory and gross-to-net movements
Europe	• ES-SCLC market penetration increased, as did the number of reimbursed markets, offsetting the COVID-19 impact on rates of diagnosis and treatment
Established RoW	• Growth driven by new reimbursements

Lynparza

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	792	121	270	335	66
Actual change	46%	39%	7%	>2x	22%
CER change	50%	43%	7%	>2x	32%

Product Sales	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	617	121	270	160	66
Actual change	14%	39%	7%	8%	22%
CER change	17%	43%	7%	16%	32%

Region	
Worldwide	• Total Revenue includes a $175m regulatory milestone received from MSD and recognised in the Europe geographic segment, in respect of the approval in the US for the adjuvant treatment of patients with breast cancer, based on the data from the OlympiA Phase III trial • Product sales growth was driven by further launches across multiple cancer types globally. *Lynparza* remains the leading medicine in the PARP[46]-inhibitor class globally across four tumour types, as measured by total prescription volume
Emerging Markets	• Patient access to *Lynparza* increased following admission to China's NRDL as a 1st-line treatment for ovarian cancer patients with effect from March 2021 and launches in other markets
US	• Growth in use in ovarian, breast and prostate cancers, offset by an adverse gross-to-net movement related to seasonal increase in Part-D related deductions typically seen in the first quarter, and reductions in inventory held by distributors
Europe	• Reimbursements introduced in additional countries, increasing BRCAm-testing rates, and successful 1st-line BRCAm ovarian, 2nd-line HRRm[47] prostate and gBRCAm HER2-negative advanced breast cancer launches
Established RoW	• Strong year on year growth driven by new product launches and high levels of HRD testing in Japan

[45] Extensive stage non-small cell lung cancer.

[46] Poly ADP ribose polymerase.

[47] Homologous recombination repair gene mutation.

Enhertu

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	86	9	57	20	1
Actual change	>2x	>7x	61%	>5x	n/m
CER change	>2x	>7x	61%	>5x	n/m

Region	
Worldwide	• Excluding Japan, global in-market sales recorded by Daiichi Sankyo Company Limited (Daiichi Sankyo) and AstraZeneca, amounted to $166m in the quarter (Q1 2021: $81m)
US	• US in-market sales, recorded by Daiichi Sankyo, amounted to $119m in the quarter (Q1 2021: $73m)
Established RoW	• In Japan, AstraZeneca receives a mid-single-digit percentage royalty on sales made by Daiichi Sankyo

Calquence

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	414	7	339	55	13
Actual change	98%	>3x	74%	>5x	>4x
CER change	100%	>3x	74%	>6x	>4x

Region	
US	• Strong performance despite COVID-19 impacts on CLL diagnosis rates, benefitting from increased new patient market share
Europe	• Increased market share in new patient starts after launches in the region

Orpathys

Total Revenue of $11m in the quarter (2021: $nil) was driven by the 2021 launch in China, where *Orpathys* has been approved for patients with lung cancer and MET[48] gene alterations.

Other Oncology medicines

Total Revenue	Q1 2022 $m	% Change Actual	% Change CER	Commentary
Zoladex	247	10	13	• Increase driven by usage in emerging markets
Faslodex	93	(24)	(20)	
Iressa	32	(47)	(47)	
Arimidex	32	(27)	(25)	
Casodex	21	(48)	(47)	
Others	12	1	6	

[48] Mesenchymal–epithelial transition.

BioPharmaceuticals

Including Vaccines & Immune Therapies medicines, BioPharmaceuticals Total Revenue increased by 49% (53% at CER) in Q1 2022 to $5,617m, representing 49% of overall Total Revenue (Q1 2021: 51%). Growth was driven by strong *Farxiga* performance and growth in the COVID-19 medicines.

Cardiovascular, Renal & Metabolism

CVRM Total Revenue increased by 14% (18% at CER) in Q1 2022, driven by strong *Farxiga* performance, to $2,219m and represented 19% of overall Total Revenue (Q1 2021: 26%).

Farxiga

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	1,001	391	193	318	99
Actual change	60%	50%	48%	83%	64%
CER change	67%	54%	48%	97%	76%

Region	
Worldwide	• The SGLT2[49] inhibitor class saw growth in many regions, with *Farxiga* volume growing faster than the overall SGLT2 market in most major regions. Performance also reflecting further HF and CKD launches and updated treatment guidelines including from ESC[50], AHA[51] and ACC[52], and beneficial impact from gross-to-net adjustments in the US versus Q1 2021
Emerging Markets	• China performance was enhanced by uACR[53] and MRF[54] testing program, and solid growth in ex-China Emerging Markets. *Forxiga's* NRDL status in China was renewed in the fourth quarter of 2021
US	• Continued strong growth, following the regulatory approval for HFrEF in May 2020, the approval for the treatment of CKD in May 2021, and the aforementioned gross-to-net adjustments. Both approvals included patients with and without T2D[55]. *Farxiga* continued to gain in-class brand share driven by HF and CKD launches.
Europe	• SGLT2 inhibitor class growth, the beneficial addition of cardiovascular outcomes trial data to the label, the HFrEF regulatory approval in November 2020, and CKD regulatory approval in August 2021
Established RoW	• In Japan, sales to collaborator Ono Pharmaceutical Co., Ltd, which records in-market sales, more than doubled to $69m

Brilinta

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	325	69	166	76	14
Actual change	(13%)	(35%)	-	(13%)	(5%)
CER change	(10%)	(32%)	-	(6%)	(1%)

Region	
Worldwide	• Continued adverse China VBP impact and fewer elective procedures in the EU and US due to the effects of the pandemic

[49] Sodium-glucose co-transporter-2.
[50] European Society of Cardiology.
[51] American Heart Association.
[52] American College of Cardiology.
[53] Urine albumin creatine ratio.
[54] Meaured renal function.
[55] Type-2 diabetes.

Lokelma

Total Revenue increased 92% (97% at CER) to $63m in the quarter, driven by *Lokelma* extending its branded market share lead in the US and continued progress from recent launches across Europe. In China, *Lokelma* was included on the NRDL from 1 January 2022.

Andexxa

On a pro forma basis, Total Revenue increased 48% (49% at CER) to $43m.

Roxadustat

Total Revenue increased 1% (2% decrease at CER) to $41m. Total Revenue also increased sequentially, benefitting from increased volumes in China following NRDL price cuts.

Other CVRM medicines

Total Revenue	Q1 2022 $m	% Change Actual	% Change CER	
Crestor	268	(2)	-	• Sales decline in the US and Europe offset by growth in Emerging Markets
Seloken/Toprol-XL	245	(2)	(1)	• Emerging Markets sales impacted by China VBP implementation of *Betaloc*[56] oral in H2 2021. *Betaloc ZOK* VBP to be implemented later in 2022
Bydureon	68	(34)	(33)	• Continued competitive pressures
Onglyza	68	(33)	(31)	• Continued declines in DPP-4[57] inhibitor class
Others	98	(15)	(13)	

Respiratory & Immunology

R&I Total Revenue, which included Collaboration Revenue of $75m, increased by 2% in Q1 2022 (4% at CER) to $1,584m and represented 14% of overall Total Revenue (Q1 2021: 21%). COVID-19 continued to have a material impact across markets and the portfolio.

Symbicort

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	674	167	259	157	91
Actual change	(2%)	1%	(2%)	(7%)	(1%)
CER change	-	3%	(2%)	-	3%

Region	
Worldwide	• *Symbicort* remains the global market-volume and value leader within the ICS/LABA class. • Market share performance was driven by Established RoW and Emerging Markets, and growth in anti-inflammatory reliever launch markets • The global ICS/LABA market continues to be eroded as fixed-dose triple therapies (LAMA/LABA/ICS) continue to launch
Emerging Markets	• Driven by growth outside China. China continues to be impacted by fixed-dose triple therapy launches
US	• Maintained total prescription market share in a declining ICS/LABA market as fixed-dose triple therapy launches continue. Continued growth in the authorised generic
Established RoW	• Sales in Japan declined due to continued generic erosion

[56] *Betaloc* is the brand name for *Seloken* in China.

[57] Dipeptidyl peptidase IV.

Fasenra

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	308	7	189	75	37
Actual change	18%	>2x	22%	20%	(5%)
CER change	22%	>2x	22%	29%	2%

Region	
Worldwide	• Expanded total market leadership in eosinophilic asthma, *Fasenra* is the leading IL-5 class biologic, in major markets (US, Japan and some EU countries). COVID-19 continues to impact total severe asthma market growth with most regions experiencing a slower growth
US	• Sustained growth driven by volume
Europe	• Increased volume from sustained leadership in new to brand prescriptions, in most EU markets
Established RoW	• In Japan, revenues declined by 13% (5% at CER) to $23m, with rising demand and sustained leadership in new to brand prescriptions, offset by reduced demand from distributors ahead of expected mandatory price reduction in April

Breztri

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	87	22	53	5	7
Actual change	>3x	>2x	>4x	>7x	46%
CER change	>3x	>2x	>4x	>8x	59%

Region	
Worldwide	• Continued to gain market share within the fixed-dose triple markets; in US, China and Japan.
Emerging Markets	• Continued its market share leadership within the fixed-dose triple market in China, which continues to gain share from the ICS/LABA class
US	• Progress made in new to brand market share growth in the fixed-dose triple market
Europe	• Launches continued in Europe
Established RoW	• Sales in Japan were impacted by COVID-19 restrictions

Saphnelo

Total Revenue of $11m in the quarter (Q1 2021: $nil) was driven by the 2021 launch in the US, where *Saphnelo* has been approved for SLE.

Tezspire

Tezspire is being developed in collaboration with Amgen, and was approved in the US for severe asthma in December 2021. Amgen will record sales in the US and AstraZeneca's share of gross profits in the US will be recognised as Collaboration Revenue. Outside of the US, AstraZeneca will record Product Sales. In Q1 2022, AstraZeneca recognised $3m of Collaboration Revenue from $7m of in-market sales recorded by Amgen (Q1 2021: $nil).

Other R&I Medicines

	Q1 2022	% Change		
Total Revenue	$m	Actual	CER	
Pulmicort	217	(34)	(34)	• Revenue from Emerging Markets decreased 43% to $164m • *Pulmicort Respules* was included in the latest round of VBP in China, implemented in October 2021, resulted in significantly lower market access and a mandatory price reduction.
Daliresp	51	(16)	(16)	
Bevespi	15	15	14	
Others	218	32	32	

Vaccines & Immune Therapies

Total Revenue from Vaccines and Immune Therapies medicines increased from $301m in Q1 2021 to $1,814m in Q1 2022 and represented 16% of overall Total Revenue (Q1 2021: 4%).

Vaxzevria

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	1,145	530	79	135	400
Actual change	>4x	>10x	n/m	(40%)	>10x
CER change	>4x	>10x	n/m	(37%)	>10x

Region	
Worldwide	• The majority of revenue in Q1 2022 came from initial, not-for-profit contracts
Emerging Markets	• Growth was driven by initial and commercial contracts in Latin America and Asia • $46m of Collaboration Revenue came from a Chinese sub-licensee
US	• Purchases by the US government for donation overseas
Europe	• Sales were down versus Q1 2021, when Europe accounted for 82% of *Vaxzevria* revenue as vaccination programmes were rolled out in the UK and the EU
Established RoW	• Sales in Japan, Canada and Australia

Evusheld

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	469	89	307	66	8
Actual change	n/m	n/m	n/m	n/m	n/m
CER change	n/m	n/m	n/m	n/m	n/m

Region	
US	• Emergency Use Authorisation was granted in December 2021, and in Q1 2022 • AstraZeneca fulfilled a proportion of the US government order for 1.7m units of *Evusheld* (a unit consists of one 150mg vial of cilgavimab and one 150mg vial of tixagevimab). The remainder of that order will be fulfilled before the end of 2022
Emerging Markets	• Multiple government contracts
Europe	• *Evusheld* was approved in the EU in the quarter

Other V&I Medicines

Total Revenue	Q1 2022 $m	% Change Actual	% Change CER	
Synagis	200	>8x	>8x	• Q1 2022 captures all global revenues from *Synagis* by destination. In the comparable period, revenues reflected AstraZeneca's ex-US collaboration agreement with AbbVie, which expired on 30 June 2021 in which all ex-US revenue was reported in Europe. The regional growth rates shown in Table 22 have also been impacted by the change
FluMist	(1)	n/m	n/m	• Normal seasonality of *FluMist* sales

Rare Disease

Rare Disease Total Revenue increased by 3% (7% at CER) pro forma in Q1 2022 to $1,694m, representing 15% of overall Total Revenue (Q1 2021: 0%). Performance was driven by continued durability of the C5 franchise, including continued conversion from *Soliris* to *Ultomiris* in PNH and aHUS as well as *Soliris* growth in Neurology indications, gMG and NMOSD.

The pro forma growth rates on medicines acquired with Alexion shown in these tables have been calculated by comparing Q1 revenues with the corresponding prior year pre-acquisition revenues previously published by Alexion.

Soliris

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	990	71	591	221	107
Actual change	(5%)	(41%)	7%	(15%)	4%
CER change	-	(28%)	7%	(8%)	11%

Region	
US	• Performance driven by *Soliris* growth in neurology indications, gMG and NMOSD, offset by continued conversion to *Ultomiris* in PNH and aHUS
Ex-US	• Strong underlying demand growth in EU and ERoW, EM growth impacted by prior year tender market order timing

Ultomiris

Total Revenue	Worldwide	Emerging Markets	US	Europe	Established RoW
Q1 2022 $m	419	24	220	105	70
Actual change	20%	n/m	6%	54%	(4%)
CER change	25%	n/m	6%	65%	7%

Region	
Worldwide	• Continued conversion and launches in new markets outside the US • Quarter-on-quarter revenue growth variability can be expected due to *Ultomiris* every eight-week dosing schedule and lower average annual treatment cost per patient compared to *Soliris*
US	• Continued COVID-19 impact on rate of aHUS diagnoses and treatment coupled with hospital reimbursement dynamics favouring Soliris
Ex-US	• Performance driven by new market approvals for PNH

Other Rare Disease medicines

Total Revenue	Q1 2022 $m	% Change Actual	% Change CER	Commentary
Strensiq	208	5	7	• Performance impacted by inventory and payer dynamics
Koselugo	39	82	85	• Reimbursed in 14 markets with ambition to continue expansion
Kanuma	38	9	15	• Performance driven by markets outside the US

Other medicines (outside the main disease areas)

Total Revenue	Q1 2022 $m	% Change Actual	% Change CER	Commentary
Nexium	338	(17)	(13)	• Nexium (oral) was included in China's VBP programme implemented in February 2021 and Nexium (i.v.) was implemented in the fifth round of VBP in October 2021.
Others	97	(22)	(21)	

Financial performance

Table 8: Reported Profit and Loss

	Q1 2022	Q1 2021	% Change	
	$m	$m	Actual	CER
Total Revenue	**11,390**	**7,320**	**56**	**60**
- Product Sales	10,980	7,257	51	56
- Collaboration Revenue	410	63	n/m	n/m
Cost of Sales	(3,511)	(1,864)	88	98
Gross Profit	**7,879**	**5,456**	**44**	**48**
Gross Margin	*68.0%*	*74.3%*	*-6*	*-7*
Distribution Expense	(125)	(99)	26	32
% Total Revenue	*1.1%*	*1.4%*	-	-
R&D Expense	(2,133)	(1,713)	24	26
% Total Revenue	*18.7%*	*23.4%*	*+5*	*+5*
SG&A Expense	(4,840)	(2,929)	65	68
% Total Revenue	*42.5%*	*40.0%*	*-2*	*-2*
OOI[58] & Expense	97	1,180	(92)	(92)
% Total Revenue	*0.9%*	*16.1%*	*-15*	*-15*
Operating Profit	**878**	**1,895**	**(54)**	**(46)**
Operating Margin	*7.7%*	*25.9%*	*-18*	*-18*
Net Finance Expense	(319)	(283)	13	7
Joint Ventures and Associates	(6)	(4)	38	53
Profit before tax	**553**	**1,608**	**(66)**	**(56)**
Taxation	(165)	(46)	n/m	n/m
Tax rate	30%	3%		
Profit after tax	**388**	**1,562**	**(75)**	**(68)**
Earnings per share	**$0.25**	**$1.19**	**(79)**	**(73)**

Table 9: Reconciliation of Reported Profit before tax to EBITDA

	Q1 2022	Q1 2021	% Change	
	$m	$m	Actual	CER
Reported Profit before tax	553	1,608	(66)	(56)
Net Finance Expense	319	283	13	7
Joint Venture and Associates	6	4	38	53
Depreciation, Amortisation and Impairment	1,309	797	64	56
EBITDA	**2,187**	**2,692**	**(19)**	**(16)**

EBITDA of $2,187m in the quarter (Q1 2021: $2,692m) has been negatively impacted by the $1,180m (Q1 2021: $nil) unwind of inventory fair value uplift recognised on the acquisition of Alexion. The unwind of inventory fair value is expected to depress EBITDA over the year in line with associated revenues.

[58] Other Operating Income.

Table 10: Reconciliation of Reported to Core financial measures

Q1 2022	Reported	Restructuring	Intangible Asset Amortisation & Impairments	Acquisition of Alexion	Other	Core[59]	Core % Change	
	$m	$m	$m	$m	$m	$m	Actual	CER
Gross Profit	**7,879**	**51**	**8**	**1,181**	**-**	**9,119**	**66**	**70**
Gross Margin	*68.0%*					*79.3%*	*+5*	*+4*
Distribution Expense	(125)	1	-	-	-	(124)	25	30
R&D Expense	(2,133)	5	(69)	11	-	(2,186)	33	36
SG&A Expense	(4,840)	17	1,098	17	762	(2,946)	23	25
Total Operating Expense	(7,098)	23	1,029	28	762	(5,256)	27	29
OOI & Expense	97	1	-	-	-	98	(92)	(92)
Operating Profit	**878**	**75**	**1,037**	**1,209**	**762**	**3,961**	**57**	**60**
Operating Margin	*7.7%*					*34.8%*	-	-
Net Finance Expense	(319)	-	-	-	67	(252)	35	23
Taxation	(165)	(15)	(191)	(280)	(121)	(772)	n/m	n/m
EPS	**$0.25**	**$0.04**	**$0.55**	**$0.60**	**$0.45**	**$1.89**	**16**	**20**

Profit and Loss drivers

Gross Profit

- The Gross Profit Margin (Reported and Core) in the quarter was impacted by:
  - Mix effects. The increased sales of *Vaxzevria,* and medicines with profit-sharing arrangements (primarily *Lynparza*) have a dilutive impact on the Gross Margin. The increased contribution from Rare Disease and Oncology medicines have a positive impact on the Gross Margin
  - Pricing pressure relating to the VBP and NRDL procurement programmes in China
- Reported Gross Profit was also impacted by the unwind of the fair value adjustment to Alexion inventories at the date of acquisition. The fair value uplift is expected to unwind through Reported Cost of Sales over 2022 in line with associated revenues, and in Q1 2022, the impact of the fair value uplift unwind on Cost of Sales was $1,180m
- Variations in Gross Margin performance between periods can be expected to continue

R&D Expense

- The increased Reported and Core R&D Expense was driven by:
  - Increased investment in several late-stage Oncology trials and the advancement of a number of Phase II clinical development programmes in BioPharmaceuticals
  - The acquisition of Alexion in July 2021
- Reported R&D Expense in Q1 was also impacted by intangible asset impairment reversals

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

SG&A Expense

- The increased Reported and Core SG&A Expense was driven primarily by the acquisition of Alexion in July 2021
- Reported SG&A Expense was also impacted by amortisation of intangible assets related to the Alexion acquisition and a $775m legal settlement with Chugai Pharmaceutical Co. Ltd

Other Operating Income

- Other Operating Income of $97m consisted primarily of royalties and disposal proceeds on small divestments
- In Q1 2021, Other Operating Income of $1,180m included $776m of divestment gains from AstraZeneca's share of Viela and $309m from the commercial rights to Crestor in over 30 countries in Europe (excluding UK and Spain)

Net Finance Expense

- The increase in Net Finance Expense in the quarter was driven by financing costs on debt for the Alexion transaction, increased interest on tax, and exchange movements

Taxation

- Both Reported and Core Tax rates are higher than the prior period due to one-off items in 2021, including the non-taxable gain on the divestment of Viela and updates to estimates of prior period tax liabilities following settlements with tax authorities
- The net cash paid for the quarter was $228m (Q1 2021: $332m) representing 41% of Reported Profit Before Tax (Q1 2021: 21%)
- The Reported Tax rate of 30% was higher than Core Tax rate of 21% due to the impact of Non-Core charges on the level of Reported Profit Before Tax

Table 11: Cash Flow summary

	Q1 2022 $m	Q1 2021 $m	Change $m
Reported Operating Profit	878	1,895	(1,017)
Depreciation, Amortisation and Impairment	1,309	797	512
Decrease in Working Capital and Short-term Provisions	1,804	1,210	594
Gains on Disposal of Intangible Assets	(10)	(310)	300
Gains on Disposal of Investments in Associates and Joint Ventures	-	(776)	776
Non-Cash and Other Movements	(327)	(363)	36
Interest Paid	(194)	(187)	(7)
Taxation Paid	(228)	(332)	104
Net Cash Inflow from Operating Activities	**3,232**	**1,934**	**1,298**
Net Cash Inflow before Financing Activities	**3,064**	**2,489**	**575**
Net Cash Outflow from Financing Activities	**(3,740)**	**(2,731)**	**(1,009)**

The increase in Net Cash Inflow from Operating Activities of $1,298m primarily reflected an underlying improvement in business performance, including the contribution from Alexion.

The Reported Operating Profit of $878m in the quarter includes a negative impact of $1,180m relating to the unwind of the inventory fair value uplift recognised on the acquisition of Alexion. This is offset by a corresponding item (positive impact of $1,180m) in Decrease in Working Capital and Short-term Provisions. Overall, the unwind of the fair value uplift has no impact on Net Cash Inflow from Operating Activities.

The change in Working Capital and Short-term Provisions of $594m, whilst being positively impacted by the aforementioned inventory fair value uplift unwind, has been adversely impacted by the reduction of *Vaxzevria* working capital balances predominantly within Trade and other payables.

Capital Expenditure

Capital Expenditure amounted to $219m in the quarter (Q1 2021: $220m). The Company anticipates an increase in Capital Expenditure relative to FY 2021, partly driven by an expansion in its capacity for growth and the acquisition of Alexion.

Table 12: Net Debt summary

	At 31 Mar 2022 $m	At 31 Dec 2021 $m	At 31 Mar 2021 $m
Cash and cash equivalents	5,762	6,329	7,636
Other investments	61	69	129
Cash and investments	**5,823**	**6,398**	**7,765**
Overdrafts and short-term borrowings	(805)	(387)	(581)
Lease liabilities	(949)	(987)	(680)
Current instalments of loans	(1,264)	(1,273)	(1,461)
Non-current instalments of loans	(28,081)	(28,134)	(17,410)
Interest-bearing loans and borrowings (Gross Debt)	**(31,099)**	**(30,781)**	**(20,132)**
Net derivatives	59	61	162
Net Debt	**(25,217)**	**(24,322)**	**(12,205)**

Net Debt increased by $895m in the year to date to $25,217m. Details of the committed undrawn bank facilities are disclosed within the going concern section of Note 1. Details of the Company's solicited credit ratings are disclosed in Note 3.

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. The Company's capital allocation priorities include investing in the business and pipeline, maintaining a strong, investment-grade credit rating, potential value-enhancing business development opportunities, and supporting the progressive dividend policy.

In approving the declaration of dividends, the Board considers both the liquidity of the company and the level of reserves legally available for distribution. Dividends are paid to shareholders from AstraZeneca PLC, a Group holding company with no direct operations. The ability of AstraZeneca PLC to make shareholder distributions is dependent on the creation of profits for distribution and the receipt of funds from subsidiary companies. The consolidated Group reserves set out in the Condensed consolidated statement of financial position do not reflect the profit available for distribution to the shareholders of AstraZeneca PLC.

Summarised financial information for guarantee of securities of subsidiaries

AstraZeneca Finance LLC ("AstraZeneca Finance") is the issuer of 0.700% Notes due 2024, 1.200% Notes due 2026, 1.750% Notes due 2028 and 2.250% Notes due 2031 (the "AstraZeneca Finance Notes"). Each series of AstraZeneca Finance Notes has been fully and unconditionally guaranteed by AstraZeneca PLC. AstraZeneca Finance is 100% owned by AstraZeneca PLC and each of the guarantees by AstraZeneca PLC is full and unconditional and joint and several.

The AstraZeneca Finance Notes are senior unsecured obligations of AstraZeneca Finance and rank equally with all of AstraZeneca Finance's existing and future senior unsecured and unsubordinated indebtedness. The guarantee by AstraZeneca PLC of the AstraZeneca Finance Notes is the senior unsecured obligation of AstraZeneca PLC and ranks equally with all of AstraZeneca PLC's existing and future senior unsecured and unsubordinated indebtedness. Each guarantee by AstraZeneca PLC is effectively subordinated to any secured indebtedness of AstraZeneca PLC to the extent of the value of the assets securing such indebtedness. The AstraZeneca Finance Notes are structurally subordinated to indebtedness and other liabilities of the subsidiaries of AstraZeneca PLC, none of which guarantee the AstraZeneca Finance Notes.

AstraZeneca PLC manages substantially all of its operations through divisions, branches and/or investments in subsidiaries and affiliates. Accordingly, the ability of AstraZeneca PLC to service its debt and guarantee obligations is also dependent upon the earnings of its subsidiaries, affiliates, branches and divisions, whether by dividends, distributions, loans or otherwise.

Please refer to the consolidated financial statements of AstraZeneca PLC in our Annual Report on Form 20-F and reports on Form 6-K with our quarterly financial results as filed or furnished with the SEC for further financial information regarding AstraZeneca PLC and its consolidated subsidiaries. For further details, terms and conditions of the AstraZeneca Finance Notes please refer to AstraZeneca PLC's Form 6-K furnished to the SEC on 28 May 2021.

Pursuant to Rule 13-01 and Rule 3-10 of Regulation S-X under the Securities Act of 1933, as amended (the "Securities Act"), we present below the summary financial information for AstraZeneca PLC, as Guarantor, excluding its consolidated subsidiaries, and AstraZeneca Finance, as the issuer, excluding its consolidated subsidiaries. The following summary financial information of AstraZeneca PLC and AstraZeneca Finance is presented on a combined basis and transactions between the combining entities have been eliminated. Financial information for non-guarantor entities has been excluded. Intercompany balances and transactions between the obligor group and the non-obligor subsidiaries are presented on separate lines.

Table 13: Obligor group summarised Statement of comprehensive income

	Q1 2022 $m	Q1 2021 $m
Total revenue	-	-
Gross profit	-	-
Operating loss	(1)	(20)
Loss for the period	(155)	(166)
Transactions with subsidiaries that are not issuers or guarantors	164	2,148

Table 14: Obligor group summarised Statement of financial position information

	At 31 Mar 2022 $m	At 31 Mar 2021 $m
Current assets	19	28
Non-current assets	-	-
Current liabilities	(1,682)	(1,656)
Non-current liabilities	(25,605)	(17,072)
Amounts due from subsidiaries that are not issuers or guarantors	8,652	6,243
Amounts due to subsidiaries that are not issuers or guarantors	(297)	(295)

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 15: Currency sensitivities

The Company provides the following currency-sensitivity information:

		Average exchange rates versus USD			Annual impact of 5% strengthening in exchange rate versus USD ($m)[60]	
Currency	**Primary Relevance**	**FY 2021[61]**	**Q1 2022[62]**	**% Change**	**Total Revenue**	**Core Operating Profit**
CNY	Total Revenue	6.43	6.35	1	277	158
EUR	Total Revenue	0.85	0.89	(5)	317	160
JPY	Total Revenue	109.83	116.32	(6)	229	158
Other[63]					420	196
GBP	Operating Expense	0.73	0.75	(2)	61	(93)
SEK	Operating Expense	8.58	9.33	(8)	6	(82)

[60] Based on best prevailing assumptions around currency profiles.

[61] Based on average daily spot rates in FY 2021.

[62] Based on average daily spot rates from 1 January 2022 to 31 March 2022.

[63] Other currencies include AUD, BRL, CAD, KRW and RUB.

Sustainability

Since the last quarterly report, AstraZeneca:

- Published its eighth annual Sustainability Report and Sustainability Data summary via its website and social media, released in conjunction with the Annual Report. Two fireside discussions from the accompanying investor roadshow are available on the AstraZeneca IR website
- Facilitated a Climate and Health Policy Roundtable at Expo 2020 Dubai with global experts from the World Health Organisation, UNFCCC, Sustainability Healthcare Coalition, and health and environmental authorities from Sweden, Egypt, and the UAE to discuss the health of people and the planet
- Convened a hybrid summit on health system sustainability and resilience, culminating in a global call to action to rebuild health system integrity following the COVID-19 pandemic

Access to healthcare

- Released, along with its sub-licensees, more than 2.8 billion vaccine doses, for supply in over 180 countries. Approximately two-thirds of the doses have gone to low and middle-income countries
- The Company's Healthy Heart Africa (HHA) programme expanded into Nigeria, its ninth country of operation, with the signing of a Memorandum of Understanding with the Federal Government of Nigeria. Launched the second phase in Tanzania with the Ministry of Health and our local partner PATH. The two-year project aims to reach over 500,000 people, providing services and support at 35 primary health care facilities. Since the programme launched in 2015, HHA has conducted over 25 million blood pressure screenings, identified over 4.8 million elevated readings, activated over 950 sites and trained more than 9,000 healthcare workers and volunteers
- Expanded its Young Health Programme (YHP) into Italy and Israel, bringing the number of countries to 34
- Awards to two youth-led organisations tackling air pollution, through the Lead2030 Challenge in partnership with One Young World (OYW), in line with the Company's commitment to SDG3. Winners receive mentorship from AstraZeneca, and a Scholarship to attend the OYW Summit

Environmental protection

- Announced a collaboration with Honeywell to develop next-generation respiratory inhalers (pMDI) with a near-zero Global Warming Potential propellant. The innovation, using the propellant HFO-1234ze, is a key element supporting the delivery of AstraZeneca's Ambition Zero Carbon goals. AstraZeneca also announced that by the end of 2025, 95% of its key suppliers will have targets to limit global warming to <1.5C
- Announced two new forestry commitments in Ghana (three million trees) and the US (one million trees) at the Global Forest Summit, building on existing AZ Forest projects in Australia, Indonesia, the UK
- Marked World Water Day with an updated Position Paper on Water Stewardship. The Company has championed a water risk assessment of the global pharmaceutical supply chain in collaboration with WWF Sweden. AstraZeneca also joined the Alliance for Water Stewardship (AWS)
- Featured in the Financial Times' list of Europe's Climate Leaders, for the second year running. This recognises companies with the highest reduction in Scope 1 and 2 emissions from 2015 to 2020

Ethics and transparency

- Revised its Global Standard for Bioethics, which ensures its ethical principles cover evolving R&D activities
- Marked International Day of Women and Girls in Science and International Women's Day with external and internal communications campaigns featuring members of the Senior Executive team and other Company scientists. AstraZeneca also signed the Wellbeing of Women Menopause Workplace Pledge
- Observed Black History Month, with events hosted by the AstraZeneca African Heritage Business Resource Group, Alexion Black Professionals Network, AZ Inspire and the Inclusion and Diversity (I&D) team
- Became a founding member of Neurodiversity in Business and celebrated Neurodiversity Week with the Company's TH!NK ERG programme of events

Research and development

This section covers R&D events and milestones in the period since the prior results announcement.

A comprehensive view of AstraZeneca's pipeline of medicines in human trials can be found in the latest clinical trials appendix, available on www.astrazeneca.com/investor-relations. The clinical trials appendix includes tables with details of the ongoing clinical trials for AstraZeneca medicines and new molecular entities in the pipeline.

Oncology

Significant new trials in Oncology included, EMERALD-3, a Phase III trial of *Imfinzi* plus tremelimumab, with and without lenvatinib, in combination with transarterial chemoembolisation in patients with locoregional HCC, PACIFIC-9, a Phase III trial of *Imfinzi* plus oleclumab and *Imfinzi* plus monalizumab in patients with locally advanced, Stage III, unresectable non-small cell lung cancer who have not progressed following platinum-based cCRT, and SAFFRON - a Phase III trial of *Tagrisso* in combination with AstraZeneca and HUTCHMED's *Orpathys* in patients EGFR-mutated NSCLC patients with MET-driven tumours following progression after treatment with *Tagrisso.*

AstraZeneca presented new data across its diverse portfolio of cancer medicines at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in February 2022. Presentations included a late-breaking presentation by AstraZeneca and MSD from the PROpel Phase III trial of *Lynparza* plus abiraterone, which showed the combination significantly delayed disease progression in 1st-line metastatic castration-resistant prostate cancer regardless of biomarker status. *Lynparza* is the first PARP inhibitor to demonstrate clinical benefit in combination with a new hormonal agent in this setting.

At the American Association for Cancer Research General Meeting 2022, new preclinical and early clinical data was presented across its pipeline. Data from 60 presentations, including five oral and three mini-oral presentations, featured the Company's next wave of potential cancer medicines spanning its immuno-oncology, DNA Damage Response and Antibody Drug Conjugate scientific platforms. This includes key data shared from three potential new medicines that illustrate the Company's innovative approach to designing molecules that address key challenges in treating cancer, including the ability to target different, complementary mechanisms.

Imfinzi

During the period, the Company announced that the CALLA Phase III trial for *Imfinzi* given concurrently with CRT did not achieve statistical significance for the primary endpoint of improving progression-free survival versus CRT alone in the treatment of patients with locally advanced cervical cancer.

In April 2022 the Company announced the regulatory submission acceptance for tremelimumab with Priority Review in the US, by the US FDA. The submission is supported by data from the HIMALAYA trial, in which a single priming dose of the anti-CTLA4[64] antibody added to *Imfinzi* for the treatment of patients with unresectable hepatocellular carcinoma significantly improved overall survival. A supplemental Biologics Licence Application has also been submitted for *Imfinzi* in this indication. The Prescription Drug User Fee Act date, the US FDA action date for their regulatory decision, is during the fourth quarter of 2022, following the use of a priority review voucher.

During the period, AstraZeneca completed regulatory submissions for tremelimumab and *Imfinzi* in Japan. The submissions were based on data from the aforementioned HIMALAYA trial, as well as the TOPAZ-1 trial in which *Imfinzi*, in combination with standard-of-care chemotherapy, demonstrated a statistically significant and clinically meaningful overall survival benefit versus chemotherapy alone as a 1st-line treatment for patients with advanced biliary tract cancer.

[64] An immune checkpoint receptor.

Lynparza

In February 2022, AstraZeneca presented results from the PROpel Phase III trial at the aforementioned 2022 ASCO GU meeting. AstraZeneca and MSD's *Lynparza* in combination with abiraterone demonstrated a statistically significant and clinically meaningful improvement in rPFS[65] versus abiraterone as a 1st-line treatment for patients with mCRPC[66] with or without HRR[67] gene mutations.

Lynparza in combination with abiraterone reduced the risk of disease progression or death by 34% versus abiraterone alone (HR[68] 0.66; 95% CI 0.54-0.81; p<0.0001). Median rPFS was 24.8 months for *Lynparza* plus abiraterone versus 16.6 for abiraterone alone.

Results also showed a favourable trend towards improved OS[69] with *Lynparza* plus abiraterone versus abiraterone alone, however the difference did not reach statistical significance at the time of this data cut-off (analysis at 29% data maturity). The trial will continue to assess OS as a key secondary endpoint.

During the period, *Lynparza* was also approved in the US for the adjuvant treatment of patients with germline BRCA-mutated HER2-negative high-risk early breast cancer who have already been treated with chemotherapy either before or after surgery. The approval by the US FDA was based on results from the OlympiA Phase III trial, in which *Lynparza* demonstrated a statistically significant and clinically meaningful improvement in invasive disease-free survival, reducing the risk of invasive breast cancer recurrences, second cancers or death, by 42% versus placebo (based on a HR of 0.58; 95% CI 0.46-0.74; p<0.0001).

In March, new updated results from the OlympiA trial presented at the European Society for Medical Oncology virtual plenary showed *Lynparza* demonstrated a statistically significant and clinically meaningful improvement in the key secondary endpoint of OS, reducing the risk of death by 32% versus placebo (based on a HR of 0.68; 95% CI 0.50-0.91; p=0.0091).

Enhertu

In February 2022, AstraZeneca announced positive high-level results from the DESTINY-Breast04 Phase III trial. *Enhertu* demonstrated a statistically significant and clinically meaningful improvement in both PFS[70] and OS in patients with HER2-low unresectable and/or metastatic breast cancer previously treated with one or two prior lines of chemotherapy, regardless of hormone receptor (HR) status, versus physician's choice of chemotherapy.

The US FDA has subsequently notified AstraZeneca and Daiichi Sankyo that the sBLA[71] for *Enhertu* has been accepted and granted Breakthrough Therapy Designation for the treatment of HER2-low unresectable and/or metastatic breast cancer in patients previously treated with one or two prior lines of chemotherapy.

The sBLA is being reviewed under the Real-Time Oncology Review (RTOR) programme. RTOR allows the FDA to review components of an application before submission of the complete application.

In April 2022, AstraZeneca and Daiichi Sankyo were notified by the US FDA that the sBLA for *Enhertu* has been accepted and granted Priority Review for the treatment of adult patients with previously treated HER2-mutant metastatic non-small cell lung cancer based on the results of the DESTINY-Lung01 Phase II trial.

Primary results from previously-treated patients with HER2-mutations (cohort 2) of DESTINY-Lung01 demonstrated a confirmed objective response rate (ORR) of 54.9% (95% CI: 44.2-65.4) in patients treated with *Enhertu* (6.4mg/kg).

During the period, the China Center for Drug Evaluation granted Breakthrough Therapy Designation for *Enhertu* for the 2nd-line treatment of patients with HER2+ metastatic breast cancer based on the results of the DESTINY-Breast03 Phase III trial.

[65] Radiographic progression-free survival.

[66] Metastatic castration-resistant prostate cancer.

[67] Homologous recombination repair.

[68] Hazard ratio.

[69] Overall survival.

[70] Progression-free survival.

[71] Supplemental Biologics License Application.

BioPharmaceuticals - CVRM

Brilinta

During the period, the US FDA granted AstraZeneca six months paediatric exclusivity for *Brilinta*.

Andexxa

During the period, *Ondexxya* was approved in Japan for patients treated with Factor Xa inhibitors apixaban, rivaroxaban or edoxaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleedings. *Ondexxya* is approved in the EU, and in the US under the trade name *Andexxa*.

AZD8233

At the American College of Cardiology's 71st Annual Scientific Session, AstraZeneca and Ionis Pharmaceuticals, Inc. presented Phase IIb data for AZD8233, an antisense oligonucleotide, in development for the treatment of hypercholesterolemia. In the ETESIAN Phase IIb trial, AZD8233 showed reduction in LDL-C[72] levels of 73% and PCSK9 reduction of 89%.

BioPharmaceuticals – R&I

As disclosed in the Sustainability section, AstraZeneca announced a collaboration with Honeywell, to develop next-generation respiratory inhalers (pMDI) using the propellant HFO-1234ze, which has up to 99.9% less Global Warming Potential (GWP) than propellants currently used in respiratory medicines. Recent results from the first in-human Phase I trial of the near-zero GWP propellant HFO-1234ze in a pMDI containing budesonide, glycopyrronium, formoterol fumarate in healthy adults were positive, demonstrating similar safety, tolerability and systemic exposure of the active ingredients when compared to *Breztri Aerosphere* (budesonide/glycopyrronium/formoterol fumarate). AstraZeneca expects *Breztri* to be the first medicine to transition to this new pMDI platform, subject to regulatory approval.

As of 29 April 2022, significant new trials in Respiratory & Immunology in which the first patient was dosed included; HUDSON, a Phase III trial of *Fasenra* in eosinophilic gastritis and eosinophilic gastroenteritis and, OBERON and TITANIA, Phase III trials of tozorakimab in COPD.

Fasenra

During the period, the US FDA issued a CRL[73] regarding the sBLA for *Fasenra* for patients with inadequately controlled CRwNP

The sBLA included data from the OSTRO Phase III trial, which met both co-primary endpoints with a safety profile consistent with the known profile of the medicine. The CRL requested additional clinical data and AstraZeneca is working closely with the US FDA regarding next steps. AstraZeneca remains committed to bringing *Fasenra* to patients with CRSwNP and a second Phase III trial, ORCHID, in this indication is ongoing.

Saphnelo

During the period, *Saphnelo* received approval in the EU as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive SLE, despite receiving standard therapy, making it the first biologic for SLE approved in Europe with an indication that is not restricted to patients with a high degree of disease activity. The approval is based on results from the *Saphnelo* clinical development programme, which included the TULIP 1 and TULIP 2 Phase III trials and the MUSE Phase II trial. In these trials, more patients treated with *Saphnelo* experienced a reduction in overall disease activity across all affected organ systems from baseline and achieved sustained reduction in oral corticosteroid use compared to placebo, with both groups receiving standard therapy.

[72] Low-density lipoprotein cholesterol.

[73] Complete response letter.

BioPharmaceuticals – Vaccines and Immune Therapies

Evusheld

During the period, *Evusheld* was granted marketing authorisation in the EU for the pre-exposure prophylaxis (prevention) of COVID-19 in a broad population of adults and adolescents aged 12 years and older weighing at least 40kg.

Preclinical authentic 'live' virus data from Washington University School of Medicine demonstrated that *Evusheld* retains neutralising activity against the highly transmissible Omicron BA.2 subvariant. This study also showed that *Evusheld* reduced viral burden and limited inflammation in the lungs (in vivo) across all tested Omicron variants.

Detailed results from the PROVENT Phase III pre-exposure prophylaxis (prevention) trial, published in *The New England Journal of Medicine*, showed that AstraZeneca's *Evusheld* reduced the risk of developing symptomatic COVID-19 by 77% in the primary analysis and by 83% in the six-month follow-up analysis, compared to placebo. There were no cases of severe disease or COVID-19 related deaths in the *Evusheld* group through the six-month follow up.

Nirsevimab

Nirsevimab was accepted under an accelerated assessment procedure by the EMA, for the prevention of medically attended LRTI[74] in all infants from birth entering their first RSV season.

Detailed results from the MELODY Phase III trial were published in the New England Journal of Medicine and demonstrated that nirsevimab showed 74.5% efficacy against medically attended LRTI caused by RSV in healthy infants compared to placebo. Additionally, results from the MEDLEY Phase II/III trial were also published in the journal. The results demonstrated nirsevimab had a similar safety and tolerability profile compared to *Synagis*, and that serum levels of nirsevimab following dosing (on day 151) in this trial were comparable with those observed in the MELODY Phase III trial.

Rare Disease

Ultomiris

Ultomiris was approved in the US for the treatment of adult patients with gMG who are anti-acetylcholine receptor antibody-positive, which represents 80% of people living with the disease. The approval by the US FDA was based on positive results from the CHAMPION-MG Phase III trial, in which *Ultomiris* was superior to placebo in the primary endpoint of change from baseline in the Myasthenia Gravis-Activities of Daily Living Profile (MG-ADL) total score at Week 26, a patient-reported scale that assesses patients' abilities to perform daily activities.

[74] Lower respiratory tract infections.

Interim Financial Statements

Table 16: Q1 2022 - Condensed consolidated statement of comprehensive income

For the **quarter** ended 31 March	**2022 $m**	**2021 $m**
Total Revenue	**11,390**	**7,320**
Product Sales	*10,980*	*7,257*
Collaboration Revenue	*410*	*63*
Cost of Sales	(3,511)	(1,864)
Gross profit	**7,879**	**5,456**
Distribution expense	(125)	(99)
Research and development expense	(2,133)	(1,713)
Selling, general and administrative expense	(4,840)	(2,929)
Other operating income and expense	97	1,180
Operating profit	**878**	**1,895**
Finance income	17	20
Finance expense	(336)	(303)
Share of after tax losses in associates and joint ventures	(6)	(4)
Profit before tax	**553**	**1,608**
Taxation	(165)	(46)
Profit for the period	**388**	**1,562**
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Remeasurement of the defined benefit pension liability	335	481
Net gains/(losses) on equity investments measured at fair value through other comprehensive income	18	(108)
Fair value movements related to own credit risk on bonds designated as fair value through profit or loss	-	1
Tax on items that will not be reclassified to profit or loss	(94)	(94)
	259	**280**
Items that may be reclassified subsequently to profit or loss		
Foreign exchange arising on consolidation	(219)	(107)
Foreign exchange arising on designated borrowings in net investment hedges	(32)	(302)
Fair value movements on cash flow hedges	5	(86)
Fair value movements on cash flow hedges transferred to profit or loss	11	121
Fair value movements on derivatives designated in net investment hedges	(8)	13
Costs of hedging	-	(1)
Tax on items that may be reclassified subsequently to profit or loss	1	26
	(242)	(336)
Other comprehensive income/(loss) for the period, net of tax	**17**	**(56)**
Total comprehensive income for the period	**405**	**1,506**
Profit attributable to:		
Owners of the Parent	386	1,561
Non-controlling interests	2	1
	388	1,562
Total comprehensive income attributable to:		
Owners of the Parent	405	1,506
Non-controlling interests	-	-
	405	1,506
Basic earnings per $0.25 Ordinary Share	$0.25	$1.19
Diluted earnings per $0.25 Ordinary Share	$0.25	$1.18
Weighted average number of Ordinary Shares in issue (millions)	1,548	1,312
Diluted weighted average number of Ordinary Shares in issue (millions)	1,561	1,319

Table 17: Condensed consolidated statement of financial position

	At 31 Mar 2022 $m	At 31 Dec 2021 $m	At 31 Mar 2021 $m
Assets			
Non-current assets			
Property, plant and equipment	9,061	9,183	8,189
Right-of-use assets	954	988	660
Goodwill	19,963	19,997	11,765
Intangible assets	41,265	42,387	20,347
Investments in associates and joint ventures	63	69	88
Other investments	1,174	1,168	972
Derivative financial instruments	87	102	115
Other receivables	864	895	549
Deferred tax assets	4,195	4,330	3,506
	77,626	**79,119**	**46,191**
Current assets			
Inventories	7,624	8,983	4,278
Trade and other receivables	8,683	9,644	6,281
Other investments	61	69	129
Derivative financial instruments	54	83	64
Intangible assets	96	105	-
Income tax receivable	367	663	347
Cash and cash equivalents	5,762	6,329	7,636
Assets held for sale	-	368	-
	22,647	**26,244**	**18,735**
Total assets	**100,273**	**105,363**	**64,926**
Liabilities			
Current liabilities			
Interest-bearing loans and borrowings	(2,069)	(1,660)	(2,042)
Lease liabilities	(225)	(233)	(216)
Trade and other payables	(17,864)	(18,938)	(17,370)
Derivative financial instruments	(35)	(79)	(16)
Provisions	(1,423)	(768)	(875)
Income tax payable	(1,124)	(916)	(994)
	(22,740)	**(22,594)**	**(21,513)**
Non-current liabilities			
Interest-bearing loans and borrowings	(28,081)	(28,134)	(17,410)
Lease liabilities	(724)	(754)	(464)
Derivative financial instruments	(47)	(45)	(1)
Deferred tax liabilities	(5,626)	(6,206)	(2,823)
Retirement benefit obligations	(1,991)	(2,454)	(2,545)
Provisions	(949)	(956)	(576)
Other payables	(3,756)	(4,933)	(5,148)
	(41,174)	(43,482)	(28,967)
Total liabilities	**(63,914)**	**(66,076)**	**(50,480)**
Net assets	**36,359**	**39,287**	**14,446**
Equity			
Capital and reserves attributable to equity holders of the Parent			
Share capital	387	387	328
Share premium account	35,131	35,126	7,976
Other reserves	2,050	2,045	2,037
Retained earnings	(1,228)	1,710	4,089
	36,340	**39,268**	**14,430**
Non-controlling interests	19	19	16
Total equity	**36,359**	**39,287**	**14,446**

Table 18: 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 2021	328	7,971	2,024	5,299	15,622	16	15,638
Profit for the period	-	-	-	1,561	1,561	1	1,562
Other comprehensive loss	-	-	-	(55)	(55)	(1)	(56)
Transfer to other reserves	-	-	13	(13)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(2,490)	(2,490)	-	(2,490)
Issue of Ordinary Shares	-	5	-	-	5	-	5
Share-based payments charge for the period	-	-	-	82	82	-	82
Settlement of share plan awards	-	-	-	(295)	(295)	-	(295)
Net movement	-	5	13	(1,210)	(1,192)	-	(1,192)
At 31 Mar 2021	**328**	**7,976**	**2,037**	**4,089**	**14,430**	**16**	**14,446**
At 1 Jan 2022	**387**	**35,126**	**2,045**	**1,710**	**39,268**	**19**	**39,287**
Profit for the period	-	-	-	386	386	2	388
Other comprehensive income	-	-	-	19	19	(2)	17
Transfer to other reserves	-	-	5	(5)	-	-	-
Transactions with owners:							
Dividends	-	-	-	(3,046)	(3,046)	-	(3,046)
Issue of Ordinary Shares	-	5	-	-	5	-	5
Share-based payments charge for the period	-	-	-	182	182	-	182
Settlement of share plan awards	-	-	-	(474)	(474)	-	(474)
Net movement	-	5	5	(2,938)	(2,928)	-	(2,928)
At 31 Mar 2022	**387**	**35,131**	**2,050**	**(1,228)**	**36,340**	**19**	**36,359**

Table 19: Condensed consolidated statement of cash flows

For the **quarter** ended 31 March	**2022 $m**	**2021 $m**
Cash flows from operating activities		
Profit before tax	553	1,608
Finance income and expense	319	283
Share of after tax losses of associates and joint ventures	6	4
Depreciation, amortisation and impairment	1,309	797
Decrease in working capital and short-term provisions	1,804	1,210
Gains on disposal of intangible assets	(10)	(310)
Gains on disposal of investments in associates and joint ventures	-	(776)
Non-cash and other movements	(327)	(363)
Cash generated from operations	**3,654**	**2,453**
Interest paid	(194)	(187)
Tax paid	(228)	(332)
Net cash inflow from operating activities	**3,232**	**1,934**
Cash flows from investing activities		
Payments upon vesting of employee share awards attributable to business combinations	(55)	-
Payment of contingent consideration from business combinations	(182)	(171)
Purchase of property, plant and equipment	(219)	(220)
Disposal of property, plant and equipment	-	4
Purchase of intangible assets	(144)	(249)
Disposal of intangible assets and assets held for sale	385	418
Purchase of non-current asset investments	(4)	-
Disposal of non-current asset investments	32	-
Movement in short-term investments, fixed deposits and other investing instruments	21	28
Payments to associates and joint ventures	(5)	(55)
Disposal of investments in associates and joint ventures	-	776
Interest received	3	24
Net cash (outflow)/inflow from investing activities	(168)	555
Net cash inflow before financing activities	**3,064**	**2,489**
Cash flows from financing activities		
Proceeds from issue of share capital	5	5
Repayment of loans and borrowings	(4)	(4)
Dividends paid	(2,971)	(2,469)
Hedge contracts relating to dividend payments	(77)	(23)
Repayment of obligations under leases	(74)	(50)
Movement in short-term borrowings	301	(190)
Payment of Acerta Pharma share purchase liability	(920)	-
Net cash outflow from financing activities	**(3,740)**	**(2,731)**
Net decrease in cash and cash equivalents in the period	(676)	(242)
Cash and cash equivalents at the beginning of the period	6,038	7,546
Exchange rate effects	(9)	(67)
Cash and cash equivalents at the end of the period	**5,353**	**7,237**
Cash and cash equivalents consist of:		
Cash and cash equivalents	5,762	7,636
Overdrafts	(409)	(399)
	5,353	**7,237**

Notes to the Interim Financial Statements

Note 1: Basis of preparation and accounting policies

These unaudited Interim Financial Statements for the three months ended 31 March 2022 have been prepared in accordance with UK-adopted International Accounting Standards and with the requirements of the Companies Act 2006 as applicable to companies reporting under those standards. The Interim Financial Statements also comply fully with International Financial Reporting Standards (IFRSs) as issued by the International Accounting Standards Board (IASB) and International Accounting Standards as adopted by the European Union.

The unaudited Interim Financial Statements for the three months ended 31 March 2022 include Alexion's results for the period. Alexion was consolidated into the Group's results from 21 July 2021, hence Alexion's results are not included in the comparative periods shown.

The unaudited Interim Financial Statements for the three months ended 31 March 2022 were approved by the Board of Directors for publication on 29 April 2022.

The annual financial statements of the Group for the year ended 31 December 2021 were prepared in accordance with UK-adopted International Accounting Standards and with the requirements of the Companies Act 2006. The annual financial statements also comply fully with IFRSs as issued by the IASB and International Accounting Standards as adopted by the European Union. Except for the estimation of the interim income tax charge, 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 2021.

The comparative figures for the financial year ended 31 December 2021 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.

Global and/or geopolitical events

There were no material accounting impacts identified relating to COVID-19 during the three months ended 31 March 2022.

The Group's current focus is to continue compliant business operations in Russia and Ukraine, focussing on safeguarding our employees, ensuring continuity of supply of essential and life-saving medicines and contributing to humanitarian relief efforts. There are no material accounting impacts arising from the conflict impacting our Q1 2022 reporting. The situation is dynamic and any future impact on our business is uncertain. We continue to closely monitor the situation.

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

Going concern

The Group has considerable financial resources available. As at 31 March 2022, the Group had $10.7bn in financial resources (cash and cash-equivalent balances of $5.8bn and undrawn committed bank facilities of $4.9bn available until April 2025, with only $2.3bn of borrowings due within one year). All facilities contain no financial covenants and were undrawn at 31 March 2022.

The Group's revenues are largely derived from sales of medicines covered by patents which provide a relatively high level of resilience and predictability to cash inflows, although government price interventions in response to budgetary constraints are expected to continue to affect adversely revenues in some of our significant markets. The Group, however, anticipates new revenue streams from both recently launched medicines and those in development, and the Group has a wide diversity of customers and suppliers across different geographic areas.

Consequently, the Directors believe that, overall, the Group is well-placed to manage its business risks successfully.

Accordingly, the going concern basis has been adopted in these Interim Financial Statements.

Legal proceedings

The information contained in Note 5 updates the disclosures concerning legal proceedings and contingent liabilities in the Group's Annual Report and Form 20-F Information 2021.

Note 2: Intangible assets

In accordance with IAS 36 'Impairment of Assets', reviews for triggers at an individual asset or cash-generating-unit level were conducted, and impairment tests carried out where triggers were identified. As a result, total net impairment reversals of $94m have been recorded against intangible assets during the three months ended 31 March 2022 (Q1 2021: $55m charge). Net impairment reversals in respect of medicines in development and launched medicines were $77m (Q1 2021: $nil) and $nil (Q1 2021: $55m charge) respectively.

Note 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 28 of the Annual Report and Form 20-F Information 2021. Net Debt is a non-GAAP financial measure.

Table 20: Net Debt

	At 1 Jan 2022 $m	Cash flow $m	Non-cash & other $m	Exchange movements $m	At 31 Mar 2022 $m
Non-current instalments of loans	(28,134)	-	6	47	(28,081)
Non-current instalments of leases	(754)	-	21	9	(724)
Total long-term debt	**(28,888)**	**-**	**27**	**56**	**(28,805)**
Current instalments of loans	(1,273)	4	5	-	(1,264)
Current instalments of leases	(233)	70	(66)	4	(225)
Commercial paper	-	(256)	-	-	(256)
Bank collateral	(93)	12	-	-	(81)
Other short-term borrowings excluding overdrafts	(3)	(57)	-	1	(59)
Overdrafts	(291)	(123)	-	5	(409)
Total current debt	**(1,893)**	**(350)**	**(61)**	**10**	**(2,294)**
Gross borrowings	**(30,781)**	**(350)**	**(34)**	**66**	**(31,099)**
Net derivative financial instruments	61	66	(68)	-	59
Net borrowings	**(30,720)**	**(284)**	**(102)**	**66**	**(31,040)**
Cash and cash equivalents	6,329	(553)	-	(14)	5,762
Other investments - current	69	(10)	-	2	61
Cash and investments	**6,398**	**(563)**	**-**	**(12)**	**5,823**
Net Debt	**(24,322)**	**(847)**	**(102)**	**54**	**(25,217)**

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

The Group has agreements with some bank counterparties whereby the parties agree to post cash collateral on financial derivatives, for the benefit of the other, equivalent to the market valuation of the derivative positions above a predetermined threshold. The carrying value of such cash collateral held by the Group was $81m (31 December 2021: $93m) and the carrying value of such cash collateral posted by the Group was $64m (31 December 2021: $47m). Cash collateral posted by the Group is presented within Cash and cash equivalents.

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 share purchase liability of $1,564m (31 December 2021: $2,458m), $824m of which is shown in current other payables and $740m is shown in non-current other payables.

Net Debt increased by $895m in the year to date to $25,217m. Details of the committed undrawn bank facilities are disclosed within the going concern section of Note 1.

During the three months to 31 March 2022, there were no changes to the Company's solicited credit ratings issued by Standard and Poor's (long term: A-; short term: A-2) and from Moody's (long term: A3; short term: P-2).

Note 4: Financial Instruments

As detailed in the Group's most recent annual financial statements, the principal financial instruments consist of derivative financial instruments, other investments, trade and other receivables, cash and cash equivalents, trade and other payables, lease liabilities and interest-bearing loans and borrowings.

All fair value gains and/or losses that are presented in Net gains/(losses) on equity investments measured at fair value through other comprehensive income in the Condensed consolidated statement of comprehensive income for the three months ending 31 March 2022 are Level 1 fair value measurements.

Financial instruments measured at fair value include $1,235m of other investments, $4,175m held in money-market funds, $308m of loans designated at fair value through profit or loss and $59m of derivatives as at 31 March 2022. The total fair value of interest-bearing loans and borrowings at 31 March 2022, which have a carrying value of $31,099m in the Condensed consolidated statement of financial position, was $31,902m.

Table 21: Financial instruments - contingent consideration

	2022			2021
	Diabetes alliance $m	Other $m	Total $m	Total $m
At 1 January	2,544	321	2,865	3,323
Settlements	(173)	(9)	(182)	(171)
Disposals	-	(121)	(121)	-
Discount unwind	41	1	42	55
At 31 March	**2,412**	**192**	**2,604**	**3,207**

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

The contingent consideration balance relating to BMS's share of the global diabetes alliance of $2,412m (31 December 2021: $2,544m) would increase/decrease by $241m with an increase/decline in sales of 10%, as compared with the current estimates.

Note 5: Legal proceedings and contingent liabilities

AstraZeneca is involved in various legal proceedings considered typical to its business, including litigation and investigations relating to product liability, commercial disputes, infringement of intellectual property (IP) rights, the validity of certain patents, anti-trust law and sales and marketing practices. The matters discussed below constitute the more significant developments since publication of the disclosures concerning legal proceedings in the Company's Annual Report and Form 20-F Information 2021 (the Disclosures). Unless noted otherwise below or in the Disclosures, no provisions have been established in respect of the claims discussed below.

As discussed in the Disclosures, the majority of claims involve highly complex issues. Often these issues are subject to substantial uncertainties and, therefore, the probability of a loss, if any, being sustained and/or an estimate of the amount of any loss is difficult to ascertain.

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

There is one matter concerning legal proceedings in the Disclosures, which is considered probable that an outflow will be required, but for which we are unable to make an estimate of the possible loss or range of possible losses at this stage.

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

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

Matters disclosed in respect of the fourth quarter of 2021 and to 29 April 2022

Patent litigation

Enhertu

US patent proceedings

As previously disclosed, in October 2020, Seagen Inc. (Seagen) filed a complaint against Daiichi Sankyo Company, Limited (Daiichi Sankyo) in the US District Court for the Eastern District of Texas alleging that *Enhertu* infringes US Patent No. 10,808,039 (the '039 patent). AstraZeneca co-commercialises *Enhertu* with Daiichi Sankyo, Inc. in the US. The trial took place in April 2022. The jury found that the '039 patent was infringed and awarded Seagen $41.82m in past damages. The parties await the schedules for a bench trial on equitable issues and for consideration of post-trial motions.

As previously disclosed, in December 2020 and January 2021, AstraZeneca and Daiichi Sankyo filed post-grant review petitions with the US Patent and Trademark Office (USPTO) alleging, inter alia, that the '039 patent is invalid for lack of written description and enablement. The USPTO initially declined to institute the post-grant reviews, but in April 2022, the USPTO granted the rehearing requests, instituting both post-grant review petitions. An oral hearing is scheduled for January 2023 and a decision is expected by April 2023.

Imfinzi

US patent proceedings

In March 2022, Bristol-Myers Squibb Co. and E.R. Squibb & Sons, LLC filed a lawsuit in US District Court for the District of Delaware against AstraZeneca alleging that AstraZeneca's marketing of *Imfinzi* infringes several of their patents. No trial date has been scheduled.

Patent proceedings outside the US

In February 2022, Ono Pharmaceuticals filed a lawsuit in Tokyo District Court, Civil Division against AstraZeneca alleging that AstraZeneca's marketing of *Imfinzi* in Japan infringes several of their patents. No trial date has been scheduled.

Symbicort

US patent proceedings

As previously disclosed, AstraZeneca is involved in ongoing ANDA patent litigation with Mylan Pharmaceuticals Inc. (Mylan) and Kindeva Drug Delivery L.P. (Kindeva) brought in the US District Court for the Northern District of West Virginia (the District Court). In March 2022, the US Court of Appeals for the Federal Circuit (the Federal Circuit) denied AstraZeneca's Combined Petition for Panel Rehearing and Rehearing En Banc of the Federal Circuit's December 2021 decision and the case was remanded back to the District Court for further proceedings. In April 2022, the District Court entered a Stipulation and Order dismissing patent infringement claims related to various asserted patents and otherwise narrowing the issues for trial. A trial in the matter is scheduled to commence in May 2022.

In April 2022, AstraZeneca filed another ANDA action against Mylan and Kindeva in the District Court asserting patent infringement.

Tagrisso

US patent proceedings

In February 2020, in response to Paragraph IV notices from multiple ANDA filers, AstraZeneca filed patent infringement lawsuits in the US District Court for the District of Delaware. In its complaint, AstraZeneca alleged that a generic version of *Tagrisso*, if approved and marketed, would infringe a US Orange Book-listed *Tagrisso* patent. In the fourth quarter of 2021, AstraZeneca entered into settlement agreements with Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Limited, MSN Laboratories Pvt. Ltd., and MSN Pharmaceuticals Inc. In April 2022, AstraZeneca entered into a settlement agreement with Alembic Pharmaceuticals Limited. These settlements resolve all US patent litigation between the parties relating to *Tagrisso*.

Patent proceedings outside the US

In Russia, in October 2021, AstraZeneca filed a lawsuit in the Arbitration Court of the Moscow Region against Axelpharm, LLC to prevent it from obtaining authorisation to market a generic version of *Tagrisso* prior to the expiration of AstraZeneca's patents covering *Tagrisso*. The lawsuit also names the Ministry of Health of the Russian Federation as a third party. In March 2022, the court dismissed the lawsuit, and AstraZeneca has filed an appeal.

Ultomiris

As previously disclosed, Chugai Pharmaceutical Co., Ltd. (Chugai) filed lawsuits against Alexion in the Delaware District Court as well as in Tokyo District Court, alleging that *Ultomiris* infringed US and Japanese patents held by Chugai.

In March 2022, Alexion entered into a settlement agreement with Chugai that resolves all patent disputes between the two companies related to *Ultomiris*.

In accordance with the settlement agreement, Alexion and Chugai have taken steps to withdraw patent infringement proceedings filed with US District Court for the District of Delaware and Tokyo District Court. Under the terms of the agreement, Alexion will make a single payment of $775m in the second quarter of 2022, for which a related charge was recognised through the non-core P&L in the first quarter of 2022. No further amounts are payable by either party.

Product liability litigation

Onglyza and *Kombiglyze*

In the US, AstraZeneca is defending various lawsuits alleging heart failure, cardiac injuries, and/or death from treatment with *Onglyza* or *Kombiglyze*. In February 2018, the Judicial Panel on Multidistrict Litigation ordered the transfer of various pending federal actions to the US District Court for the Eastern District of Kentucky (the District Court) for consolidated pre-trial proceedings with the federal actions pending in the District Court. In the previously disclosed California State Court coordinated proceeding, AstraZeneca's motion for summary judgment was granted in March 2022. A motion for summary judgment is pending in the District Court.

Commercial litigation

Pay Equity Litigation (US)

AstraZeneca is defending a putative class and collective action matter in the US District Court for the Northern District of Illinois brought by three named plaintiffs, who are former AstraZeneca pharmaceutical sales representatives. The case involves claims under the federal and Illinois Equal Pay Acts, with the plaintiffs alleging they were paid less than male employees who performed substantially similar and/or equal work. The plaintiffs seek various damages on behalf of themselves and the putative class and/or collective, including without limitation backpay, liquidated damages, compensatory and punitive damages, attorneys' fees, and interest.

The Court has not set a trial date and no class or collective certification has been sought or granted as of this time.

Government investigations/proceedings

COVID-19 Vaccine Supply and Manufacturing Inquiries

As previously disclosed, in June 2021, Argentina's Federal Criminal Prosecutor's Office (the Prosecutor) contacted AstraZeneca Argentina seeking documents and electronic records in connection with a local criminal investigation relating to the public procurement and supply of *Vaxzevria* in that country. In October 2021, the Prosecutor filed a submission with the presiding court requesting dismissal of the criminal investigation, and that request was granted by the court in February 2022. This matter is now closed.

In February 2022, a Brazilian Public Prosecutor filed a lawsuit against several defendants including the Brazilian Federal Government, AstraZeneca, and other COVID-19 vaccine manufacturers. In April 2022, a Brazilian Court issued an order dismissing the lawsuit.

US 340B Litigations and Proceedings

As previously disclosed, AstraZeneca is involved in several matters relating to its contract pharmacy recognition policy under the 340B Drug Pricing Program in the US. AstraZeneca has sought to intervene in three lawsuits against several US government agencies and their officials relating to the appropriate interpretation of the governing statute for the 340B Drug Pricing Program. Two of the three cases are currently stayed pending further proceedings and the third case has been dismissed. Administrative Dispute Resolution proceedings have also been initiated against AstraZeneca before the US Health Resources and Services Administration.

As previously disclosed, in January 2021, AstraZeneca filed a separate lawsuit in federal court in Delaware alleging that an Advisory Opinion issued by the Department of Health and Human Services violates the Administrative Procedure Act. In June 2021, the Court found in favour of AstraZeneca, invalidating the Advisory Opinion. Prior to the Court's ruling, however, in May 2021, the US government issued new and separate letters to AstraZeneca (and other companies) asserting that our contract pharmacy policy violates the 340B statute. AstraZeneca amended the complaint to include allegations challenging the letter sent in May, and in February 2022, the Court ruled in favour of AstraZeneca invalidating those letters sent by the US Government. The US government has appealed the decision.

Table 22: Q1 2022 - Product Sales year-on-year analysis[75]

	World			Emerging Markets			US		Europe			Established RoW		
	$m	Act % chg	CER % chg	$m	Act % chg	CER % chg	$m	% Change	$m	Act % chg	CER % chg	$m	Act % chg	CER % chg
Oncology	**3,388**	**14**	**18**	**895**	**17**	**19**	**1,374**	**17**	**650**	**13**	**21**	**469**	**4**	**12**
Tagrisso	1,304	14	17	406	32	33	439	6	252	12	21	207	2	11
Imfinzi	599	8	11	58	2	3	315	8	125	15	23	101	4	12
Lynparza	617	14	17	121	39	43	270	7	160	8	16	66	22	32
Calquence	414	98	n/m	7	n/m	n/m	339	74	55	n/m	n/m	13	n/m	n/m
Enhertu	11	n/m	n/m	6	n/m	n/m	-	-	4	n/m	n/m	1	n/m	n/m
Orpathys	13	n/m	n/m	13	n/m	n/m	-	-	-	-	-	-	-	-
Zoladex	240	9	12	167	22	23	4	(19)	34	(9)	(3)	35	(18)	(9)
Faslodex	93	(24)	(20)	44	3	6	5	(41)	17	(59)	(56)	27	(8)	-
Iressa	32	(47)	(47)	27	(50)	(50)	2	(16)	1	(48)	(44)	2	(35)	(30)
Arimidex	32	(27)	(25)	25	(30)	(29)	-	51	1	(56)	(56)	6	(7)	1
Casodex	21	(48)	(47)	13	(59)	(59)	-	n/m	-	(24)	(24)	8	(10)	(1)
Others	12	1	6	8	3	7	-	n/m	1	49	61	3	(29)	(24)
BioPharmaceuticals: CVRM*	**2,207**	**14**	**17**	**1,025**	**8**	**11**	**522**	**7**	**482**	**31**	**40**	**178**	**28**	**37**
Farxiga	1,000	60	67	391	50	54	193	48	318	83	97	98	66	78
Brilinta	325	(13)	(10)	69	(35)	(32)	166	-	76	(13)	(6)	14	(5)	(1)
Lokelma	63	92	97	3	n/m	n/m	39	62	6	n/m	n/m	15	n/m	n/m
Roxadustat	41	6	4	41	6	4	-	-	-	-	-	-	-	-
*Andexxa**	33	13	14	-	-	-	24	(7)	9	n/m	n/m	-	-	-
Crestor	267	(2)	-	197	4	6	18	(16)	11	(48)	(44)	41	(2)	6
Seloken/Toprol-XL	244	(2)	(1)	238	(2)	(1)	-	n/m	4	13	7	2	(7)	-
Bydureon	68	(34)	(33)	1	60	63	57	(34)	10	(28)	(23)	-	(92)	(91)
Onglyza	68	(33)	(31)	34	(42)	(40)	18	(2)	11	(31)	(26)	5	(45)	(44)
Others	98	(15)	(13)	51	5	7	7	(58)	37	(20)	(19)	3	(27)	(20)
BioPharmaceuticals: R&I	**1,509**	**(2)**	**-**	**437**	**(19)**	**(19)**	**645**	**17**	**277**	**(7)**	**(1)**	**150**	**-**	**5**
Symbicort	674	(2)	-	167	1	3	259	(2)	157	(7)	-	91	(1)	3
Fasenra	308	18	22	7	n/m	n/m	189	22	75	20	29	37	(5)	2
Pulmicort	217	(34)	(34)	164	(43)	(43)	22	26	18	11	20	13	24	28
Breztri	87	n/m	n/m	22	n/m	n/m	53	n/m	5	n/m	n/m	7	46	59
Saphnelo	11	n/m	n/m	-	-	-	11	n/m	-	-	-	-	-	-
Daliresp	51	(16)	(16)	1	(28)	(25)	47	(13)	3	(45)	(41)	-	6	7
Bevespi	15	15	14	2	51	30	11	10	2	16	24	-	24	35
Others	146	(9)	(9)	74	(3)	(4)	53	47	17	(62)	(60)	2	(53)	(51)
BioPharmaceuticals: V&I	**1,757**	**n/m**	**n/m**	**630**	**n/m**	**n/m**	**386**	**n/m**	**286**	**15**	**22**	**455**	n/m	n/m
Vaxzevria	1,089	n/m	n/m	475	n/m	n/m	79	n/m	135	(40)	(37)	400	n/m	n/m
Evusheld	469	n/m	n/m	89	n/m	n/m	307	n/m	65	n/m	n/m	8	n/m	n/m
Synagis	200	n/m	n/m	66	n/m	n/m	-	(97)	87	n/m	n/m	47	-	-
FluMist	(1)	n/m	n/m	-	(98)	(98)	-	n/m	(1)	n/m	n/m	-	(4)	(2)
Rare Disease*	**1,694**	**3**	**7**	**115**	**(12)**	**3**	**1,020**	**7**	**361**	**-**	**8**	**198**	**1**	**10**
*Soliris**	990	(5)	-	71	(41)	(28)	591	7	221	(15)	(8)	107	4	11
*Ultomiris**	419	20	25	24	n/m	n/m	220	6	105	54	65	70	(4)	7
*Strensiq**	208	5	7	9	65	68	161	3	19	(1)	6	19	7	19
Koselugo	39	82	85	5	n/m	n/m	30	43	4	n/m	n/m	-	-	-
*Kanuma**	38	9	15	6	42	59	18	8	12	(1)	7	2	10	15
Other medicines	**425**	**(19)**	**(15)**	**204**	**(31)**	**(29)**	**39**	**(24)**	**36**	**(31)**	**(28)**	**146**	**19**	**30**
Nexium	332	(18)	(13)	144	(38)	(36)	33	4	15	(17)	(11)	140	17	28
Others	93	(22)	(22)	60	(4)	(4)	6	(71)	21	(39)	(37)	6	n/m	n/m
Total Product Sales	**10,980**	**51**	**56**	**3,306**	**28**	**30**	**3,986**	**76**	**2,092**	**36**	**46**	**1,596**	**83**	**97**

[75] 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. * FY 2022 Q1 growth rates on medicines acquired with Alexion have been calculated on a pro forma basis comparing to the corresponding period in the prior year, pre-acquisition as previously published by Alexion. The growth rates shown for Rare Disease and CVRM disease area totals include these pro forma adjustments.

Table 23: Collaboration Revenue

	Q1 2022 $m	Q1 2021 $m
Lynparza: regulatory milestones	175	-
Enhertu: share of gross profits	75	38
Royalty income	73	18
Tralokinumab: sales milestones	70	-
Other Ongoing Collaboration Revenue	17	7
Total	410	63

Table 24: Other Operating Income and Expense

	Q1 2022 $m	Q1 2021 $m
Brazikumab licence termination funding	35	26
Divestment of Viela Bio, Inc. shareholding	-	776
Crestor (Europe ex-UK and Spain)	-	309
Other	62	69
Total	97	1,180

Other shareholder information

Financial calendar

Announcement of half year and second quarter results	29 July 2022
Announcement of year to date and third quarter results	10 November 2022
Announcement of full year and fourth quarter results	9 February 2023 (tentative)

Dividends are normally be paid as follows:
First interim: Announced with the half-year and second-quarter results and paid in September
Second interim: Announced with full-year and fourth-quarter results and paid in March

The record date for the first interim dividend for 2022, payable on 12 September 2022, will be 12 August 2022. The ex-dividend date will be 11 August 2022.

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

- the risk of failure or delay in delivery of pipeline or launch of new medicines
- the risk of failure to meet regulatory or ethical requirements for medicine development or approval
- the risk of failures or delays in the quality or execution of the Group’s commercial strategies
- the risk of pricing, affordability, access and competitive pressures
- the risk of failure to maintain supply of compliant, quality medicines
- the risk of illegal trade in the Group’s medicines
- the impact of reliance on third-party goods and services
- the risk of failure in information technology or cybersecurity
- the risk of failure of critical processes
- the risk of failure to collect and manage data in line with legal and regulatory requirements and strategic objectives
- the risk of failure to attract, develop, engage and retain a diverse, talented and capable workforce
- the risk of failure to meet regulatory or ethical expectations on environmental impact, including climate change
- the risk of the safety and efficacy of marketed medicines being questioned
- the risk of adverse outcome of litigation and/or governmental investigations
- intellectual property-related risks to our products
- the risk of failure to achieve strategic plans or meet targets or expectations
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- the risk of unexpected deterioration in the Group’s financial position
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